#### Nos. 16-70496 & 16-70497

# IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

## ALTERA CORPORATION & SUBSIDIARIES, Petitioner – Appellee,

v.

# $\begin{array}{c} \text{COMMISSIONER OF INTERNAL REVENUE,} \\ Respondent-Appellant. \end{array}$

Appeal from the United States Tax Court, Nos. 6253-12, 9963-12

# SUPPLEMENTAL EXCERPTS OF RECORD VOLUME 2

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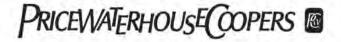
# COMMENTS ON THE PROPOSED REGULATIONS ON THE TREATMENT OF STOCK-BASED COMPENSATION FOR QUALIFIED COST SHARING ARRANGEMENTS

response to
Notice of Proposed Rulemaking
REG 106359-02

Docket Nos. 6253-12, 9963-12

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Exhibit 13-P



# COMMENTS ON THE PROPOSED REGULATIONS ON THE TREATMENT OF STOCK-BASED COMPENSATION FOR QUALIFIED COST SHARING ARRANGEMENTS Response to Notice of Proposed Rulemaking REG 106359-02

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#### INTRODUCTION AND SUMMARY OF COMMENTS

PricewaterhouseCoopers LLP ("PwC") is pleased to respond to the request of the Treasury and the Internal Revenue Service ("IRS") in Notice of Proposed Rulemaking REG106359-02 for comments on proposed regulations relating to the treatment of stock-based compensation for purposes of qualified cost sharing arrangements (the "Proposed Regulations").

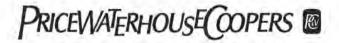
The Proposed Regulations would require companies to use one of two methods to account for stock-based compensation of employees for purposes of determining costs to be shared. As a general rule, companies would use a valuation method that is generally based on the spread at exercise and consistent with the U.S. corporate tax deduction for many types of stock-based compensation (the "general rule"). Public companies traded on a U.S. exchange would be permitted to elect to value the options at grant using an economic model (such as Black-Scholes) in conformity with the alternative valuation typically reported in companies' financial statement footnotes (the "grant-date election").

PwC expects that the IRS and Treasury will receive numerous comments criticizing the Proposed Regulations on grounds that they are not consistent with the arm's length standard. Criticisms can be made based on evidence from actual arm's length dealings, from economic and accounting perspectives, and by reference to case law, federal legislation or international tax treaties. PwC agrees that the Proposed Regulations are fundamentally flawed in these respects, but is confident that other comments will competently address these points. Therefore, although we strongly urge the IRS and Treasury to withdraw the Proposed Regulations in their entirety, we will limit our detailed comments here to suggestions to improve the fairness and usefulness of the Proposed Regulations if the IRS and Treasury are determined to finalize them at this time in spite of their serious defects.



We suggest that, at the least, finalization of Proposed Regulations should be deferred until greater international consensus and coordination with other transfer pricing rules can be achieved. These issues are currently being studied by the Organization of Economic Cooperation and Development ("OECD"). In order to reduce the incidence of double taxation, it is crucial that the IRS and Treasury at least wait until an international consensus begins to form. Likewise, it is not reasonable for the IRS and Treasury to address this issue in a piecemeal fashion; rather, the implications of these rules on other transfer pricing issues should be fully considered before finalization.

When and if the Proposed Regulations are finalized, they should be prospective only and transition rules should be provided. The grant-date election should be available to all taxpayers, not just public companies that trade on a U.S. stock exchange, and should be allowed on extended returns. Exercise-date valuation should be fully conformed to tax deduction rules (even for incentive stock options) and pro-ration over the option's vesting period should be allowed. For the grant-date valuation, any reasonable method should be allowed rather than requiring conformity with financial accounting rules – alternatively, a "minimum value" method could be specified.



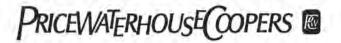
#### COMMENTS

#### A. The Proposed Regulations Are Not Consistent With the Arm's Length Standard

PwC expects that the IRS and Treasury will receive numerous comments criticizing the Proposed Regulations on grounds that they are not consistent with the arm's length standard. PwC agrees that the Proposed Regulations are fundamentally flawed in this respect, and is confident that other comments will extensively address these points. Because the arm's length standard is the central principle and foundation of international transfer pricing, we believe that promulgating these regulations will lead to numerous international tax disputes and increase the incidence of double taxation to the detriment of U.S. businesses. Therefore, we strongly urge the IRS and Treasury to withdraw the Proposed Regulations in their entirety.

PwC fears that there is a strong possibility that the IRS and Treasury will choose to finalize these regulations in spite of their fundamental flaws. As a result, we feel a duty to our worldwide clients to offer suggestions that will improve the fairness and usefulness of the Proposed Regulations if the IRS and Treasury are not persuaded by the public comments and hearings to withdraw them. While our detailed comments below will be limited to such suggestions, we want to emphasize that the comments are in no way intended to undermine our strong message that the regulations should not be finalized in any form.

Before turning to our detailed suggestions, we wish to briefly outline some of the chief reasons why the Proposed Regulations are not consistent with the arm's length standard. The central inquiry in an arm's length analysis of cost sharing arrangements should be what costs independent parties would share under the same circumstances, and how they would measure and share such costs. The evidence from both private sector and



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government contracts demonstrates that independent parties do not, in fact, agree to share any amounts based on the other party's employee stock options.

Far from being surprising, these actual business contracting practices are precisely what would be predicted by sound economic reasoning. An arm's length party would not be expected to agree to reimburse the spread-at-exercise value of another party's employee stock options because the payments would be dependent on stock market fluctuations that are uncertain in time and amount, and entirely out of the payer's control. Arm's length parties would not be expected to agree to share amounts based on grant-date valuations either because Black-Scholes and the other economic models commonly used to value options are highly speculative and inaccurate when applied to employee stock options, which have much longer terms and many more restrictions than the market-traded options for which the models were designed.

# B. Treasury Should Reassess Burden Imposed on Taxpayers by the Proposed Regulations

At the outset, PwC would like to comment on the accuracy of the Proposed Regulations' estimates of the reporting and record-keeping burden imposed on taxpayers. Based on our experience advising clients that have both cost sharing arrangements and employee stock option plans, we believe that the additional burden imposed by the Proposed Regulations would be significantly in excess of two to seven hours for each affected taxpayer, and the average burden would be significantly in excess of four hours.

In our assessment, the initial tasks of designing procedures and systems to comply with the Proposed Regulations will require several days of effort for most affected taxpayers. The decision whether to make the grant-date election or follow the general rule is itself a significant and far-reaching decision that warrants extensive research, thorough modeling and careful consideration of both the tax and financial accounting implications. Systems then need to be put in place to capture relevant information about



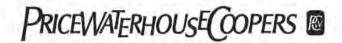
each employee receiving stock options, including details about the options received and the employee's activities and responsibilities at the time.

As for the recurring annual burden of complying with the Proposed Regulations, the necessary procedures are significantly different for each of the two allowed methods:

- Under the grant-date election, the most difficult and time-consuming step of the process would be to apply the valuation model each time that an option grant is made. After each option grant, it would be necessary to determine the aggregate value of the options, make applicable adjustments (such as the adjustment for estimated forfeitures), and then determine how much of the adjusted total value is allocable to the cost sharing pool. Thereafter, the total allocated value would simply be amortized into the cost pool each quarter during the vesting period.
- Under the general rule, on the other hand, pooling and amortization conventions
  could not be applied. Instead, each and every exercise of an option by an
  employee would have to be traced back to the initial option grant, a
  determination made whether (and to what extent) the employee was involved in
  cost-shared activities at that time, and the amount of the spread at exercise
  computed and added to the cost pool for the quarter.

The annual burden on taxpayers would therefore depend critically on the frequency of option grants or exercises (depending on the method) and the complexity of the stock option plans. The upper estimate of seven hours may be accurate for the least complex cases, but it is likely to require significantly more hours each year for most taxpayers.

The Proposed Regulations also estimate that the number of taxpayers burdened by these rules to be about 500. Since nearly every taxpayer that participates in a cost sharing arrangement would be affected by the rules, we feel the actual number may be twice or three times as high. In any case, however, we would warn Treasury not to take the



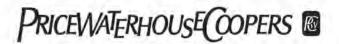
relatively low number of affected taxpayers as an indication of the importance of this issue. The principles of the Proposed Regulations could easily be extended to all areas of intercompany transfer pricing where they would affect taxpayers in the hundreds of thousands. For example, it has been reported that Treasury and IRS are seriously considering adopting a similar approach to employee stock option issues in the update of the regulations on transfer pricing for services, which are expected to be completed during this Treasury business plan year.

Lastly, we take issue with the claim of the Proposed Regulations that they would not have a significant economic impact on a substantial number of small entities. PwC is aware of many small companies, especially in the high technology sector, that have both cost sharing arrangements and stock option plans and so would be directly affected.

## C. Treasury Should Defer Finalization At Least Until International Consensus and Coordination with Other Transfer Pricing Rules Can be Achieved

#### 1. International Consensus

Accounting for employee stock options raises very difficult issues that are currently being studied by a number of key international bodies. In fact, the treatment of stock options for transfer pricing purposes is currently being studied by the Organization of Economic Coordination and Development ("OECD"), which is the most influential voice in the transfer pricing arena. Due to the significant risks of double taxation in this area, it would be very unfortunate if the U.S. Treasury were to promulgate inconsistent rules so soon before the OECD speaks on the issue.



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<sup>&</sup>lt;sup>1</sup> See, e.g., "Angus Says Proposals on Cost Sharing, Services Under Section 482 Coming Soon," BNA Transfer Pricing Journal, Tues., Oct. 22, 2002, page G6.

Employee stock options play a key role in the U.S. economy, particularly within the small business sector, providing the fuel for growth and innovation. Options motivate employees to give peak performances, and allow them to share the rewards if the enterprise is successful. As Senator Joseph Lieberman said in introducing a bill on stock option accounting in 1993:

"Equity is America's edge in global competition. It's our secret weapon. Neither the Europeans nor the Japanese have yet learned how to generate the kind of employee creativity and commitment that broad-based employee stock option plans have demonstrated for U.S. companies."<sup>2</sup>

Until now, the United States has been at the forefront of encouraging companies to use employee stock options. It would be unfortunate break with this tradition if the U.S. Treasury leads the way in imposing onerous rules relating to stock options that will lead to international double taxation and jeopardize their continued viability as a form of compensation. PwC strongly urges the IRS and Treasury not to finalize the Proposed Regulations before an international consensus begins to form.

#### 2. Coordination of Transfer Pricing Rules

The arm's length standard applies to all areas of intercompany transfer pricing. We do not believe it is reasonable or prudent for the IRS and Treasury to create rules for the treatment of employee stock options that apply only to cost sharing arrangements, which are only one aspect of intercompany transfer pricing. Adopting transfer pricing rules in such a piecemeal manner is likely to create unfair "traps for the unwary" or give rise to other unforeseen consequences.

<sup>&</sup>lt;sup>2</sup> Quoted in Testimony of Douglas I. Maine in U.S. Senate, EMPLOYEE STOCK OPTIONS, HEARING BEFORE THE SUBCOMMITTEE ON SECURITIES (October 21, 1993).



Many examples of such unforeseen consequences are possible. Here we provide a single example in an area most closely related to cost sharing: determination of a "buy-in" royalty for use of pre-existing intangible property.

Consider a U.S. company with a cutting-edge product line that reports substantial net margins on its public financial statements. As a result of its high-profile products and strong profit margins, the U.S. company has seen its stock price soar over the past few years and so many long-time employees of the company have exercised their stock options. As a result of the stock option deduction, this company has little or no taxable income due to the high number of employees exercising their options at this time (and paying substantial individual income taxes on the income).

Now, assume that, in connection with its global expansion, this company were to enter into an R&D cost sharing arrangement with a newly formed foreign affiliate. The Proposed Regulations would require both companies to share future stock option deductions in proportion to their shares of the benefits from the R&D program. Because only the U.S. company owns any pre-existing intangible property, the new foreign affiliate would also have to pay a "buy-in" royalty to the U.S. parent. Applying the principles of the Proposed Regulations and accounting for employee option spreads at exercise as an expense, the company finds it has had little or no profits for several years and does not expect to have any profits for several years into the future.

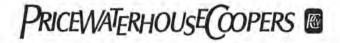
Under the commensurate with income standard, "profit potential" is key to determining the amount of the "buy-in" royalty no matter what transfer pricing method is used. Assuming the company uses the comparable profits method to determine the "buy-in" royalty, the result will be a very low royalty rate since expected profits after stock option exercises scarcely cover the routine return for the new affiliate's manufacturing and sales functions. In contrast, if financial accounting standards were used for the transfer pricing analysis, rather than the principles of the Proposed Regulations, the "buy-in" royalty would be quite substantial — in proportion to the strong reported profit



margins - since the value of employee stock option exercises would be recorded only on the statement of equity and would not affect the company's income statement.

Another way to conceptualize this issue is to consider how an independent foreign marketing company that was considering entering into a joint venture with our cutting-edge U.S. company would react if asked to share the spread-at-exercise value of its employee stock options. Suppose further that the foreign venturer was able to overcome its deep misgivings about agreeing to make uncertain future payments that would be dependent on stock market fluctuations. As a quid-pro-quo for agreeing to such an unusual arrangement, the foreign venturer would likely demand that the "buy-in" royalty it would otherwise be willing to pay the U.S. company being greatly reduced or waived entirely. Otherwise, it would be risking hefty losses if the venture were successful when it would effectively have to pay the U.S. company twice for pre-existing intangibles, once in the form of the "buy-in" royalty and then again by reimbursing multiple-year increases in the U.S. company's stock market value when its employees exercise their options.

As this example shows, the effects of applying the principles of the Proposed Regulations to other areas of transfer pricing would be quite far-reaching, and often would be detrimental to the U.S. Treasury. The preamble to the Proposed Regulations indicates that the IRS and Treasury are also studying the issue more broadly. PwC believes it is not reasonable or prudent for the IRS and Treasury to finalize these regulations without considering the impact of their principles on all areas of transfer pricing. If the Proposed Regulations are not withdrawn in their entirety, PwC strongly urges the IRS and Treasury to postpone finalization at least until the treatment of employee stock options for all U.S. transfer pricing purposes can be harmonized.



### D. If Not Withdrawn, Regulations Should Be Prospective Only and Should Provide Transition Rules

The preamble to the Proposed Regulations states: "No inference is intended with respect to the treatment of stock-based compensation granted in taxable years beginning before the effective date of the final regulations." Meanwhile, PwC observes that the IRS continues to raise the stock option/cost sharing issue in audits and to litigate the issue in its dispute with Xilinx, Inc. (Tax Court docket #4142-01).

In our opinion, the current cost sharing regulations clearly permit taxpayers to apply any reasonable accounting method to determine costs and revenues, provided the method is applied consistently, and specifically sanction the use of U.S. generally accepted accounting principles ("U.S. GAAP") for this purpose. Moreover, we believe that it is not appropriate for the IRS to attempt to create new rules for the treatment of stock options in cost sharing by means of audits and litigation; rather, we believe that the current notice-and-comment process is the appropriate way to create broad new rules of this sort.

Accordingly, we recommend that the IRS cease pursuing stock-option related adjustments in audits and cases against taxpayers that have consistently applied U.S. GAAP for cost sharing purposes.<sup>5</sup> If the IRS and Treasury are determined to finalize the

<sup>&</sup>lt;sup>5</sup> We note, with approval, that the IRS has already ceased pursuing the issue for years governed by the 1968 Regulations. See, e.g., Industry Directive on Stock Options and Cost Sharing Agreements issued by Thomas W. Wilson, Jr., IRS Industry Director for Communications, Technology and Media on January 25,



<sup>&</sup>lt;sup>3</sup> See Treas, Reg. §§ 1.482-7(i) & (j)(i)(D). For both cost sharing and financial reporting purposes, most companies follow the "intrinsic value" method of accounting for employee stock options as specified in Accounting Principles Board Opinion No. 25, under which at-the-money options (options with a strike price equal to the stock's market price at grant) result in no additional compensation expense.

<sup>&</sup>lt;sup>4</sup> See, e.g., United States v. Mead Corp., 121 S. Ct. 2164 (2001). We have chosen not to address, in these Comments, the question of whether the Proposed Regulations are consistent with the Congressional mandate under Internal Revenue Code section 482.

Proposed Regulations, we urge that they be made entirely prospective in effect. Clear transitions rules are needed to protect taxpayers from adjustments to prior years. At the very least, the second sentence of section 1.482-7(d)(2)(ii) should be revised as follows: "Accordingly, all stock-based compensation that is granted after the effective date of this paragraph (d)(2), during the term of the qualified cost sharing arrangement and is related at date of grant to the development of intangibles covered by the arrangement is included as an intangible development cost under paragraph (d)(1) of this section."

## E. If Regulations are Not Withdrawn, Election to use Grant-Date Valuation Method Should be Available to All Taxpayers and Further Liberalized

We commend the IRS and Treasury for introducing an element of flexibility to taxpayers in the Proposed Regulations in the form of the grant-date election. However, if the IRS and Treasury are determined to finalize these regulations in some form, we suggest that further liberalization of the election is needed to make the regulations more fair and useful.

Most importantly, the fact that the Proposed Regulation only allows public companies that trade on U.S. exchanges to make the grant-date election unfairly penalizes privatelyheld and foreign companies. We recognize the great difficulty of valuing private company stock options, but strongly believe that this difficulty does not justify favoring U.S. public companies over those that are privately held by allowing only the former companies to make an election with such potentially dramatic tax effects. In any case, the valuation of private company stock, as would be required by the general rule, is itself difficult and contentious; the further difficulties of valuing private company options would be largely mitigated if our comments on minimum value method (Section G below) were to be favorably received. As for foreign public companies, the disparate

2002 ("Industry Directive"). We urge that the IRS extend this policy to the years governed by the final cost sharing regulations issued in 1995.



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treatment may provide an additional avenue for such companies to challenge the regulations by invoking tax treaty non-discrimination clauses.

We also have two comments regarding the time and manner of making the grantdate election provided by the Proposed Regulations. First, we suggest that the IRS and Treasury reconsider the requirement that the election must be explicitly made in the written cost sharing agreement. This requirement raises difficult questions of enforcement and proof, especially if the agreement is written in a language other than English. It would be more practical for the taxpayer to make the election on its U.S. tax return – either under explicit disclosure requirement or, preferably, by its treatment of employee stock options in reporting the results of cost sharing in the first year that they are relevant.

Second, we believe that time requirement for making the grant-date election in the Proposed Regulation is more stringent than is reasonable or necessary. Under the transition rule, there is no compelling reason to disregard elections made by the time that a timely, but extended, return is filed. The few extra months of stock market information available to the taxpayer would not negatively impact the Treasury in the long run since the election will be binding on the taxpayer for all subsequent years. It is not fair to cut short the time available to taxpayers for research, modeling and consideration before making such a significant and far-reaching decision.

F. If Regulations are Not Withdrawn, Exercise-Date Valuation Approach Should be Fully Conformed to Tax Deduction Rules and Pro-Ration Over Vesting Period Should be Allowed

#### 1. Conformity with Tax Deduction

PwC doubts that any rational argument exists to support the case that exercisedate accounting for employee stock options is consistent with the arm's length standard. That is, we do not believe that arm's length parties would ever agree to share an uncertain future amount that is dependent on stock market fluctuations, not directly related to their



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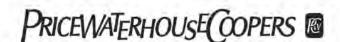
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activities and entirely out of their control. Nonetheless, considering the difficulties of valuing options on grant date, we commend the IRS and Treasury for allowing exercise-date accounting. In fact, we do not fault the Proposed Regulations for choosing exercise-date accounting over grant-date as the general rule since exercise-date accounting is marginally simpler (in that it does not require use of complex valuation models) and is not as speculative (i.e., it does not penalize companies suffering stock market downturns).

Many companies may choose exercise-date accounting over grant-date accounting, if a choice becomes required, because its effects on a company's income tax provision under U.S. GAAP appear to be clearer and less onerous. If the exercise-date method is applied, it is probable that any tax detriment caused by the Proposed Regulations would be reported as on the company's statement of equity rather than its income statement, which is the same treatment required by U.S. GAAP to account for any tax benefits from stock option deductions.

However, to the extent the Proposed Regulation's treatment of stock options differs from their treatment for other U.S. corporate tax purposes, their harmony with U.S. GAAP tax provision rules is similarly diminished. Therefore, if the Proposed Regulations must be finalized, we recommend that the general rule be more fully conformed to tax deduction rules. Thus, we approve of the wording of the general rule that the amount subject to cost sharing "is equal to the amount allowable to the controlled participant as a deduction for federal income tax purposes with respect to that stock-based compensation." Prop. Reg. § 1.482-7(d)(2)(iii)(A). On the other hand, we believe that the exception from the general rule for incentive stock options which makes section 421 inapplicable for purposes of the determining the cost pool [Prop. Reg. § 1.482-7(d)(2)(iii)(A)(i)], is unwarranted and should be removed if the regulations are finalized. If the exception is removed, incentive stock options would give rise to a compensation expense for cost sharing only if the employee makes a disqualifying disposition, and the



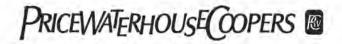
amount would be based on the spread on the disposition date rather than the exercise date.

Removing the exception for incentive stock options would greatly reduce the administrative burden on taxpayers adopting the general rule because they would not be required to apply different rules for different purposes. Although the general rule of the Proposed Regulations cannot be defended on policy grounds of upholding the arm's length standard, a possible policy rationale may be a concern that it is "unfair" to the Treasury for taxpayers to get a "generous" deduction for stock options under the tax code while being allowed to apply the "miserly" rules of U.S. GAAP for cost sharing purposes. Full conformity with the tax deduction rules is consistent with this rationale.

#### 2. Pro-Ration Over Vesting Period

One reason exercise-date valuation of employee stock options is not consistent with the arm's length standard is that it ignores the economic implications of vesting rules. It is irrational to consider any increases in stock value that occur after the options are fully vested to constitute compensation expense – such increases should instead be considered the result of the individual employee's investment decisions.

In order to improve the arm's length nature of the Proposed Regulations and reduce likelihood of double tax, we suggest that the IRS and Treasury consider allowing taxpayers to include in the cost pool only a pro-rated amount of the tax deduction relating to the period between grant and vesting dates during which employees were engaged in cost-shared activities. While we recognize that such a rule would increase the burden of complying the regulations, we believe that the extra burden is justified by the increase in fairness.



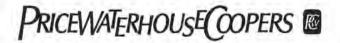
G. If Regulations are Not Withdrawn, Any Reasonable Method Should be Allowed for Grant-Date Valuation Election and Minimum Value Method Should be Considered as Alternative

#### 1. Any Reasonable Method

In previous non-binding written guidance, the IRS has posited that the taxpayer could use "any reasonable method" to account for stock options in cost sharing arrangements. We believe that the retreat to only two allowable methods under the Proposed Regulations is unwarranted. In particular, we believe that it is unfair to preclude the use of reasonable methods allowed by international accounting standards or use of home country GAAP by cost sharing groups that have foreign parent companies.

If the regulations are finalized, we specifically recommend elimination of the requirement that the grant-date valuation method used for cost sharing purposes conform to the "fair value of the stock options reflected as a charge against income in audited financial statements or disclosed in footnotes to such financial statements, prepared in accordance with [U.S. GAAP] by or on behalf of the company issuing the publicly traded stock." If the grant-date election is made available to private and foreign companies, as we recommend above, this approach would introduce an unwarranted requirement that a U.S. GAAP audit be performed.

Furthermore, the U.S. GAAP "fair value" conformity requirement would be inappropriate for companies that would use significantly different assumptions to value options granted to employees performing cost-shared R&D activities than for all employees. For example, the forfeiture rate and average life of options granted to such employees may differ greatly. Neither the IRS nor the company tax department should



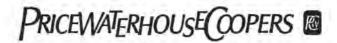
<sup>&</sup>lt;sup>6</sup> FSA 200003010; see also Industry Directive.

be bound by the aggregate assumptions adopted by the accountants for purposes of the "fair value" footnote.

Currently, most taxpayers use the "intrinsic value" method to account for employee stock options for purposes of both cost sharing and U.S. GAAP reporting. PwC believes that this method is, in fact, a "reasonable method" that properly reflects stock option expense. The "intrinsic value" method measures the amount of stock-based compensation by the difference between the option's exercise price and the value of the underlying stock at the time of grant. While it is evident from the market for publicly traded stock options that such options have a "time value" to the investor in addition to their intrinsic value, we do not agree that the time element of employee stock options constitutes a true "expense" to the company. The grant of at-the-money employee stock options does not reduce corporate cash flow, and the exercise of such options will not require any outlay of cash either. The grant of such options represents no more than the potential dilution of existing shareholders' ownership.

This is the same debate that took place when the Financial Advisory Standards Board ("FASB") considered requiring companies to treat the "fair value" of employee stock options as an expense for U.S. GAAP purposes nearly ten years ago. After extensive public comments on the issue, the final rule allows companies to continue to use the historic intrinsic value method if they believe it is appropriate and only requires companies to disclose "fair value" information in the footnotes to their financial statements. The question of whether the intrinsic value or the "fair value" method of accounting for options better reflects the company's true financial condition is a question that management of U.S. public companies must consider each time they release GAAP financial statements.

Based on its litigating positions and prior guidance, it is apparent that the IRS disagrees with us that the intrinsic value method allowed by U.S. GAAP is a "reasonable method" for cost sharing purposes. If the IRS and Treasury continue to hold this view



Docket Nos. 6253-12, 9963-12

Exhibit 13-P

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after considering the comments and testimony on the Proposed Regulations, then the regulations could be modified to allow "any reasonable method" of accounting for stock options but specify that a method must include a "time value" element in order to be considered reasonable.

#### 2. Minimum Value Alternative

The so-called "minimum value" method is an alternative approach that the IRS and Treasury should consider if determined to finalize the Proposed Regulations. When the FASB considered accounting for stock options ten years ago, the minimum value method was considered as a possible approach for all companies and was adopted as an alternative to the "fair value" method for private companies. The minimum value method accounts for stock options' "time value" by assuming the underlying stock will grow at the risk free interest rate.

The minimum value is the value derived from the Black-Scholes model when the assumed volatility of the underlying stock approaches zero. Volatility is probably the most controversial and speculative of the variables required by the Black-Scholes model in the context of employee stock options. While the short-term volatility of public company stock can be estimated with reasonable accuracy from available market data, such estimates become highly speculative over the much longer terms of employee stock options. Further, a basic assumption of the Black-Scholes model is that volatility is constant over time is challenged by empirical data showing that volatility can change significantly over time and that volatility in latter periods is dynamically affected by actual results in prior periods.

Thus, requiring use of the minimum value method rather than allowing "any reasonable method" for transfer pricing purposes has the advantage of reducing uncertainty and potential for contentious disputes. It also serves the purpose insuring equal treatment of all taxpayers, whether private or public, domestic or foreign, and



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Comments On Proposed Regulations on Cost Sharing and Stock Options
Notice of Proposed Rulemaking REG106359-02 Page 18

whatever approach management takes to determine the options' "fair value" under U.S. GAAP rules.

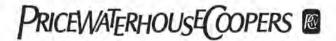
If the IRS and Treasury were to promulgate regulations for using the minimum value method, the regulations would need to address the same issues that the FASB addressed with respect to "fair value" accounting. First, the estimated term of the options should be based on average employee holding periods rather than the options' nominal term to account for early exercise. Second, the aggregate value of options issued to relevant employees under the plan should be reduced by a factor based on expected turnover rates to deal with pre-vesting forfeitures. Finally, the regulations could provide guidelines for determining the risk free rate of return by reference to the applicable federal rate ("AFR") used for other tax purposes.

PwC encourages the IRS and Treasury to reconsider the Proposed Regulations in light of our comments. We are planning to testify at the public hearing scheduled for November 20, 2002, and would be more than happy to discuss or expand upon these comments if requested.

Respectfully Submitted,

Dated: October 28, 2002

PricewaterhouseCoopers LLP



From: postoffice@www.qai.irs.gov Sent: Monday, October 28, 2002 4:51 PM To: guy.r.traynor@irscounsel.treas.gov Subject: Comment from Web Site From: eric.ryan@us.pwcglobal.com reg=Compensatory Stock Options category=taxregs

Begin Comment Text -----

email=eric.ryan@us.pwcglobal.com

Printed version to follow (tommorrow).

#### INTRODUCTION AND SUMMARY OF COMMENTS

REG-106359-02 REGULATIONS UNIT CC:ITA:RU

OCT 2 9 2002

**ROOM 5226** Giblen/Beck

PricewaterhouseCoopers LLP (PwC) is pleased to respond to the request of the Treasury and the Internal Revenue Service (IRS) in Notice of Proposed Rulemaking REG106359-02 for comments on proposed regulations relating to the treatment of stock-based compensation for purposes of qualified cost sharing arrangements (the Proposed Regulations). The Proposed Regulations would require companies to use one of two methods to account for stock-based compensation of employees for purposes of determining costs to be shared. As a general rule, companies would use a valuation method that is generally based on the spread at exercise and consistent with the U.S. corporate tax deduction for many types of stock-based compensation (the general rule). Public companies traded on a U.S. exchange would be permitted to elect to value the options at grant using an economic model (such as Black-Scholes) in conformity with the alternative valuation typically reported in companies financial statement footnotes (the grant-date election). PwC expects that the IRS and Treasury will receive numerous comments criticizing the Proposed Regulations on grounds that they are not consistent with the arms length standard. Criticisms can be made based on evidence from actual arms length dealings, from economic and accounting perspectives, and by reference to case law, federal legislation or international tax treaties. PwC agrees that the Proposed Regulations are fundamentally flawed in these respects, but is confident that other comments will competently address these points. Therefore, although we strongly urge the IRS and Treasury to withdraw the Proposed Regulations in their entirety, we will limit our detailed comments here to suggestions to improve the fairness and usefulness of the Proposed Regulations if the IRS and Treasury are determined to finalize them at this time in spite of their serious defects. We suggest that, at the least, finalization of Proposed Regulations should be deferred until greater international consensus and coordination with other transfer pricing rules can be achieved. These issues are currently being studied by the Organization of Economic Cooperation and Development (OECD). In order to reduce the incidence of double taxation, it is crucial that the IRS and Treasury at least wait until an international consensus begins to form. Likewise, it is not reasonable for the IRS and Treasury to address this issue in a piecemeal fashion; rather, the implications of these rules on other transfer pricing issues should be fully considered before finalization. When and if the Proposed Regulations are finalized, they should

prospective only and transition rules should be provided. The grant-date election should be

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available to all taxpayers, not just public companies that trade on a U.S. stock exchange, and should be allowed on extended returns. Exercise-date valuation should be fully conformed to tax deduction rules (even for incentive stock options) and pro-ration over the option's vesting period should be allowed. For the grant-date valuation, any reasonable method should be allowed rather than requiring conformity with financial accounting rules alternatively, a minimum value method could be specified.

#### **COMMENTS**

#### A. The Proposed Regulations Are Not Consistent With the Arm's Length Standard

PwC expects that the IRS and Treasury will receive numerous comments criticizing the Proposed Regulations on grounds that they are not consistent with the arm's length standard. PwC agrees that the Proposed Regulations are fundamentally flawed in this respect, and is confident that other comments will extensively address these points. Because the arm's length standard is the central principle and foundation of international transfer pricing, we believe that promulgating these regulations will lead to numerous international tax disputes and increase the incidence of double taxation to the detriment of U.S. businesses. Therefore, we strongly urge the IRS and Treasury to withdraw the Proposed Regulations in their entirety. PwC fears that there is a strong possibility that the IRS and Treasury will choose to finalize these regulations in spite of their fundamental

flaws. As a result, we feel a duty to our worldwide clients to offer suggestions that will improve the fairness and usefulness of the Proposed Regulations if the IRS and Treasury are not persuaded by the public comments and hearings to withdraw them. While our detailed comments below will be limited to such suggestions, we want to emphasize that the comments are in no way intended to undermine our strong message that the regulations should not be finalized in any form. Before turning to our detailed suggestions, we wish to briefly outline some of the chief reasons why the Proposed Regulations are not consistent with the arm's length standard. The central inquiry in an arm's length analysis of cost sharing arrangements should be what costs independent parties would share under the same circumstances, and how they would measure and share such costs. The evidence from both private sector and government contracts demonstrates that independent parties do not, in fact, agree to share any amounts based on the other party's employee stock options. Far from being surprising, these actual business contracting practices are precisely what would be predicted by sound economic reasoning. An arm's length party would not be expected to agree to reimburse the spread-at-exercise value of another party's employee stock options

because the payments would be dependent on stock market fluctuations that are uncertain in time and amount, and entirely out of the payer's control. Arm's length parties would not be expected to agree to share amounts based on grant-date valuations either because Black-Scholes and the other economic models commonly used to value options are highly speculative and inaccurate when applied to employee stock options, which have much longer terms and many more restrictions than the market-traded options for which the models were designed.

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### B. Treasury Should Reassess Burden Imposed on Taxpayers by the Proposed Regulations

At the outset, PwC would like to comment on the accuracy of the Proposed Regulations estimates of the reporting and record-keeping burden imposed on taxpayers. Based on our experience advising clients that have both cost sharing arrangements and employee stock option plans, we believe that the additional burden imposed by the Proposed Regulations would be significantly in excess of two to seven hours for each affected taxpayer, and the average burden would be significantly in excess of four hours. In our assessment, the initial tasks of designing procedures and systems to comply with the Proposed Regulations will require several days of effort for most affected taxpayers. The decision whether to make the grant-date election or follow the general rule is itself a significant and far-reaching decision that warrants extensive research, thorough modeling and careful consideration of both the tax and financial accounting implications. Systems then need to be put in place to capture relevant information about each employee receiving stock options, including details about the options received and the employee's activities and responsibilities at the time. As for the recurring annual burden of complying with the Proposed Regulations, the necessary procedures are significantly different for each of the two allowed methods:

Under the grant-date election, the most difficult and time-consuming step of the process would be to apply the valuation model each time that an option grant is made. After each option grant, it would be necessary to determine the aggregate value of the options, make applicable adjustments (such as the adjustment for estimated forfeitures), and then determine how much of the adjusted total value is allocable to the cost sharing pool. Thereafter, the total allocated value would simply be amortized into the cost pool each quarter during the vesting period.

Under the general rule, on the other hand, pooling and amortization conventions could not be applied. Instead, each and every exercise of an option by an employee would have to be traced back to the initial option grant, a determination made whether (and to what extent) the employee was involved in cost-shared activities at that time, and the amount of the spread at exercise computed and added to the cost pool for the quarter.

The annual burden on taxpayers would therefore depend critically on the frequency of option grants or exercises (depending on the method) and the complexity of the stock option plans. The upper estimate of seven hours may be accurate for the least complex cases, but it is likely to require significantly more hours each year for most taxpayers. The Proposed Regulations also estimate that the number of taxpayers burdened by these rules to be about 500. Since nearly every taxpayer that participates in a cost sharing arrangement would be affected by the rules,

we feel the actual number may be twice or three times as high. In any case, however, we would warn Treasury not to take the relatively low number of affected taxpayers as an indication of the importance of this issue. The principles of the Proposed Regulations could easily be extended to all areas of intercompany transfer pricing where they would affect taxpayers in the hundreds of thousands. For example, it has been reported that Treasury and IRS are seriously considering adopting a similar approach to employee stock option issues in the update of the regulations on transfer pricing for services, which are expected to be completed during this Treasury business plan year. Lastly, we take issue with the claim of the Proposed Regulations that they would not

have a significant economic impact on a substantial number of small entities. PwC is aware of many small companies, especially in the high technology sector, that have both cost sharing arrangements and stock option plans and so would be directly affected.

C. Treasury Should Defer Finalization At Least Until International Consensus and Coordination with Other Transfer Pricing Rules Can be Achieved

#### 1. International Consensus

Accounting for employee stock options raises very difficult issues that are currently being studied by a number of key international bodies. In fact, the treatment of stock options for transfer pricing purposes is currently being studied by the Organization of Economic Coordination and Development (OECD), which is the most influential voice in the transfer pricing arena. Due to the significant risks of double taxation in this area, it would be very unfortunate if the U.S. Treasury were to promulgate inconsistent rules so soon before the OECD speaks on the issue. Employee stock options play a key role in the U.S. economy, particularly within the small business sector, providing the fuel for growth and innovation. Options motivate employees to give peak performances, and allow them to share the rewards if the enterprise is successful. As Senator Joseph Lieberman said in introducing a bill on stock option accounting in 1993: Equity is America's edge in global competition. It's our secret weapon. Neither the Europeans nor the Japanese have yet learned how to generate the kind of employee creativity and commitment that broad-based employee stock option plans have demonstrated for U.S. companies. Until now, the United States has been at the forefront of encouraging companies to use employee stock options. It would be unfortunate break with this tradition if the U.S. Treasury leads the way in imposing onerous rules relating to stock options that will lead to international double taxation and jeopardize their continued viability as a form of compensation. PwC strongly urges the IRS and Treasury not to finalize the Proposed Regulations before an international consensus begins to form.

#### 2. Coordination of Transfer Pricing Rules

The arm's length standard applies to all areas of intercompany transfer pricing. We do not believe it is reasonable or prudent for the IRS and Treasury to create rules for the treatment of employee stock options that apply only to cost sharing arrangements, which are only one aspect of

intercompany transfer pricing. Adopting transfer pricing rules in such a piecemeal manner is likely to create unfair traps for the unwary or give rise to other unforeseen consequences. Many examples of such unforeseen consequences are possible. Here we provide a single example in an area most closely related to cost sharing: determination of a buy-in royalty for use of pre-existing intangible property. Consider a U.S. company with a cutting-edge product line that reports substantial net margins on its public financial statements. As a result of its high-profile products and strong profit margins, the U.S. company has seen its stock price soar over the past few years and so many long-time employees of the company have exercised their stock options. As a result

of the stock option deduction, this company has little or no taxable income due to the high number of employees exercising their options at this time (and paying substantial individual income taxes on the income). Now, assume that, in connection with its global expansion, this company were to enter into an R&D cost sharing arrangement with a newly formed foreign affiliate. The Proposed Regulations would require both companies to share future stock option deductions in proportion to their shares of the benefits from the R&D program. Because only the U.S. company owns any pre-existing intangible property, the new foreign affiliate would also have to pay a buy-in royalty to the U.S. parent. Applying the principles of the Proposed Regulations and accounting for employee option spreads at exercise as an expense, the company finds it has had little or no profits for several years and does not expect to have any profits for several years into the future. Under the commensurate with income standard, profit potential is key to determining the amount of the buy-in royalty no matter what transfer pricing method is used. Assuming the company uses the comparable profits method to determine the buy-in royalty, the result will be a very low royalty rate since expected profits after stock option exercises scarcely cover the routine return for the new affiliate's manufacturing and sales functions. In contrast, if financial accounting standards were used for the transfer pricing analysis, rather than the principles of the Proposed Regulations, the buy-in royalty would be quite substantial in proportion to the strong reported profit margins since the value of employee stock option exercises would be recorded only on the statement of equity and would not affect the company's income statement. Another way to conceptualize this issue is to consider how an independent foreign marketing company that was considering entering into a joint venture with our cutting-edge U.S. company would react if asked to share the spread-at-exercise value of its employee stock options. Suppose further that the foreign venturer was able to overcome its deep misgivings about agreeing to make uncertain future payments that would be dependent on stock market fluctuations. As a quid-pro-quo for agreeing to such an unusual arrangement, the foreign venturer would likely demand that the buy-in royalty it would otherwise be willing to pay the U.S. company being greatly reduced or waived entirely. Otherwise, it would be risking hefty losses if the venture were successful when it would effectively have to pay the U.S. company twice for pre-existing intangibles, once in the form of the buy-in royalty and then again by reimbursing

multiple-year increases in the U.S. company's stock market value when its employees exercise their options. As this example shows, the effects of applying the principles of the Proposed Regulations to other areas of transfer pricing would be quite far-reaching, and often would be detrimental to the U.S. Treasury. The preamble to the Proposed Regulations indicates that the IRS and Treasury are also studying the issue more broadly. PwC believes it is not reasonable or prudent for the IRS and Treasury to finalize these regulations without considering the impact of their principles on all areas of transfer pricing. If the Proposed Regulations are not withdrawn in their entirety, PwC strongly urges the IRS and Treasury to postpone finalization at least until the treatment of employee stock options for all U.S. transfer pricing purposes can be harmonized.

D. If Not Withdrawn, Regulations Should Be Prospective Only and Should Provide Transition Rules

The preamble to the Proposed Regulations states: No inference is intended with respect to the treatment of stock-based compensation granted in taxable years beginning before the effective date of the final regulations. Meanwhile, PwC observes that the IRS continues to raise the stock option/cost sharing issue in audits and to litigate the issue in its dispute with Xilinx, Inc. (Tax Court docket #4142-01). In our opinion, the current cost sharing regulations clearly permit taxpayers to apply any reasonable accounting method to determine costs and revenues, provided the method is applied consistently, and specifically sanction the use of U.S. generally accepted accounting principles (U.S. GAAP) for this purpose. Moreover, we believe that it is not appropriate for the IRS to attempt to create new rules for the treatment of stock options in cost sharing by means of audits and litigation; rather, we believe that the current notice-and-comment process is the appropriate way to create broad new rules of this sort. Accordingly, we recommend that the IRS cease pursuing stock-option related adjustments in audits and cases against taxpayers that have consistently applied U.S. GAAP for cost sharing purposes. If the IRS and Treasury are determined to finalize the Proposed Regulations, we urge that they be made entirely prospective in effect. Clear transitions rules are needed to protect taxpayers from adjustments to prior years. At the very least, the second sentence of section 1.482-7(d)(2)(ii) should be revised as follows: Accordingly, all stock-based compensation that is granted after the effective date of this paragraph (d)(2), during the term of the qualified cost sharing arrangement and is related at date of grant to the development of intangibles covered by the arrangement is included as an intangible development cost under paragraph (d)(1) of this section.

E. If Regulations are Not Withdrawn, Election to use Grant-Date Valuation Method Should be Available to All Taxpayers and Further Liberalized

We commend the IRS and Treasury for introducing an element of flexibility to taxpayers in the Proposed Regulations in the form of the grant-date election. However, if the IRS and Treasury are determined to finalize these regulations in some form, we suggest that further liberalization of the election is needed to make the regulations more fair and useful. Most importantly, the fact that the Proposed Regulation only allows public companies that trade on U.S. exchanges to make the grant-date election unfairly penalizes privatelyheld and foreign companies. We recognize the great difficulty of valuing private company stock options, but strongly believe that this difficulty does not justify favoring U.S. public companies over those that are privately held by allowing only the former companies to make an election with such potentially dramatic tax effects. In any case, the valuation of private company stock, as would be required by the general rule, is itself difficult and contentious; the further difficulties of valuing private company options would be largely mitigated if our comments on minimum value method (Section G below) were to be favorable received. As for foreign public companies, the disparate treatment may provide an additional avenue for such companies to challenge the regulations by invoking tax treaty non-discrimination clauses. We also have two comments regarding the time and manner of making the grant-date election provided by the Proposed Regulations. First, we suggest that the IRS and Treasury reconsider the requirement that the election must be explicitly made in the written cost sharing agreement. This requirement raises difficult questions of enforcement and proof,

especially if the agreement is written in a language other than English. It would be more practical for the taxpayer to make the election on its U.S. tax return either under explicit disclosure requirement or, preferably, by its treatment of employee stock options in reporting the results of cost sharing in the first year that they are relevant. Second, we believe that time requirement for making the grant-date election in the Proposed Regulation is more stringent than is reasonable or necessary. Under the transition rule, there is no compelling reason to disregard elections made by the time that a timely, but extended, return is filed. The few extra months of stock market information available to the taxpayer would not negatively impact the Treasury in the long run since the election will be binding on the taxpayer for all subsequent years. It is not fair to cut short the time available to taxpayers for research, modeling and consideration before making such a significant and far-reaching decision.

F. If Regulations are Not Withdrawn, Exercise-Date Valuation Approach Should be Fully Conformed to Tax Deduction Rules and Pro-Ration Over Vesting Period Should be Allowed

#### 1. Conformity with Tax Deduction

PwC doubts that any rational argument exists to support the case that exercise-date accounting for employee stock options is consistent with the arm's length standard. That is, we do not believe that arm's length parties would ever agree to share an uncertain future amount that is dependent on stock market fluctuations, not directly related to their activities and entirely out of their control. Nonetheless, considering the difficulties of valuing options on grant date, we commend the IRS and Treasury for allowing exercise-date accounting. In fact, we do not fault the Proposed Regulations for choosing exercise-date accounting over grant-date as the general rule since exercise-date accounting is marginally simpler (in that it does not require use of complex valuation models) and is not as speculative (i.e., it does not penalize companies suffering stock market downturns). Many companies may choose exercise-date accounting over grant-date accounting, if a choice becomes required, because its effects on a company's income tax provision under U.S. GAAP appear to be clearer and less onerous. If the exercise-date method is applied, it is probable that any tax detriment caused by the Proposed Regulations would be reported as on the company's statement of equity rather than its income statement, which is the same treatment required by U.S. GAAP to account for any tax benefits from stock option deductions. However, to the extent the Proposed Regulation s treatment of stock options differs from their treatment for other U.S. corporate tax purposes, their harmony with U.S. GAAP tax provision rules is similarly diminished. Therefore, if the Proposed Regulations must be finalized, we recommend that the general rule be more fully conformed to tax deduction rules. Thus, we approve of the wording of the general rule that the amount subject to cost sharing is equal to the amount allowable to the controlled participant as a deduction for federal income tax purposes with respect to that stock-based compensation. Prop. Reg.1.482-7(d)(2)(iii)(A). On the other hand, we believe that the exception from the general rule for incentive stock options which makes section 421 inapplicable for purposes of the determining the cost pool [Prop. Reg. 1.482-7(d)(2)(iii)(A)(i)], is unwarranted and should be removed if the regulations are finalized. If the exception is removed, incentive stock options would give rise to a compensation expense

for cost sharing only if the employee makes a disqualifying disposition, and the amount would be based on the spread on the disposition date rather than the exercise date. Removing the exception for incentive stock options would greatly reduce the administrative burden on taxpayers adopting the general rule because they would not be required to apply different rules for different purposes. Although the general rule of the Proposed Regulations cannot be defended on policy grounds of upholding the arm's length standard, a possible policy rationale may be a concern that it is unfair to the Treasury for taxpayers to get a generous deduction for stock options under the tax code while being allowed to apply the miserly rules of U.S. GAAP for cost sharing purposes. Full conformity with the tax deduction rules is consistent with this rationale.

#### 2. Pro-Ration Over Vesting Period

One reason exercise-date valuation of employee stock options is not consistent with the arm's length standard is that it ignores the economic implications of vesting rules. It is irrational to consider any increases in stock value that occur after the options are fully vested to constitute compensation expense such increases should instead be considered the result of the individual employee's investment decisions. In order to improve the arm's length nature of the Proposed Regulations and reduce likelihood of double tax, we suggest that the IRS and Treasury consider allowing taxpayers to include in the cost pool only a pro-rated amount of the tax deduction relating to the period between grant and vesting dates during which employees were engaged in cost-shared activities. While we recognize that such a rule would increase the burden of complying the regulations, we believe that the extra burden is justified by the increase in fairness.

G. If Regulations are Not Withdrawn, Any Reasonable Method Should be Allowed for Grant-Date Valuation Election and Minimum Value Method Should be Considered as Alternative

#### 1. Any Reasonable Method

In previous non-binding written guidance, the IRS has posited that the taxpayer could use any reasonable method to account for stock options in cost sharing arrangements. We believe that the retreat to only two allowable methods under the Proposed Regulations is unwarranted. In particular, we believe that it is unfair to preclude the use of reasonable methods allowed by international accounting standards or use of home country GAAP by cost sharing groups that have foreign parent companies. If the regulations are finalized, we specifically recommend elimination of the requirement that the grant-date valuation method used for cost sharing purposes conform to the fair value of the stock options reflected as a charge against income in audited financial statements or disclosed in footnotes to such financial statements, prepared in accordance with [U.S. GAAP] by or on behalf of the company issuing the publicly traded stock.

If the grant-date election is made available to private and foreign companies, as we recommend above, this approach would introduce an unwarranted requirement that a U.S. GAAP audit be performed. Furthermore, the U.S. GAAP fair value conformity requirement would be

inappropriate for companies that would use significantly different assumptions to value options granted to employees performing cost-shared R&D activities than for all employees. For example, the forfeiture rate and average life of options granted to such employees may differ greatly.

Neither the IRS nor the company tax department should be bound by the aggregate assumptions adopted by the accountants for purposes of the fair value footnote. Currently, most taxpayers use the intrinsic value method to account for employee stock options for purposes of both cost sharing and U.S. GAAP reporting. PwC believes that this method is, in fact, a reasonable method that properly reflects stock option expense. The intrinsic value method measures the amount of stock-based compensation by the difference between the option's exercise price and the value of

the underlying stock at the time of grant. While it is evident from the market for publicly traded stock options that such options have a time value to the investor in addition to their intrinsic value, we do not agree that the time element of employee stock options constitutes a true expense to the company. The grant of at-the-money employee stock options does not reduce corporate cash flow, and the exercise of such options will not require any outlay of cash either. The grant of such options represents no more than the potential dilution of existing shareholders ownership. This is the same debate that took place when the Financial Advisory Standards Board (FASB) considered requiring companies to treat the fair value of employee stock options as an expense for U.S. GAAP purposes nearly ten years ago. After extensive public comments on the issue, the final rule allows companies to continue to use the historic intrinsic value method if they believe it is appropriate and only requires companies to disclose fair value information in the footnotes to their financial statements. The question of whether the intrinsic value or the fair value method of accounting for options better reflects the company's true financial condition is a question that management of U.S. public companies must consider each time they release GAAP financial statements. Based on its litigating positions and prior guidance, it is apparent that the IRS disagrees with us that the intrinsic value method allowed by U.S. GAAP is a reasonable method for cost sharing purposes. If the IRS and Treasury continue to hold this view after considering the comments and testimony on the Proposed Regulations, then the regulations could be modified to allow any reasonable method of accounting for stock options but specify that a method must include a time value element in order to be considered reasonable.

#### 2. Minimum Value Alternative

The so-called minimum value method is an alternative approach that the IRS and Treasury should consider if determined to finalize the Proposed Regulations. When the FASB considered accounting for stock options ten years ago, the minimum value method was considered as a possible approach for all companies and was adopted as an alternative to the fair value method for private companies. The minimum value method accounts for stock options time value by assuming the underlying stock will grow at the risk free interest rate. The minimum value is the value derived from the Black-Scholes model when the assumed volatility of the underlying stock approaches zero. Volatility is probably the most controversial and speculative of the variables required by the Black-Scholes model in the context of employee stock options. While the

short-term volatility of public company stock can be estimated with reasonable accuracy from available market data, such estimates become highly speculative over the much longer terms of employee stock options. Further, a basic assumption of the Black-Scholes model is that volatility is constant over time is challenged by empirical data showing that volatility can change significantly over time and that volatility in latter periods is dynamically affected by actual results in prior periods. Thus, requiring use of the minimum value method rather than allowing any reasonable method for transfer pricing purposes has the advantage of reducing uncertainty and potential for contentious disputes. It also serves the purpose insuring equal treatment of all taxpayers, whether private or public, domestic or foreign, and whatever approach management takes to determine the options fair value under U.S. GAAP rules. If the IRS and Treasury were to promulgate regulations for using the minimum value method, the regulations would need to address the same issues that the FASB addressed with respect to fair value accounting. First, the estimated term of the options should be based on average employee holding periods rather than the options nominal term to account for early exercise. Second, the aggregate value of options issued to relevant employees under the plan should be reduced by a factor based on expected turnover rates to deal with pre-vesting forfeitures. Finally, the regulations could provide guidelines for determining the risk free rate of return by reference to the applicable federal rate (AFR) used for other tax purposes.

PwC encourages the IRS and Treasury to reconsider the Proposed Regulations in light of our comments. We are planning to testify at the public hearing scheduled for November 20, 2002, and would be more than happy to discuss or expand upon these comments if requested.

Respect	Turry Submitted,		
Dated:	October 28, 2002		
Pricewa	terhouseCoopers LLP		
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**2003** APR 11 P 1: 58 150 Almaden Boulevard San Jose CA 95113

RECEIVED

B. John Williams Chief Counsel Internal Revenue Service 1111 Constitution Ave, N.W. Suite 3026 Washington, DC 20224

April 8, 2003

Re: PricewaterhouseCoopers Submission to OECD on Stock Options and Cost Sharing

Dear Mr. Williams:

We enclose for your reference a complete copy of our recent submission to Caroline Silberstein of the OECD relating to the issue of the arm's length standard and inclusion of stock options in cost sharing arrangements. As you will see from our submission, we provide a number of examples of publicly available documents which demonstrate that parties at arm's length do not share such activity. As we understand it, this topic is under consideration by Working Group #6 of the OECD this month.

We have noted, with interest, your recent statements on the subject of stock options and cost sharing in the context of the proposed U.S. regulations under Treas. Reg. Sec. 1.482-7. We at PricewaterhouseCoopers participated in the public comment process on those proposed regulations. We suggested, inter alia, that the Treasury not finalize those until an international consensus was achieved. So, while we expect you will be receiving a copy of our submission from the OECD, we would like to take this opportunity to provide copies directly to you and the IRS and Treasury personnel involved in the regulations project.

Our submission to the OECD addresses several concerns that have been raised by the IRS about the apparent need for change in this area. First, the submission presents evidence from actual agreements between unrelated parties that have been filed with the SEC, which demonstrate employee stock option expenses are not shared or reimbursed at arm's length. Second, the submission discusses how these findings may be understood within the theory of arm's length behavior, with a particular focus on the perspective of the option-granting party. In short, the submission notes that the motivational and retentive benefits of stock options accrue chiefly to the option-granting party and are not diminished or transferred by entering into a joint venture with another party.

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Finally, we would like to emphasize that evolving positions on the accounting treatment of employee stock options under U.S. and international standards (including those of our firm) have no direct bearing on the transfer pricing issues, which are governed by the arm's length standard. What information on employee stock options is provided to shareholders and how it is presented does not answer the question of whether independent parties would consider stock option "costs" to be an operating item relevant to arm's length negotiations or a non-operating item akin to interest expense.

Should you or others at the Treasury or the IRS want to discuss the contents of our OECD submission more fully, we would be pleased to meet or discuss the items with you.

Sincerely,

Eric D. Ryan

Partner, Transfer Pricing Services

Encl.

cc: Steve Musher, Deputy Associate Chief Counsel, IRS

Elizabeth Beck, Chief, Branch 6, IRS

Douglas Giblen, Senior Counsel, Branch 6, IRS

Rocco Femia, Attorney-Advisor, Treasury Department

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Caroline Silberztein
Head of Transfer Pricing Unit
Tax Treaties & Transfer Pricing Division
Centre for Tax Policy & Administration
OECD, 2 rue André Pascal, 75016 Paris

April 1, 2003

Re: Stock Options and Transfer Pricing

Dear Caroline:

We are enclosing three (3) copies of PricewaterhouseCooper's discussion paper for the OECD on the transfer pricing treatment of stock options. In this paper, we present evidence of actual arm's length dealings based on public filings with the Securities and Exchange Commission (SEC). These filings suggest that independent parties do not agree to share or reimburse "costs" related to another party's employee stock options. The paper also discusses how these findings may be understood within the theory of arm's length behaviour.

Exhibit A, attached to the discussion paper, summarizes our review of relevant SEC filings. As the paper indicates, a number of searches were undertaken using a variety of search tools and strategies, including key word searches and industry-specific searches. Due to the complexity of this type of arrangement, undertaking a rigorous search and comprehensive review of agreements proves to be a difficult and time-consuming process. Among other things, we would seek your views on whether a broader and more formal search, perhaps expanded to other jurisdictions, would be useful.

Lastly, we are enclosing single copies of each of the three SEC-filed agreements discussed in the paper (Healtheon-BSC, AgraQuest-Rohm & Haas, and Amylin-HMR). Exhibit A provides exact citations to the SEC's website for these and all other agreements reviewed; we would be happy to provide copies if desired.

Please feel free to distribute these materials to your Delegates in Working Group #6.

Sincerely,

Eric D. Ryan, Partner, Transfer Pricing Services

Encl.



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## TREATMENT OF EMPLOYEE STOCK OPTION IN INTRA-GROUP TRANSFER PRICING ARRANGEMENTS

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# TREATMENT OF EMPLOYEE STOCK OPTION IN INTRA-GROUP TRANSFER PRICING ARRANGEMENTS

#### A. Introduction

The U.S. transfer pricing services group of PricewaterhouseCoopers ("PwC") is pleased to present this discussion paper for consideration by the Organisation of Economic Cooperation and Development ("OECD"). This paper discusses the proper treatment of employee stock options in intra-group transfer pricing arrangements.

PwC has been actively involved with stock option issues in the context of cost sharing (cost contribution) arrangements, where U.S. tax authorities have urged that employee stock options should be treated as development costs. PwC has represented a high technology industry group in filing a brief amicus curiae on the issue with the U.S. Tax Court. PwC also provided comments to U.S. tax authorities with regard to recently proposed regulations.

PwC's transfer pricing group has also been closely following option-related developments in U.S. and international accounting standards. Clearly, the arm's length principle must govern the treatment of stock options for transfer pricing purposes, regardless what the accounting outcomes turn out to be. In this paper, we first present evidence of actual arm's length arrangements between independent parties, and secondly address the issue from the theory of arm's length behaviour.

Both evidence and theory lead to the same conclusions. Independent parties do not, and would not, agree to share or reimburse purported "costs" relating to another party's employee stock options. Option-granting companies consider their stock option plans to be important for motivating and retaining employees, but also recognise that these benefits accrue principally to the company itself and so do not look to recover putative "cost" of the stock options from potential joint venture partners or collaborators. In addition, it is much more likely that stock option compensation paid to employees working on a joint development project is related directly to the current and near-term success of the employing companies than to the highly speculative results of the development project.

<sup>&</sup>lt;sup>1</sup> This paper chiefly discusses options that are "at-the-money" when granted, which do not give rise to compensation expense under accounting standards currently used by most companies. While the issues may warrant further thought, this paper does not address treatment of "in-the-money" options because such grants are very rare in practice and therefore evidence of arm's length behaviour is scarce.



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Finally, this paper will demonstrate that the same considerations lead to somewhat different conclusions in the case of stock option "recharge" agreement. That is, because companies recognise the motivational value of stock option plans, they would be willing to make payments to secure stock options that can be granted to their own employees.

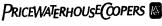
# B. Evidence from Actual Agreements

Evidence from actual arm's length arrangements provides the best indication of arm's length terms and conditions for comparable arrangements between controlled parties. This principle is fundamental under both OECD Guidelines and U.S. Treasury Regulations. Expressing scepticism that independent parties enter into arrangements that are comparable to cost sharing arrangements, the IRS has relied on hypothetical examples and theoretic arguments to reach the conclusion that stock option expense would be shared at arm's length. However, this paper will show that information in the public domain provides evidence on how independent parties treat employee stock options in comparable arrangements.

Corporate filings with the U.S. Securities and Exchange Commission ("SEC") provide a wealth of reliable information on arm's length dealings, including the actual text of the filing company's material contracts.<sup>2</sup> Certain inferences can also be drawn from regulations controlling contracts between the U.S. government and private companies. Any cost-based agreements (not merely cost sharing agreements) may provide evidence relevant to our inquiry although fixed fee and revenue-based agreements will not. In practice, cost-based arrangements are most common for research and development activities where the revenue impact of the activities is uncertain and difficult to measure.

Cost-based agreements with relevant evidence that have been identified range from contract development agreements, where one party performs the activities and the other party owns any resulting developments, to collaborative development agreements, where each party makes certain contributions to the development activities and receives specified interests in developments. Below, this paper describes search efforts generally, discusses three specific private agreements, discusses U.S. government contracting regulations, and then draws certain conclusions about the arm's length treatment of employee stock options. The evidence on the stock option issue may not be overwhelming in volume but, taken together, shows quite compellingly that independent parties do not agree to make payments based on another party's employee stock options.

<sup>&</sup>lt;sup>2</sup> Although portions of agreements, including specific dollar amounts and mark-up rates, may be granted confidential treatment and filed separately with the SEC, material provisions relevant to cost determinations and accounting standards are ordinarily disclosed in full detail.



# 1. Summary of Search Efforts

A number of searches of SEC filings for relevant cost-based agreements have been undertaken using a variety of search tools and strategies. Some searches have focused on industries where collaborative research is particularly common, such as the bio-technology industry. Others have used database search tools to locate potentially relevant agreements by way of search terms, such as "cost sharing" or "collaboration."

Several general observations can be made about the findings of these searches. First, it is clear that cost sharing (cost contribution) agreements in which independent parties jointly develop intellectual property for separate exploitation actually do exist. Therefore, tax authorities cannot dismiss evidence of actual arm's length behaviour when reviewing, or setting rules for, controlled cost sharing arrangements.

Second, in arm's length agreements, research and development activities are typically compensated based on either fixed fees for achieving specific "milestones" or fixed rates for "full-time equivalent" employees devoted to the activities. To break such fees into component elements would require detailed knowledge of the company's cost structures and negotiating strategies. In any event, because the fixed fees and rates are determined in advance of commencing work, it is clear that the spread-at-exercise values of employee stock options cannot be included.<sup>3</sup>

Third, in those agreements with a significant cost-based component, costs are typically defined by reference to generally accepted accounting practices ("GAAP") used by the parties. Exhibit A of this paper catalogues all cost-based agreements that have been identified as well as the employee stock option policies and accounting methods used by the parties. In all cases, the companies follow an accounting method that does not recognise any expense for employee stock options that are at-the-money when granted.

Fourth, three of the agreements provide additional evidence that stock options are excluded from relevant cost bases. One explicitly excludes any expense related to stock options that may be granted; another narrowly defines costs to be shared to "out-of-pocket costs"; and the third includes a provision to insure that material costs continue to

<sup>&</sup>lt;sup>4</sup> In many cases, GAAP accounting is specified in the agreement; in others, it is implied by provisions for audits of records by a major accounting firm. Each variation is documented in Exhibit A to this paper.



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<sup>&</sup>lt;sup>3</sup> Due to stock market volatility, spread-at-exercise values cannot be known in advance of the time individual employees exercise their options. Since grant-date option valuations are also dependent on the grant-date price of the underlying stock, the value of future option grants can typically only be estimated on the date of entering into the arm's length agreement

be determined in the same way even if GAAP standards were to change. These agreements are described in detail in the following sections of this paper.

Finally, it is important to note the complete lack of counter-evidence. Not one agreement has been identified in which an independent party agrees to share or reimburse another party for its employee stock options. While some may speculate that arm's length behaviour may change if GAAP is modified to require stock option expensing, the actual evidence is to the contrary. Most arm's length agreements appear to take current GAAP rules as a given, but those few that anticipate possible changes in the parties' option-granting practices or GAAP accounting rules include provisions that would exclude stock option compensation expense from cost determinations.

# 2. Healtheon-BSC Agreement

The first agreement to consider is the "Master Services, Development and License Agreement" dated November 1999 between Healtheon Corporation ("Healtheon") and Beach Street Corporation ("BSC"), attached as Exhibit 10.34 to WebMD Corporation's ("WebMD") Form 10-K405 filed March 30, 2000. WebMD, which was formed in 1999 through a merger of Healtheon and three other companies, provides web-based healthcare information and services to facilitate connectivity and transactions among physicians, patients, payers and other healthcare industry participants.

BSC is both a major customer and a "strategic partner" of WebMD. The Healtheon-BSC Agreement governs both the basic services provided by BSC as well as the development of a new software product. In general, WebMD is responsible for performing all service and development activities while BSC makes certain funding commitments. In exchange, WebMD and BSC each receive certain ownership rights in developments.

Under Exhibit A of the Healtheon-BSC agreement, BSC pays fees equal to a fixed percentage mark-up on "direct" expenses associated with "IT Employees" plus fixed monthly management fees. Exhibit A defines direct expenses to include salaries and benefits (at an assumed rate) but explicitly provides: "In the event that Healtheon decides to provide any of the IT Employees with Healtheon stock options, Healtheon agrees that it will not charge BSC any expenses associated with any such grants."

In fact, in connection with the merger creating it, WebMD assumed all of the merging companies' outstanding options and thereafter adopted its own employee stock option plan. However, WebMD is precluded from charging BSC for these options by the

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<sup>&</sup>lt;sup>5</sup> Available at <a href="http://www.sec.gov/Archives/edgar/data/1088917/0000950144-00-004229-index.html">http://www.sec.gov/Archives/edgar/data/1088917/0000950144-00-004229-index.html</a>. Healtheon/WebMD was formed in November 1999 by a merger of Healtheon, WebMD, MedE America and Greenberg News Network, and changed its name to WebMD Corp. in August 2000.



explicit terms of Exhibit A. This example clearly demonstrates that, when faced with the likely prospect of new options, parties negotiating at arm's length agree to exclude any expense relating to the options from cost-based fee determinations.

## 3. AgraQuest-Rohm & Haas Agreement

The second agreement to consider is the "Research and Development Agreement" dated October 2000 between AgraQuest Inc. ("AgraQuest") and Rohm and Haas Company (since acquired by Dow LLC ("Dow")), attached as Exhibit 10.7 to AgraQuest's Form S-1/A filed January 11, 2002. AgraQuest is a development stage biotechnology company that conducts proprietary research and development on natural pest management products.

Under this agreement, Dow has the exclusive, worldwide rights to commercialise seven of AgraQuest's product candidates for uses other than human health, animal health and aquaculture. For each product candidate selected, Dow pays AgraQuest an upfront fee, reimburses its development costs, and makes additional milestone payments. The agreement also provides for royalties if Dow commercialises any of the candidates, and provides a right of first refusal to manufacture these product candidates for Dow in exchange for cost reimbursements plus a share in the profits. Dow selected its first product candidate to develop and commercialise under this agreement in November 2000.

Under section 6.4 of the agreement, governing the third stage of development efforts, Dow must reimburse AgraQuest for the "Actual Costs" of its activities provided that AgraQuest obtains prior written approval if the costs exceed a specified threshold. Actual Costs are defined in section 2.1 of the agreement as "the out-of-pocket costs, including labor costs and indirect overhead expenses (head-count driven facilities and administrative allocation)."

The limitation of reimbursement to "out-of-pocket costs" is particularly significant because AgraQuest reports some stock-based compensation expense in its SEC-filed financial statements under current GAAP standards. The expense relates to options granted prior to AgraQuest's initial public offering that were later determined to have been "in-the-money" at grant. This agreement demonstrates that, in this instance, independent parties explicitly chose not to share or reimburse employee stock option expenses even though they were recognised under GAAP.

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<sup>&</sup>lt;sup>6</sup> Available at <<a href="http://www.sec.gov/Archives/edgar/data/1014455/000093066102000063/dex107.txt">http://www.sec.gov/Archives/edgar/data/1014455/000093066102000063/dex107.txt</a>.

### 4. Amylin-HMR Agreement

The third and final agreement to consider is the "Collaboration Agreement" between Amylin Pharmaceuticals Inc. ("Amylin") and Hoescht Marion Roussel Inc. ("HMR") (now known as Aventis Pharma) dated March 31, 1997, attached as Exhibit 10.32 to Amylin's Form 10-Q filed March 31, 1997. Amylin is a development stage company that conducts proprietary research and development on potential pharmaceutical products.

Concurrent with the Collaboration Agreement, Amylin and HMR entered into a "License and Option Agreement" under which Amylin was granted exclusive worldwide rights to a series of orally active compounds in order to evaluate their ability to improve cardiovascular risk factors associated with atherosclerosis. Under the terms of the License and Option Agreement, Amylin is responsible for conducting the preclinical evaluation and clinical development of candidate compounds; and HMR has a one-time option, upon completion of Phase II clinical trials, to elect to collaborate with Amylin in the continuing development and commercialisation of the compounds in a 50:50 cost-and-profit sharing arrangement.

If HMR exercises the option, Amylin will continue to be responsible for developing and registering the product candidates, and HMR will be responsible for manufacturing and marketing. Amylin and HMR will assume equal responsibility for all past and future research and development, manufacturing, and commercialisation expenses and will share equally in any operating profits from commercialisation. If HMR does not exercise the option, Amylin will remain responsible for all past and future research and development and will retain all development and commercialisation rights, and HMR will be entitled to a royalty based on any future net sales.

Section 3.11 of the Collaboration Agreement provides the accounting rules for determining all revenues and expenses in computing the 50:50 split of operating profits and losses. While accounting for stock options is not specifically referenced, the agreement contains very detailed provisions regarding the application of U.S. GAAP:

Except as specifically provided in this Agreement, each Party agrees to determine Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and all other costs and expenses hereunder with respect to the Products using its standard accounting procedures, consistent with United States Generally Accepted Accounting Principles, to the extent practical, as if such Products were solely owned products of the Party. The Parties also recognize that such procedures may

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<sup>&</sup>lt;sup>7</sup> Available at < <a href="http://www.sec.gov/Archives/edgar/data/881464/0000936392-97-000714.txt">http://www.sec.gov/Archives/edgar/data/881464/0000936392-97-000714.txt</a>.



change from time to time and that any such changes may affect the definition of Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and such other costs and expenses. The Parties agree that, where such changes are economically material to either Party, adjustments shall be made to compensate the affected Party in order to preserve the same economics as reflected under this Agreement under such Party's accounting procedures in effect as of the date on which the activity in question (for example, Research, Development, marketing or manufacturing) first commences under this Agreement.

Collaboration Agreement, Section 11(b) (emphasis added). The subsection continues by specifying that any change that affects development costs by five percent or more will considered economically material.

These detailed provisions have the effect of requiring Amylin to exclude stock option expense from cost and profit calculations even if GAAP standards were to change to require mandatory expensing on a grant-date fair-value basis. Initially, the provision requires Amylin to use "its standard accounting procedures" consistent with U.S. GAAP. SEC filings for 1997 and 2001 confirm that Amylin had employee stock option plans in place but did not recognise any stock-based compensation expense under GAAP.

If GAAP rules were to change to require option expensing (or if Amylin voluntarily elects expensing), then the provisions regarding "economically material changes" in accounting procedures would come into play. A careful review of the financial data disclosed in Amylin's financial statement and footnotes reveals that the resulting change in development costs would significantly exceed the five percent materiality threshold. Therefore, section 11(b) of the Collaboration Agreement would require Amylin to make adjustments "to preserve the same economics as reflected" in the initial year by disregarding the option expense. It is important to note that this provision is self-executing – it does not call for re-negotiation of the agreement.

Thus, the Collaboration Agreement is further evidence that parties negotiating at arm's length would not agree to share or reimburse each other's stock option expenses even if expensing is mandated for GAAP reporting purposes.

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<sup>&</sup>lt;sup>8</sup> Amylin Pharmaceuticals Inc., Form 10-K405 (December 31, 1997), Exhibit 13.1 at page 6; and Amylin Pharmaceuticals Inc., Form 10-K405 (December 31, 2001) at page F-8.

# 5. U.S. Government Contracting Regulations

The U.S. military contracts with private contractors for billions of dollars worth of research and development services each year. These contracts are governed by the Federal Acquisition Regulation ("FAR"). 48 C.F.R. § 1.101 et seq. Due to the uncertainties involved in contract performance, many military contracts are structured as so-called "cost-reimbursement contracts" See 48 C.F.R. § 16.301-307. For example, many are "cost-plus-incentive-fee contracts" which provide for an initially negotiated fee to be adjusted later by a formula based on the relationship of total allowable costs to total target costs. 48 C.F.R. § 16.304. Even so-called "cost-sharing contracts," which do not include a profit mark-up, are available for situations where the contractor retains title to some of intangibles developed. 48 C.F.R. § 16.303. See 48 C.F.R. 27.302(b).

Part 31 of the FAR provides the principles and procedures for all situations where payments may be based on contractor costs, including all types of cost-reimbursement contracts. See 48 C.F.R.§ 31.103. The provisions of the FAR governing accounting for compensation specifically exclude amounts that are "based on changes in prices of corporate securities or corporate security ownership, such as stock options, stock appreciation rights, phantom stock plans, and junior stock certificates." 48 C.F.R.§ 31.205-6(i). If this language leaves any doubt, the following subsection removes it by specifying that "any compensation that is calculated, or valued, based on changes in the price of corporate securities is unallowable." 48 C.F.R.§ 31.205-6(i)(1). The FAR provisions are significant because they demonstrate that thousands of private companies have entered into cost-reimbursement contracts with the U.S. military on terms that did not include any compensation for employee stock options.

# 6. Conclusions

In short, all of the evidence from actual agreements points to the same conclusion: that parties dealing at arm's length do not agree to make payments in consideration of another party's employee stock options. The agreements demonstrate that GAAP is an important reference point for parties negotiating at arm's length, but all agreements that specifically consider the possibility of option expense being recognised under GAAP contain provisions that effectively exclude the option expense from the relevant cost base.

Companies that have reviewed their own co-development and collaboration agreements confirm that the limited public evidence is consistent with their own experience. In the vast majority of cases, the companies are prevented by non-disclosure provisions from publicly revealing the terms and conditions of these agreements. However, because many companies with controlled cost sharing agreements also have similar arrangements with third parties, tax authorities will often be in the position to confirm this situation for themselves.



# C. Theory of Arm's Length Behaviour

While the evidence from actual agreements demonstrates that parties do not agree to share stock option expense, it remains worthwhile to consider the issue from a theoretical perspective as well. It is admittedly difficult to establish a high degree of comparability between the controlled and uncontrolled transactions due to the complexity of the overall arrangements. Further, some may consider the conclusions drawn from the evidence to be counter-intuitive. However, the conclusions can be reconciled with the theory of arm's length behaviour if the purposes of employee stock option plans are taken into account.

The arm's length principle means that arrangements between controlled parties should be consistent with the bargain that would be struck by two willing, independent parties. Striking the bargain may require both parties to compromise, but no deal will be concluded if either party is not satisfied with the final terms. In this case, it is crucial to look at the issue from both perspectives: that of the party that will be making payments and that of the party granting options to the employees performing the work. While it may be easy to understand why the paying party would be reluctant to pay the other party's for its options, it is less obvious why option-granting party would be willing to forego such a payment. The following sections consider each side of the deal in turn.

# 1. Perspective of Paying Party

The reasons that the payer would be unwilling to pay for the other party's stock options are well-known and will not be belaboured here. The reasons include concerns that the payments are dependent on stock market fluctuations that are uncertain in time and amount, not directly related to the joint development activity and entirely out of the payer's control. The concerns are highlighted by the extreme volatility experienced in the stock market in recent years, particularly in the option-reliant high technology sector. The paying party's concerns differ to some degree depending on whether option expense is measured on exercise date or grant date.

Deferring measurement of stock option expense until the exercise date would not provide the level of certainty required by arm's length parties to enter into cost sharing or other long-term arrangements. Exercise-date valuation would have the effect of the paying party writing a naked call option on the other party's stock, exposing it to unlimited liability without regard to whether the joint development efforts played any role in the stock's performance. Also, since exercise-date values include any increases in stock value that occur after vesting, a significant part of the value should be considered to result from employees' personal investment decisions rather than compensation.

Using an grant-date valuation model to measure employee stock option expense does not produce an arm's length result either. Economic models (such as Black-Scholes)

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were designed to value short-term options that are actively traded in equity markets. These valuation models are highly speculative and inaccurate when applied to employee stock options for many reasons, which can largely be separated in two categories: first, many restrictions on their exercise and transfer and, second, their very long term.

# 2. Perspective of Option-Granting Party

Some question why the option-granting party would be willing to allow its employees to engage in a joint effort without some consideration for stock option compensation. From this perspective, it is first important to recognise that employee stock options do not require any outlay of cash by the option-granter at grant, exercise or any other date. Whether or not this fact is relevant to the issue of whether stock options are an "expense" in the accounting sense, it is relevant to arm's length theory because the option-granting party would be more willing to compromise in arm's length negotiations on the issue of options than on other compensation elements that affect cash flows.

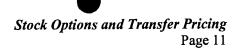
Despite the absence of cash costs, companies clearly consider stock option plans a vital and valuable part of their employee compensation programs. While accounting debates tend to focus on the value of stock options to the individual employees, it is key to the current inquiry to consider the benefits of option plans to the corporate employers. Aside from preserving the company cash resources, stock options play an important role in motivating and retaining employees. By aligning the interests of the employees with those of the shareholders, stock options provide a powerful incentive for employees to perform to the peak of their abilities. Vesting conditions associated with most stock option plans provide an further incentive for employees to remain with the company even if the options increase in value.

Entering into a joint development arrangement in no way diminishes the incentive effects of options or the resulting benefits to the company and its shareholders. Furthermore, the employee loyalty and dedication promoted by stock option plans accrues only to the employing company and in no way is transferred to the business partner. Accordingly, the existence of an employee stock option plan is irrelevant to a company's decision whether to use an employee in an in-house project or allow him to work on a joint project. As a result, at arm's length, option-granting companies would not insist on recovering the putative "cost" of the stock options from potential joint venture partners or collaborators.

### 3. Implications for General Transfer Pricing

Thus, both evidence and theory suggest that independent parties do not agree to share or reimbursement "costs" relating to other parties' stock option plans. The implications in the context of cost sharing (cost contribution) arrangements is obvious: stock option expense should not be included in the development cost pool. The





implications to transfer pricing in general are much broader and can be summarised as follows: stock-based compensation expense, even if recognised for under accounting rules, should generally not be treated as an operating expense for transfer pricing purposes. As a result, the expense should not be included in the cost base for service transactions and should not recognised when determining gross or net level profits in applying other methods (such as the resale price method or the transactional net margin method).

## 4. Implications for Stock Option Recharges

The same considerations lead to somewhat different conclusions in the case of stock option "recharge" agreement. Typically, under a recharge agreement, a foreign subsidiary purchases its parent company's stock at market prices in order to satisfy stock option exercises by the subsidiary's employees. While there are a number of variations on this theme, the key factor distinguishing recharges from other stock option issues is that the options are held by the employees of the company making the payment rather than by the company performing the services.

In the recharge situation, the employing company wants to use stock option compensation in order to motivate and retain its own employees. However, because the subsidiary is not publicly traded, options on its own stock would be far less effective than options on a public parent company's stock. Recognising the motivational value of parent company stock options, the subsidiary would be willing to make payments to secure stock options that can be granted to its own employees.

PwC encourages the OECD to consider our comments before issuing guidance on the treatment of employee stock options for transfer pricing purposes. We would welcome an opportunity to discuss or expand upon these comments with any interested parties.

		Respectfully Submitted,
Dated:	March 31, 2003	
		PricewaterhouseCoopers

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	Parties - Title - Date	Exhibit # - Edgar cite	Brief Description	Compensation Terms	Accounting Provisions	Option Plan Details
WebMD Corporation's ("WebMD") Form 10-K405 filed March 30, 2000	Master Services, Development and License Agreement between Healtheon Corporation ("Healtheon") and Beach Street Corporation ("BSC") dated November 1999	Exhibit 10.34 at <a href="http://www.scc.gov/Archives/organ/data/108917/00009">http://www.scc.gov/Archives/organ/data/108917/00009</a> sol44-00-004229-index.hmb>.	Mix of contract services and joint development; Healthcon/ WebMD performs work, BSC provides funding	Exhibit A: BSC pays fixed percent mark-up on direct IT employee expenses, plus fixed monthly management fees	Accing standards unspecified; Sectn 7.5: audit rights; Exhibit A: explicitly excludes "any expenses associated with" any stock option grants	WebMD has option plans; follows APB 25; recognises expense for "in-the-money" grants
AgraQuest Inc. ("AgraQuest") Form S-1/A filed January 11, 2002	AgraQuest Inc. ("AgraQuest") Research and Development Agreement Form S-1/A filed January 11, between AgraQuest and Rohm & Haas 2002 Company (since acquired by Dow LLC ("Dow Agrosciences")) dated October 2000	Exhibit 10.7 at chip/lwww.sec.gov/Archive secgov/Archive secgov/Archive 100610200063/dex107.tx>	License for Dow to commercialise AgraQuest product candidates; AgraQuest provides development services	Secta 6.4 (governing the third stage of efforts): Dow reimburses AgraChest for the "Actual Costs" of its activities provided that AgraChest obtains prior written approval if the costs exceed a specified threshold	Secta 2.1 defines "Actual Costs" as "the out-of-pocket costs, including labor costs and indirect overhead expenses (head-count driven facilities and admin. allocation)" thereby excluding option expense	AgraQuest has an option plan; follows APB 25; recognises expense for "in-the-money" grants
Amylin Pharmaceuticals Inc. ("Amylin") Form 10-Q filed March 31, 1997	Collaboration Agreement between Amylin and Hoescht Marion Roussel Inc. ("HMR") (aww known as Aventis Pharma) dated March 31, 1997	Exhibit 10.32 at chapt/www.scc.gov/Archves/degar/data/81464/000093 6392-97-000714.txp	At HMR's option, 50:50 cost and profit sharing with Amylin responsible for development and HMR for manufacture & commercialisation	If HMR exercises option, balancing payments to achieve 50:50 cost-and-profit split; (otherwise, Amylin funds R&D and HMR pays sales-based rovalty to Amylin)	Secta 3.11: each Party uses "its standard accounting procedures" consistent with U.S. GAAP: material changes in GAAP rules (more than 5% affect on costs) will be ignored	Amylin has option plans and follows APB 25; review of FAS 123 footnote data shows change to fair value option accrit to be material
Curagen Corporation ("Curagen") Form 10-K filed March 28, 200!	Metabolic Disorder Collaboration Agroement between Curagen and Bayer Corporation, a subsidiary of Bayer AG ("Bayer") dated January 12, 2001	Exhibit 10.24 at chapter of chapt	Collaboration to discover, develop and jointly commercialise obesity and diabetes drugs; joint & R&D finding up to \$1.3 thillion over a 15-year period, split 56% Bayer '44% Cunagen; profit sharing in same reconvitions.	Secto 4.1: R&D cost sharing; sector 4.2: milestone payments and royalties for any drugs not cost shared	Secta 4.10: Bayer uses its "then standard accounting principles consistently applied": Cungen uses "U.S. GAAP consistently applied"	Curagen has option plans, follows APB 25, and recognises no option expense; option plans are minor part of Bayer Ag's compensation programs
Neurocrine Biosciences ("Neurocrine") Form 10- K405/A filed November 20, 1997	Development and Commercialization Agreement between Neurocrine and Ciba-Geigy Limited ("Ciba", now known as Novartis AG) dated December 20, 1996	Exhibit 10.24 at chips/www.sec.gov/Archive s/edga/dan/9/1475/00089 1618-97-004738.tx>	Che funds Neurocine's development of therapeuties with milestone payments; Che owns exclusive rest-of-world rights, but Neurocine is entitled to profit share on North American sales subject to recoupunt of development costs	Sectu 9.1: Neurocrine's profit share and repayment of Recoupable Development Costs; defined in Sectn 1.27	Sectu 1.34: Ciba's costs shall be lesser of amount under Int'l Accrag Stds code (IASB) and U.S. GAAP; Sectu 10.5: audit rights	Cibe has option plans, reognises no option expense under IASB (although it would under APB 25 for its "variable plans")
	Collaboration Agreement between Scios and Genetech, Inc. ("Genetech") dated December 30, 1994	Exhibit 10.32 at chip/lwww sec.gov/Archive s/orgar/data/75512/00091 2037-95-005638.txP	Joint development and marketing of themspetic; Series bears costs until US regulatory approval, on approval, Genenited pays \$30 million milestone and parties share further N.America development and promotion costs and permits senually	Article 7: Milestones, profit sharing and royalties	Exhibit A: Sales, COGS, etc. to be determined in accordance with U.S. GAAP "as applied by the Party"	Both Scios and Genentech have option plans, follow APB 25, and recognise no option expense
Viropharma Inc. ("Viropharma") Form 10- K405 filed March 15, 2000	Collaboration and License Agreement between Viropharma and American Home Products Corporation, acting through its Wyeth-Ayerst Laboratories Divusion ("AHPC"), dated December 9, 1999	Exhibit 10.25 at chip://www.acc.gov/Archive s/ctgar/daa/946840000103 6050-00-000357-infex.hml>	Collaboration and license for therapeutics; AHPC gets rest-of-world rights for royalty; co-promotion in North America; milestones in cash and stock purchases at premium to market; North America profits to be split equally	Secta 4.6: funding of the research program, including R&D accounts, expense limitations and reconciliation provisions	U.S. GAAP specified for Sales and COGS, but silent on R&D expense; Sectu. 4.6.6: audit rights - CPA firm "of nationally recognized standing"	Both Viropharma and AHPC have option plans, follow APB 25, and recognise no option expense

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EXHIBIT A: COST-BASED AGREEMENTS FROM SEC FILINGS

PricewaterhouseCoopers LLP
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EAHIBITA: COST-BASED.	EAHIBITA: COST-BASED AGREEMENTS FROM SEC FILINGS						
SEC Filing	Parties - Title - Date	Exhibit # - Edgar cite Brief Description	Brief Description	Compensation Terms	Accounting Provisions	Option Plan Details	
Leukosite Inc. ("Leukosite") Form 10K405/A filed April 7, 1999	Research and Development Agreement between Leukosite and Warner-Lambert Company ("Warner") dated December 22, 1998	Exhibit 10.38 at chip/www.scc.gov/Archive weigardaao)1530v000104 7469-99-013906.txP	Ethibit 10.38 at At Leukosite's option, percent cost and chip//www.sec.gov/Archive profit starting with Leukosite primarily sorgardata 91.3320000104 responsible for development and Warner 1469-99-013906.tcp solely for commercilisation	If Leukosite exercise option (by reimbursing share of Development Coss), Warner to pay it Share of Profit; (otherwise Warner both funds R&D and pays Leukosite sales-based rovaltv)	Article A defines Development Costs as Warner's "actual cost plus an overhead allocation of 25%" and other types of costs based on "parties" normal internal cost accing procedures and GAAP"	Both Leukosite and Warner have option plans, follow APB 25, and recognise no option expense	
Sun Microsystems, Inc. ("Sun") Form 10-Q filed February 9, 1999	Strategic Development and Marketing Agreement between Sun and America Online ("AOL") dated November 23, 1998	Exhibit 10.93 at chtp://www.sec.gov/Archives/edgar/data/709519/000089	Exhibit 10.93 at Cooperative development and marketing chap/www.see.gov/Archive of software & services; joint & separate sedgardear/09519/000089 exploitation of developments	Secta 4.1.4.4. Gross Margins from designated software & services to be shared; also commissions & royalties	Secta 21.20: Gross Margin defined as revenue less software COGS or service personnel & associated costs, all in accord with GAAP	Both Sun and AOL have option plans, follow APB 25, and . recognise no option expense;	
Advanced Micro Devices ("AMD") Form 10-K filed March 29, 1999	Technology Deveopment and License Agreement between AMD and Motorola, Inc. ("Motorola") dated October 1, 1998	Exhibit 10.24 at claps; 10.24 at claps; www.sec.gov/Archive secgov/Archive secgov	Exhibit 10.24 at Cooperative research and development; chap;//www.sce.gov/Archue joint ownership of developments; also sedgardan248800010128 cross-licenses and foundry support 70-99-000892.tsP	Appendix D "Cost Equalization" - 1.52: quarterly equalization psyments; 1.6.1: actual costs, including compensation, used for wafer production & die R&D 1.6.2: standard rates used for non-direct costs	Silent on accounting methods (except "capitalization and depreciation" are "onsistent with the operating policies & guidelines of each party"; Sectn 3.3: Audit rights	Both AMD and Motorola have option plans, follow APB 25, and recognise no option expense;	
Orchard Biocomputer Inc. ("Orchid") Form S-1 filed February 18, 2000	Collaboration Agreement between Orchid and Affymetrix, Inc. ("Affymetrix") dated November 5, 1999	Exhibit 10.5 at chtp://www.sec.gov/Archive s/edgar/data/1107216/00009 27016-00-000640-index.html>	Exhibit 10.5 at  Cooperative development of kits  chapty/www.sc.gov/Archive integrating parties technology; cost  schaptodata/110716/00009  sharing and joint ownership of standard  27016-00-000640-  kits; supply arrangements	Secto 2.3(b): manner and proportion of Silent on accounting methods; Sector cost sharing to be determined by  4.1(e): Audit rights; books to be "in Collaboration Management Committee keeping with established bookkeeping a	Silent on accounting methods; Sectin 4.1(e): Audit rights; books to be "in keeping with established bookkeeping and accounting practices"	Both Orchid and Affymetrx have option plans; follow APB 25; & recognise expense for "in-the-money" grants	
InVision Technologies, Inc. ("InVision") Form S-1 dated March 14, 2003	Research, Development and License Agreement between InVision and EG&G Astrophysics ("EG&G") dated November 12, 1996		Exhibit 10.14 at Cooperative development of explosive edags/www.see.gov/Archeve detection system; parties equally fund and s/edgar/data/100596900009 jointly own developments	Section 4.1: each party provides initial \$1 million budget; Sectu 4.4: intent to share Development Costs equally; equalisation payments	Silent on accounting methods; Sectn 4.4 calls for joint budgeting and authorisation by joint Oversight Board for overtuns	Both Invision and EG&G have option plans, & follow APB 25; Invision recognises little option expense, EG&G none	

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Section 7.2.1 of the Letter Agreement sets out a process for dealing with an acquisition by Healtheon/WebMD of a line of business application in a "Core Category." That section allows Microsoft 15 days (the "First 15 Day Period") from notice of a proposed acquisition to notify Healtheon/WebMD of Microsoft's determination that Healtheon/WebMD's ownership of such line of business application is contrary to the parties' goals and intent. The parties are then allowed 45 days (the "45 Day Period") from such notice by Microsoft to work together to reach consensus on a resolution. If the parties fail to reach consensus by the end of the 45 Day Period, Microsoft has the right for 15 days following the end of the 45 Day Period (the "Second 15 Day Period") to terminate the Letter Agreement and the "WebMD Agreement" (as defined in the Letter Agreement). Microsoft and Healtheon/WebMD agree to modify the above referenced time periods, solely as they apply to Healtheon/WebMD's proposed acquisition of Medical Manager and CareInsite. The First 15 Day Period will begin on the closing of Healtheon/WebMD's acquisition of Medical Manager. The 45 Day Period will begin on the day following the last day of the First 15 Day Period. If the parties fail to reach consensus during the 45 Day Period, the Second 15 Day Period will begin on the day following the last day of the 45 Day Period.

By signing this letter below, Healtheon/WebMD confirms its commitment to working with Microsoft to achieve the goals and objectives of our existing agreements, including Sections 11.1, 11.2, and 11.3.

We hope the acquisition of Medical Manager proceeds promptly and quickly. We look forward to working with Healtheon/WebMD to implement the objectives of the Letter Agreement.

Sincerely,

/s/
Davide Vigano
Director, Services Markets
Microsoft Corporation

Cc: Mike Heekin, Executive VP Strategic Relations, Healtheon - WebMD Charles Stevens, Michael Leitner, Mandy Rutledge, Mark Bolender, Microsoft.

Microsoft Corporation is an equal opportunity employer.

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AGREED:

Healtheon/WebMD Corporation

/s/
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EXHIBIT 10.34

CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

MASTER SERVICES, DEVELOPMENT AND LICENSE AGREEMENT

This Master Services, Development and License Agreement ("Agreement") is made this 12th day of November, 1999 ("Effective Date") by and between Healtheon Corporation, a Delaware corporation with offices at 4600 Patrick Henry Drive, Santa Clara, California 95054 ("Healtheon") and Beech Street Corporation, a California corporation with offices at 173 Technology, Irvine, California 92618 ("BSC").

WHEREAS, Healtheon and BSC have agreed to form an alliance to address the information technology needs of BSC, develop new applications designed to address the information service needs of companies providing managed care and other administrative services and pursue other ventures which may be of mutual interest to the parties.

WHEREAS, the parties had previously entered into a Service,
Development, and License Agreement effective December 15, 1997, as amended by an
Agreement effective May 7, 1999, ("Prior Agreement") under which Healtheon
provided certain application development and information technology ("IT")
services;

WHEREAS, the parties now desire to supersede the Prior Agreement with this Agreement, thereby enabling the parties to more easily expand their relationship and allowing for multiple Service Exhibits under which Healtheon would provide services to BSC, including application development services, on-line services, and IT services.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties hereby agree as follows:

#### 1. DEFINITIONS.

- 1.1 "Additional Applications" shall mean those applications that are developed by Healtheon for BSC hereunder, but excluding the Developed Applications and the Healtheon Platform Software. As provided in the terms and conditions below, Additional Applications shall be owned by Healtheon, unless otherwise provided in the applicable Service Exhibit.
- 1.2 "BSC Client" shall mean those clients of BSC which use BSC products or services.
- 1.3 "BSC Managed Care Services" shall mean the following types of services provided by BSC to BSC Clients: personal health management (demand management), workers' compensation, medical bill review, case management, pre-admission review, concurrent review, discharge planning, hospital bill audit, retrospective non-network bill review and fee negotiation, health care provider contracting and management, preferred provider networks, data reporting, computer operations, service bureau services, consulting and other support services and such other related new products/services that BSC shall develop subsequent to the execution of this Agreement. Notwithstanding the

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foregoing, BSC Managed Care Services shall not include BSC On-Line Services.

1.4 "BSC On-Line Service" shall mean the on-line service provided by BSC that incorporates all or a portion of the Developed Applications and any derivative works thereof.

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- 1.5 "Database Information" shall mean the information provided to Healtheon by BSC and contained within the Database Structures, including but not limited to information concerning BSC's providers, provider contracts, customer and customer contracts.
- 1.6 "Database Structure" shall mean the supporting database design developed by Healtheon for use with the Developed Applications.
- 1.7 "Developed Applications" shall mean those applications, or applications under development, and any improvements thereto which Healtheon develops hereunder and which are designed to run on the Healtheon Platform, as more fully described in the applicable Service Exhibit. As provided in the terms and conditions set forth below, the Developed Applications will be owned by Healtheon.
- 1.8 "Development Work" shall mean the work to be performed hereunder by Healtheon to develop the Developed Applications.
- 1.9 "BSC End User" shall mean any employee, partner, agent or other representative of (i) BSC, or (ii) a BSC Client; who is authorized to access the BSC\_On-Line Service in conjunction with obtaining BSC Managed Care Services.
- 1.10 "Healtheon Platform" shall mean the Healtheon Platform Software, as well as certain industry standard software applications, tools, and processes which provide the operating environment which enables the use of Healtheon Developed Applications as part of an on-line service which is accessible through the Internet by using industry standard web browsers.
- 1.11 "Healtheon Platform Software" shall mean the proprietary operating system and other software which has been developed by Healtheon (but excluding the developed applications and the Additional Applications) which is part of the operating system of the Healtheon Platform.
- 1.12 "Services" shall mean the services to be performed by Healtheon hereunder pursuant to a Service Exhibit.
- 1.13 "Work Product" shall mean any and all of the work product produced or developed by Healtheon in connection with Healtheon's performance of the Services to be provided hereunder.

# PERFORMANCE OF SERVICES.

2.1 Service Exhibits. All Services to be provided by Healtheon hereunder shall be by Service Exhibits. Each Service Exhibit shall refer to this Agreement, describe the Services to be provided thereunder, and identify the work product to be produced thereunder, if any. The initial Service Exhibits are attached hereto as Service Exhibits A (for IT Services) and B (for ProviderWorks Application Development Services). Additional Service Exhibits will become effective when signed by authorized representatives of both parties.

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2.2 Incorporation; Conflicts. Each Service Exhibit is hereby incorporated in full into this Agreement by reference and shall be subject to the terms and conditions of this Agreement. In the case of a conflict among the provisions in this Agreement and a Service Exhibit, those of the Service Exhibit will control.

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#### PROJECT MANAGEMENT.

- Personnel Resources. Healtheon and BSC shall each commit the number of qualified and experienced personnel which are reasonably necessary to perform their respective obligations under this Agreement and as further outlined in the Service Exhibits. Healtheon shall have the sole right and obligation to hire, supervise, manage, contract, direct, procure, perform or cause to be performed all work to be performed by Healtheon and its personnel hereunder. Healtheon, at its option, may engage third parties to render services in connection with the performance of the Services contemplated hereunder, which may include engaging the services of certain BSC employees to provide certain information technology services. Healtheon will obtain written permission from BSC prior to engaging any BSC employees to provide information technology services. When engaging third party vendors, Healtheon will receive written approval from BSC for any resulting fees which BSC will be obligated to pay. BSC has the right to refuse on-site service from any third party vendor engaged by Healtheon to provide such services hereunder. Notwithstanding the rights of BSC in this section, BSC shall not unnecessarily withhold permissions, approvals or acceptances to Healtheon unless BSC has a good faith reason for denying permission, approval or acceptance, which shall be provided to Healtheon in a written notice. All Healtheon employees utilized to provide the Services shall have entered into Healtheon's standard form of employee nondisclosure agreement.
- 3.2 Project Management. Each party shall designate a project manager (the "Project Managers") and the appropriate resources and persons to coordinate the development and implementation of the Service Exhibits. The Project Managers shall be responsible for resolving any matters arising under this Agreement. In the event that the Project Managers are not able to resolve a dispute, such dispute shall be resolved either by a management committee, as described in Section 3.3 ("Management Committee") or by an agreed upon method as defined within the applicable Service Exhibit.
- an equal number of management-level personnel to serve on the Management Committee. The Management Committee shall conduct status meetings on a monthly basis, or as decided by the Management Committee as appropriate, detailing the performance of the Services during the prior four (4) week period and the work planned to be performed during the upcoming four (4) week period or any other agreed upon time period. The Management Committee shall be responsible for resolving any disputes which have not been resolved by the Project Managers, unless the parties specify another method in a Service Exhibit. The Management Committee shall be responsible for determining whether services based upon the Developed Applications shall be included in the definition of "BSC Managed Care Services" for the purposes of this Agreement; otherwise, such services shall be excluded. If such services are to be included, then the Management Committee shall be responsible for establishing the applicable financial arrangements, if any, pursuant to which such services may be offered by BSC.
  - 3.4 Changes to Services, Service Exhibits. The scope of the

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Services and the Service Exhibits shall not be changed in any material respect without the prior written agreement of the parties, which agreement shall not be unreasonably withheld.

# OWNERSHIP AND LICENSE RIGHTS.

4.1 Ownership. BSC acknowledges and agrees that the Healtheon Platform, and, unless otherwise specified in a Service Exhibit attached hereto, Additional Applications, and all of the Work

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Product including, but not limited to, all technology of any nature whatsoever, all notes, records, drawings, designs, inventions, improvements, developments, discoveries, trade secrets and any copyrightable material, including but not limited to, the Developed Applications, and related Database Structures, and all patentable inventions, conceived, made or discovered by Healtheon, solely or in collaboration with others, during the period of this Agreement and which relate in any manner to the Services to be performed hereunder or which Healtheon may be directed to undertake or investigate in performing the Services, including any derivative works of any of the foregoing, is the sole property of Healtheon, but excluding the Database Information, as provided by BSC to Healtheon to incorporate and operate within the Developed Applications in order to operate the Developed Applications, which may be incorporated into the Work Product Unless otherwise provided in a Service Exhibit, BSC acknowledges and agrees that Healtheon shall have all proprietary rights in and to the Work Product, including, without limitation, all copyrights, patents and trade secret rights, all moral rights, all contract and licensing rights, and all claims and causes of action of any kind with respect to any of the foregoing, whether now known or hereafter to become known, and that Healtheon shall have the sole and exclusive right to use, modify and exploit the Work Product in any manner that Healtheon may choose. Notwithstanding the foregoing, in the event BSC exercises the option for the On-Line Services under Section 5.3 for a Developed Application, Healtheon will not modify such Developed Application in such a way that the Developed Application would no longer meet in all material respects BSC's specifications as stated in the applicable Service Exhibit.

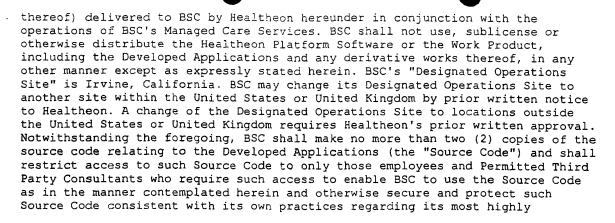
- 4.2 Proprietary Notices. BSC shall not remove or alter any trademark, trade name, copyright, or other proprietary notices, legends, symbols, or labels appearing on or in materials pertaining to the Work Product. Each portion of the Healtheon documentation reproduced by BSC shall include the intellectual property notice or notices appearing in or on the corresponding portion of such materials as delivered by Healtheon hereunder (e.g. trademark, copyright and patent notices).
- LICENSE AND SERVICE RIGHTS.
- 5.1 License Rights. In consideration for the development fees paid to Healtheon pursuant to Section 7.1, Healtheon hereby grants to BSC a nonexclusive and nontransferable, fully-paid, perpetual right and license, exercisable at BSC's Designated Operations Site, to: (i) install, use, copy, modify, create derivative works and maintain the Developed Applications, in object code and source code form, solely as (a) part of the BSC On-Line Services which are offered to BSC Clients in conjunction with the BSC Managed Care Services obtained by such BSC Clients and to enable world-wide remote access by BSC End Users in conjunction with the BSC On-Line Service and (b) for BSC's internal use in providing BSC Managed Care Services to BSC Clients, and (ii) use the Work Product (excluding the Developed Applications and any derivative works

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confidential information. "Permitted Third Party Consultants" means third party consultants for whom BSC has received Healtheon's prior written approval, which shall not be unreasonably denied, and who have executed agreements with BSC that includes confidentiality and intellectual property assignment provisions consistent with this Agreement.

- 5.2 Option to License Healtheon Platform Software. Subject to the payment of the license fee set forth below, Healtheon hereby grants to BSC a nonexclusive and nontransferable, right and license, exercisable at BSC's \_ Designated Operations Site, to use the Healtheon Platform Software as part of the Healtheon Platform to be deployed at\_BSC's Designated Operations Site to run the Developed Applications and such Additional Applications which may be licensed from Healtheon, as part of the BSC On-Line Service or other BSC Managed Care Service to be offered to BSC Clients in conjunction with the BSC Managed Care Services obtained by such BSC Client, and to enable world-wide access and use by BSC End Users at remote locations in conjunction with the use of the BSC On-Line Service and to make two back-up copies. The applicable one-time, up front fee for such license shall be [\*] dollars (\$[\*]), payable upon such commercially reasonable terms as the parties may agree to at the time of BSC's exercise of its rights hereunder; provided however, that such license fee shall be waived after January 1, 2000. BSC shall not have the right to use, sublicense or otherwise distribute the Healtheon Platform Software in any other manner except as expressly stated herein. BSC shall be solely responsible for the costs associated with acquiring all third-party hardware and software necessary to deploy the Healtheon Platform at BSC's site. BSC shall pay Healtheon for any and all associated implementation and installation services provided by or on behalf of Healtheon on a time and materials basis under the then negotiated fee schedule. In the event that BSC exercises its rights hereunder, Healtheon shall make available to BSC maintenance services on such commercially reasonable terms and conditions as may be agreed to by the parties. Healtheon shall provide all existing Healtheon documentation reasonably necessary for BSC to exercise this license option in order to make functional the Developed Applications and Healtheon Platform to the extent Healtheon has it at the time BSC exercises its option hereunder and Healtheon has the right to provide a copy to BSC.
- 5.3 Option to Use Healtheon On-Line Service. If, following the completion of the Developed Applications, BSC declines to use its licensed rights under Section 5.1, Healtheon hereby agrees to enter into a Service Exhibit with BSC containing Healtheon's standard terms and conditions whereby Healtheon shall provide BSC with (i) access to an on-line service which includes

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the Developed Applications, and (ii) the right to sublicense such access rights to BSC Clients. Healtheon shall offer such service to BSC and the BSC Clients at the rate specified in the applicable Service Exhibit.

- Media Marketing Materials. Healtheon may provide BSC with information and materials to use in creating brochure(s), describing one or more Healtheon on-line services provided hereunder ("Marketing Materials"). BSC may modify such materials to make them consistent with its other material but may not substantially change the content of such materials without Healtheon's prior written approval. BSC shall submit a letter to Healtheon describing the intended use of the Marketing Materials and any uses or references to Healtheon trademarks, materials or information regarding such use for Healtheon's evaluation and approval prior to any actual production, use or distribution of Marketing Materials by BSC. Healtheon shall provide notice of approval or rejection of the intended use of the Marketing Materials within seven (7) days of receipt of the letter from BSC. Within such seven (7) days, Healtheon may request additional information such as pre-production samples of the intended advertising, merchandising, promotional or display materials containing any Marketing Materials or description or reference to Healtheon's on-line services for Healtheon's evaluation and approval as to quality, style, appearance, usage of any Healtheon trademarks, and accuracy of the information, and Healtheon shall
- [\*] CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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provide notice or approval or rejection within five (5) days of receipt of such additional information. Subject to Healtheon's prior written approval as set forth above, BSC shall have the right to distribute Marketing Materials to its BSC Clients solely in conjunction with the identification, marketing, and promotion of Healtheon on-line services provided hereunder. All use of Healtheon trademarks by BSC accrues to the benefit of Healtheon. Neither party shall use the name of the other party, or refer to the other party, directly or indirectly, in any news release or information provided to any trade publication without such party's prior written approval.

6. TECHNOLOGY AND LICENSE RIGHTS. In the event that any Development Work requires access to or use of any other third-party technology or software, the Management Committee shall be responsible for assessing which party should obtain any necessary rights thereto.

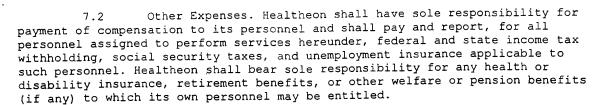
#### 7. FEES AND PAYMENT.

7.1 Fees and Expenses, Payment. BSC shall pay Healtheon the fees and expenses, as set forth in the Service Exhibits for the Services to be performed hereunder (the "Fees"). Healtheon shall submit invoices to BSC on a monthly basis for the Fees when due. Invoices shall be due and payable within ten (10) days after receipt. If a discrepancy is found on the monthly invoice received by BSC from Healtheon, BSC shall promptly notify Healtheon of such discrepancy and Healtheon agrees to exercise its best efforts to resolve the discrepancy within seven (7) business days. During the period that Healtheon is resolving the discrepancy, BSC shall not be required to pay to Healtheon the amount of the discrepancy, and no late fees shall apply to the amount in dispute. Upon resolution of the dispute, the invoice shall be due and payable within ten (10) days.

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- 7.3 Third-Party Hardware and Software. In the event that it is reasonably necessary for Healtheon to purchase or license any third-party hardware and/or software in order to perform the Services (except for Healtheon's on-line Services), the Project Managers shall determine whether such third-party hardware and/or software should be purchased and/or licensed by BSC or Healtheon and how the costs and ownership shall be allocated between the parties.
- 7.4 Taxes. All Fees and payments are exclusive of all taxes, duties or levies, however designated or computed. BSC shall be responsible for and pay all taxes upon payments due under this Agreement including, but not limited to, sales, use, or value-added taxes, duties, withholding taxes and other assessments now or hereafter imposed on or in connection with this Agreement, exclusive of taxes based upon Healtheon's net income.
- 7.5 Audit Rights. Each of the parties shall have the right, exercisable no more frequently than once per calendar quarter and exercisable upon thirty (30) days prior written notice, to audit the appropriate books and records of the other party during regular business hours to review the calculations of the amounts payable pursuant to Section 7. The costs of such audit shall be borne by the auditing party, unless the results of such audit reveal an underpayment (or overpayment) of more than ten percent (10%) for a twelve month period, in which case the reasonable expenses of the auditing party shall be reimbursed by the other party. The parties shall promptly pay (or refund) to the other, the amounts of any underpayments (or overpayments).

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#### CONFIDENTIALITY.

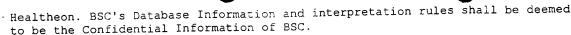
Confidential Information. The parties acknowledge that in the course of performing under this Agreement, each party may be exposed to or acquire information which is proprietary to or confidential to the other party, its suppliers or customers ("Confidential Information"). Any and all such Confidential Information of one party in any form obtained by the other party or its employees, agents, or representatives in the performance of this Agreement shall be deemed to be confidential and proprietary information of such party. The parties agree to hold such Confidential Information in strict confidence, to only permit use of such Confidential Information by its employees, representatives, and agents having a need to know in connection with performance under this Agreement, and not to copy, reproduce, sell, assign, license, market, transfer, give or otherwise disclose the Confidential Information of the other party to third parties or to use such Confidential Information for any purposes whatsoever, except as expressly contemplated by this Agreement, without the express written permission of the other party and to advise each of their employees, agents, and representatives of their obligations to keep such information confidential. The Healtheon Platform Software, Developed Applications Additional Applications (unless otherwise specified in a Service Exhibit), and Work Product shall be deemed to be the Confidential Information of

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- Exceptions to Confidential Information. Confidential 8.2 Information shall not include information that (i) was, as of the time of its disclosure, or thereafter becomes part of the public domain through a source other than the receiving party; (ii) the receiving party can demonstrate was independently known to the receiving party as of the time of its disclosure without an obligation of confidentiality; (iii) the receiving party can demonstrate it was independently developed by the receiving party without use of materials containing the Confidential Information, or (iv) the receiving party can demonstrate was subsequently learned from an independent third party not under a confidentiality obligation to the providing party. In the event that a receiving party is required to disclose certain Confidential Information of a disclosing party pursuant to applicable law, court order or government authority, the receiving party shall provide reasonable notice to the disclosing party prior to such disclosure and shall cooperate with the disclosing party to obtain protection from such disclosure. Anything to the contrary in this Agreement notwithstanding, each party may use and exploit for any purpose any programming techniques and ideas and concepts related to internet or computer technology learned by its employees as a result of their exposure to the Confidential Information of the other party and retained in the memory of such employees after their last exposure to any computer code, documentation or materials provided or owned by the other party, but excluding Healtheon Platform Software, Developed Applications and Additional Applications design, architecture and source code.
- 8.3 Reports of Third-Party Misappropriation. A receiving party shall immediately report to the disclosing party any attempt by any person of which the receiving party has knowledge (a) to use or disclose the Confidential Information without authorization from the disclosing party, or (b) to copy, reverse assemble, reverse compile or otherwise reverse engineer any part of the Healtheon Services or Healtheon software provided to BSC hereunder.

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# REPRESENTATIONS AND WARRANTIES.

- 9.1 Warranties for Services. Healtheon hereby represents and warrants that (i) each person assigned to perform the Services shall have the proper skill, training and background so as to be able to perform the Services in a competent and professional manner and (ii) all Services and any Work Product and other materials or documentation delivered under this Agreement shall have been completed in a thorough and professional manner. In the event of a breach of Healtheon's representations and warranties under this Section 9.1. Healtheon's sole obligation shall be to use commercially reasonable efforts to promptly correct any defects identified by BSC in a time frame reasonable to the impact of the defect or within established service levels as defined in the relevant Service Exhibits. Healtheon does not represent or warrant that all defects can be corrected.
- 9.2 Third-Party Technology. BSC hereby represents and warrants that it has obtained all necessary consents, licenses and/or assignments with respect to the Third-Party Technology and Software (as defined in Service Exhibit A) which is licensed and/or deployed by BSC and which are necessary in order for Healtheon to perform the Services (excluding Healtheon's on-line Services) to be performed hereunder. Healtheon hereby represents and warrants that it has obtained all necessary consents, licenses and/or assignments with

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respect to the third-party technology and software which is licensed and/or deployed by Healtheon in its performance of the Development Work to be performed becaused

- 9.3 Authority. Healtheon and BSC each hereby represents and warrants to the other that it is duly organized and validly existing under the laws of the jurisdiction in which it is organized, in good standing therein, and has the power to enter into this Agreement and to perform its obligations hereunder and, furthermore, that the performance by it of its obligations under this Agreement has been duly authorized by all necessary corporate or other action and will not violate any provision of law or regulation of any corporate charter or bylaws.
- 9.4 Infringement. Healtheon and BSC each hereby represents and warrants to the other that any information or technology provided by it to the other party in order to define the specifications or to accomplish the development objectives of this Agreement does not infringe, violate, misappropriate, or in any manner contravene or breach any U.S. patent or any trademark, copyright, trade secret right, license or other property, or proprietary right of any third party.
- 9.5 No Implied Warranties. THE WARRANTIES STATED ABOVE IN THIS SECTION 9 ARE THE ONLY WARRANTIES MADE BY EITHER PARTY. THE PARTIES DO NOT MAKE AND HEREBY DISCLAIM ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE PARTIES ACKNOWLEDGE THAT COMPLEX COMPUTER SOFTWARE AND SERVICES, SUCH AS THE DEVELOPED APPLICATIONS AND THE SERVICES, ARE RARELY FREE OF DEFECTS OR ERRORS AND HEALTHEON DOES NOT WARRANT THE SAME.

#### 10. LIMITATION OF LIABILITY.

10.1 Exclusion of Certain Damages. EXCEPT FOR CLAIMS ARISING OUT OF A BREACH OF SECTION 8 AND EXCEPT FOR DAMAGES AWARDED TO A THIRD PARTY PURSUANT TO SECTION 11, UNDER NO CIRCUMSTANCES AND UNDER NO LEGAL THEORY SHALL EITHER PARTY HAVE ANY LIABILITY FOR LOSS OF PROFITS, CONSEQUENTIAL,

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EXEMPLARY, INCIDENTAL OR PUNITIVE DAMAGES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Limitation of Liability. EXCEPT WITH RESPECT TO INDEMNIFIABLE CLAIMS AS PROVIDED IN SECTION 11.1 AND FOR CLAIMS ARISING OUT OF A BREACH OF SECTION 8, IN NO EVENT SHALL EITHER PARTY'S AGGREGATE LIABILITY FOR ALL MATTERS ARISING OUT OF THE SUBJECT MATTER OF THIS AGREEMENT, WHETHER IN CONTRACT, TORT OR OTHERWISE, EXCEED [\*] DOLLARS (\$[\*]) OVER THE PERIOD OF ANY YEAR DURING THE TERM OF THE AGREEMENT AND THEN FOR ALL TIME AFTER THE TERM OF THE AGREEMENT. (For example purposes only, if Healtheon is liable for claims equaling \$[\*] in the first year of the Agreement, and for \$[\*] in the second year, then Healtheon's liability would be \$[\*] in the first year, and \$[\*] in the second year.) THE REMEDIES PROVIDED HEREIN ARE THE PARTIES' SOLE AND EXCLUSIVE REMEDIES.

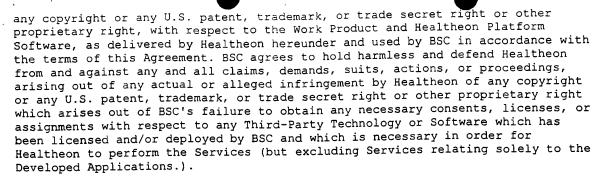
#### 11. INDEMNIFICATION.

11.1 Indemnification. Healtheon agrees to hold harmless and defend BSC from and against any and all claims, demands, suits, actions, or proceedings, arising out of any actual or alleged infringement by Healtheon of

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In the event BSC exercises its license rights under Section 5.1, BSC agrees to defend, indemnify, and hold Healtheon and its suppliers or licensors, and its and their officers, agents, employees, and contractors, harmless from any loss, damage, or expense, arising in any manner whatsoever from or otherwise in respect to (a) BSC's, BSC Client's and/or BSC End User's use of the Developed Applications, or (b) the failure of BSC to abide by the terms and conditions of this Agreement relating to BSC's use of the Developed Application.

Limitations. Healtheon shall have no indemnity obligation for 11.2 claims resulting from or alleged to result from (i) development work performed by Healtheon in compliance with BSC's specifications where Healtheon's method of compliance has been specifically compelled by the terms of BSC's specifications; or (ii) BSC's use of the Work Product in combination with any hardware or software not furnished by or authorized by Healtheon hereunder, if such combination is the cause of such claim and the Work Product is not material to the claim, or any modifications which have been made by BSC if such modification is the cause of the claim. In addition, Healtheon shall have no indemnity obligation for claims of infringement resulting or alleged to result from BSC's failure within a reasonable time frame to implement any replacement or modification which conforms to the requirements of Section 11.4 herein. BSC shall have no indemnity obligations for claims resulting from or alleged to result from Healtheon's breach of any Third-Party Technology or Software rights where appropriate consents, licenses and/or assignments were obtained and provided to Healtheon and Healtheon failed to adhere to the terms of applicable consents, licenses and/or assignments.

[\*]CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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- 11.3 Payment and Cooperation. Subject to the limitations set forth in Section 11.2 above, the indemnifying party shall pay all losses, damages, settlements, expenses, costs and reasonable attorneys' fees, incurred by the indemnified party arising out of the matters set forth in Section 11.1 provided that such payment shall be contingent on: (i) cooperation by the indemnified party with the indemnifying party in the defense and or settlement thereof, at the indemnifying party's expense; and (ii) allowing the Indemnifying Party to control the defense and all related settlement negotiations. The indemnified party shall give the indemnifying party prompt written notice of any such claim to enable the indemnifying party to defend or mitigate the claim.
- 11.4 Remedy. If, in the event of an infringement action pertaining to the Work Product, including the Developed Applications, and/or Healtheon

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Platform Software and BSC's use of the such Work Product and/or Healtheon Platform Software is disrupted, Healtheon shall, at its option, (i) provide BSC with access to software which is functionally equivalent to the infringing elements of the Work Product and/or Healtheon Platform Software as applicable, without additional charge; (ii) modify the infringing portions of the Work Product and/or Healtheon Platform Software, as applicable, to avoid the infringement; or (iii) obtain a license for BSC to continue use of such Work Product and/or Healtheon Platform Software, as applicable, for the term of the applicable license and pay, on an annual basis, if Healtheon elects not to acquire a perpetual license, the additional fee required for such license(s).

- 11.5 Sole Obligation. SECTION 11 SETS FORTH THE PARTIES' SOLE OBLIGATION, AND THE SOLE RECOURSE AGAINST THE OTHER PARTY IN THE EVENT OF ANY CLAIM OF INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.
- In the event that an error or omission by Healtheon as part of the IT Services provided to BSC under Service Exhibit A has caused a BSC Client solely to suffer actual damage and the BSC Client has received compensation from BSC for the actual damage, and if the Management Committee determines that such error or omission was the result of negligence or a failure to meet the warranties set forth in Section 9.1 above, then the Management Committee shall determine the percentage of such damages amount that shall be payable by Healtheon, taking into consideration the degree to which such error or omission was the cause of such damage in relation to other contributing facts and circumstances, including, without limitation, the errors, omissions, or negligence of BSC, and Healtheon shall pay to BSC such amount as determined by the Management Committee. Healtheon's obligations under this Section 11.6 shall be subject to the Limitation of Liability set forth in Section 10.2 above.
- 12. TERM AND TERMINATION.
- 12.1 Term. This Agreement shall continue for a fixed term of five (5) years from the Effective Date (the "Term") unless terminated earlier under the provisions of this Section 12 or by the mutual agreement of the parties. At the end of each year of the Term, the parties shall review the state of this Agreement and have the option to mutually agree to extend the Term for an additional year. For example, the parties shall meet after the first year of this Agreement and review the state of the Agreement. At that time, the parties may mutually agree to extend the term of the Agreement to a term of six years from the Effective Date. Notwithstanding the foregoing, the licenses granted in Sections 5.1 and 5.2 shall have a perpetual term unless terminated earlier pursuant to Section 12.3 or 12.4 or by the mutual consent of the parties.

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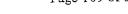
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- 12.2 Termination for Convenience. Either party may terminate this Agreement upon one year prior written notice to the other for any reason. Promptly following the notice of termination, the parties shall use good faith efforts to agree to a commercially reasonable transition plan which will enable the parties to mitigate any on-going expenses during the notice period.
- 12.3 Termination by Either Party for Default. If either party defaults in the performance of any material provision of this Agreement, then the non-defaulting party may give written notice to the defaulting party that if the default is not cured within ninety (90) days of such notice the Agreement will be terminated. If the non-defaulting party gives such notice and the default is not cured during the ninety (90) day period, then the Agreement shall automatically terminate at the end of that ninety (90) day period.

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- 12.4 Insolvency. Either party may terminate this Agreement by written notice to the other, and may regard the defaulting party as in default of this Agreement, if the defaulting party becomes insolvent, makes a general assignment for the benefit of creditors, suffers or permits the appointment of a receiver for its business or assets, becomes subject to any proceeding under any bankruptcy or insolvency law whether domestic or foreign, or has wound up or liquidated, voluntarily or otherwise.
- Effect of Termination. The provisions of Sections 7 (solely 12.5 with respect to Fees and other payments which were due and payable as of the date of termination), 4, 8, 10, 11, and 13 (to the extent applicable) shall survive the termination of this Agreement for any reason. All other rights and obligations of the parties shall cease upon termination of this Agreement. In the event of a termination, neither party shall be entitled to any refund of the fees paid or cost incurred for the development performed hereunder. Provided that this Agreement is not terminated by Healtheon pursuant to either Section 12.3 or 12.4 or by BSC pursuant to Section 12.2, upon termination, Healtheon shall deliver to BSC a copy of each Developed Application, Additional Application, Data Structure, and Database Information which has been completed as of the date of termination or is under development, in source and object code form, and the related technical and user documentation, and, in the event of the exercise of BSC's option pursuant to Section 5.2, Healtheon shall deliver to BSC a copy of the Healtheon Platform Software in object code form.
- 12.6 Return of Materials. Within thirty (30) days after the termination of this Agreement, each party shall return to the other, all Confidential Information, and other material of any kind which is the property of the other party.

#### 13. GENERAL.

- 13.1 No Exclusivity or Restriction on Other Activity. Except as expressly set forth in this Agreement, nothing herein shall preclude either party from entering into agreements to obtain similar services or development work from third parties or from providing similar services or development work to third parties.
- 13.2 Relationship of Parties. The relationship of the parties shall be that of independent contractors. Neither party will represent that it has any authority to assume or create any obligation, express or implied, on behalf of the other party, or to represent the other party as agent, employee, or in any other capacity, except as specifically provided herein.

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and inure to the benefit of the respective parties and their permitted successors and assigns. Neither party shall transfer, assign, sublicense or subcontract any right or obligation hereunder, except as expressly provided herein. In the event of a change in control of a party hereto, such party shall be permitted to assign this Agreement to the surviving or new corporation acquiring all or substantially all of the business and assets of such party by merger, acquisition, consolidation of otherwise, with the prior written consent of the other party, which consent shall not be unreasonably withheld. Either party may assign its rights under this Agreement to an entity which it controls, with the prior written consent of the other party, which consent shall not be unreasonably withheld. It shall not be unreasonable for a party to withhold its

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consent if any proposed assignment would materially increase such party's obligations under this Agreement or materially increase the scope of the other party's rights (including but not limited to the grant of rights contained in Section 5) or if such proposed assignee is a competitor of such party.

- 13.4 No Waiver. Either party's failure to exercise any right under this Agreement shall not constitute a waiver of any other terms or conditions of this Agreement with respect to any other or subsequent breach, nor a waiver by such party of its right at any time thereafter to require exact and strict compliance with the terms of this Agreement.
- 13.5 Notices. All notices or other communications which are required or permitted to be given hereunder shall be in writing and shall be sent to the address of the recipient set forth below or such other address as the recipient may designate by notice given in accordance with the provisions of this Section with copies to:

In the case of Healtheon:

In the Case of BSC:

Healtheon Corporation 4600 Patrick Henry Drive Santa Clara, California 95054 Attn: President Copy to: General Counsel Beech Street Corporation 173 Technology Irvine, California 92618 Attn: President and COO Copy to: Chief Financial Officer

Any such notice shall be delivered by either (i) first class registered or certified airmail, postage prepaid, and shall be deemed to have been served forty-eight (48) hours after posting; or (ii) express courier service, service fee prepaid, and shall be effective upon delivery.

- 13.6 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, exclusive of conflict of laws principles.
- 13.7 Severability. The invalidity of one or more phrases, sentences, clauses or articles contained in this Agreement shall not affect the remaining portions of this Agreement or any part thereof; and in the event that one or more phrases, sentences, clauses or articles shall be declared void or unenforceable this Agreement shall be amended to include only such portions of such phrases, sentences clauses or articles that are not invalid, void or unenforceable.
- 13.8 Entire Agreement; Amendments. This Agreement sets forth the entire agreement between the parties and supersedes any other prior proposals, agreements and representations between them related to its subject matter, whether written or oral, including but not limited to the Prior Agreement between the parties. No modifications or amendments to this Agreement shall be binding upon the parties unless made in writing and duly executed by authorized officials of both parties. It is

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expressly understood and agreed that no employee, agent, or other representative of Healtheon has any authority to bind Healtheon with respect to any statement, representations, warranty, or other expression unless the same is specifically set forth in this Agreement. It is also understood and agreed that no usage of trade or other regular practice or method of dealing between the parties hereto shall be used to modify, interpret, supplement, or alter in any manner the terms

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of this Agreement.

- 13.9 Attorneys' Fees. The prevailing party in any dispute shall be entitled to collect from the other party the prevailing party's reasonable attorneys' fees and costs in connection with the enforcement of this Agreement.
- 13.10 Non-Solicitation of Employees. Neither party shall solicit the services or employment of any employee or agent of the other party during the term of the Agreement, without the prior written consent of the other party. The soliciting party who violates this Section 13.10 shall pay to the other party an amount equal to one (1) years salary for any solicited employee of the other party, as liquidated damages and not as a penalty. The amount of annual salary shall be the annual salary in effect at the date the employee was solicited. Initiation by an individual of contact regarding employment or response by an individual to an advertisement or other generally available notice, shall not constitute solicitation. BSC may solicit the services or employment of Healtheon employees and agents who have a primary work location at a BSC office provided that BSC provide Healtheon with notification prior to the solicitation.
- 13.11 Bankruptcy. The parties agree that the Agreement and any related agreements are contracts under which Healtheon is a licensor of rights to intellectual property within the scope of Section 101 of the United States Bankruptcy Code and that BSC shall have all the rights of a licensee set forth in Section 365(n) of the Bankruptcy Code. Upon the commencement of a bankruptcy petition involving either party, the other party shall be entitled to retain and may fully exercise all rights and licenses available under the Bankruptcy Code, subject to the fulfillment by the other party of its obligations under this Agreement.
- 13.12 Residual Information. Without prejudice to either party's proprietary rights, neither party shall be liable for using general ideas, concepts and know-how that may be gained as a result of exposure to or contact with the other party or its materials.
- 13.13 Escrow. Healtheon agrees that it will put the Healtheon Platform Software, the Database Structures, the Database Information and the Developed Applications, in escrow with an independent escrow agent on a yearly basis. The escrow agreement will be on terms and conditions which are mutually agreeable to the parties.
- 13.14 Force Majeure. If either party is unable to perform its obligations under this Agreement due to circumstances beyond its reasonable control (other than obligations for the payment of money or the maintenance of confidentiality), including, but not limited to, acts of God, earthquakes, labor disputes and strikes, riots, war, actions decrees of governmental bodies, changes in applicable Laws, or communications line or power failures, such obligations will be suspended so long as those circumstances persist, provided that the delaying party notifies the other party promptly of the delay and its causes and uses commercially reasonable efforts to recommence performance without delay.
- 13.15 U.S. Government Restricted Rights. The Healtheon Service and the Healtheon Client Software are made available only with RESTRICTED RIGHTS. All use, duplication, or disclosure of the

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Healtheon Service or such software by the government is subject to restrictions

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as set forth in subparagraphs (c)(1)(ii) of the Rights in Technical Data Computer Software Clause at DFARs 252.22-70013 and/or subparagraphs c(1) and c(2) of the Commercial Computer Software Restricted Rights Clause at 48 C.F.R. Section 52.227-19, as applicable. The contractor/vendor/manufacturer is Healtheon Corporation, 4600 Patrick Henry Drive, Santa Clara, California 95054, U.S.A.

No Third Party Beneficiaries. This Agreement is made and 13.16 entered into for the sole protection and benefit of the parties hereto, and no other person or entity shall be a direct or indirect beneficiary of, or shall have any direct or indirect cause of action or claim in connection with this

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed as of the Effective Date.

Healtheon	Corporation		Beech Street	Corporation	
ву:	/s/		Ву:	/s/	
Title:			Title:		
Date:			Date:		
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#### SERVICE EXHIBIT A IT SERVICES

This Service Exhibit A is subject to and incorporates the terms of the Master Services, Development and License Agreement (the "Agreement") dated November \_, 1999 between Healtheon Corporation ("Healtheon") and Beech Street Corporation ("BSC").

- Scope of Services. Healtheon will operate and maintain BSC's information technology infrastructure and data processing functionality and related services (collectively referred to as "IT Services"), including the following types of services, as necessary and agreed to by the parties:
- Maintain hardware operations
- Maintain software infrastructure
- Maintain data network(s)
- Maintain desktop computing systems
- Provide internal and external technical support
- Provide project planning and management
- Provide software installation
- Provide hardware installation

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- Provide user training
- Provide IT personnel management services
- Provide IT consulting services
- Provide custom software solution design and development services
- Term. The term of this Service Exhibit A shall commence on the Effective Date of the Agreement and, unless earlier terminated as provided herein, shall continue for the term of the Agreement. The parties will review the terms of this Service Exhibit A within ninety days after the Effective Date and determine whether the IT Services to be provided should be more fully addressed in a mutually agreed-upon amendment hereto. Beginning June 30, 2000, and on each six month anniversary thereafter, BSC will review the IT Services provided hereunder, and, if BSC reasonably determines that such services do not adequately meet the requirements set forth in this Service Exhibit A or amended version thereof ("IT Requirements"), BSC may provide Healtheon with a written notice identifying those aspects not meeting such IT Requirements, and stating BSC's intent to terminate the Service Exhibit in six (6) months. If, by the end of such six (6) month period, Healtheon fails to improve the IT Services such that the IT Requirements are met, this Service Exhibit will automatically terminate.

BSC reserves the right to terminate this Service Exhibit with 90 days written notice.

3. Third Party Technology and Software. In order to perform the Services contemplated hereunder (but excluding Services relating solely to the Developed Applications), BSC represents that Healtheon will need to have access only to the third-party technology and software listed on Attachment A-1 which is licensed and/or deployed by BSC (the "Third-Party Technology and Software"). BSC hereby agrees to use commercially reasonable efforts to obtain, at its own expense, all necessary consents, licenses and/or assignments which may be necessary in order for Healtheon to perform such Services. Healtheon shall use commercially reasonable efforts to cooperate with BSC to assist BSC in obtaining any necessary consents, licenses and/or assignments to Third-Party Technology and Software. During the term of this

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Agreement, BSC hereby grants to Healtheon a nonexclusive and nontransferable right and license to use, modify and copy all technology and software owned by BSC which is necessary for Healtheon to perform the Services.

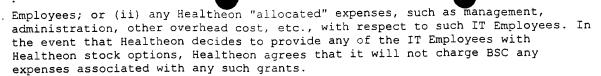
4. Fees. For IT Services performed hereunder, BSC will pay Healtheon the associated direct expenses and management fee as set forth below:

Direct Expenses: Healtheon shall charge BSC [\*]% of Healtheon's "direct" expenses associated with the IT Employees, including salary, and benefits calculated at an assumed rate equal to [\*]% of each IT Employee's salary. "IT Employees" means those Healtheon employees or contractors whose primary responsibility is the providing of IT Services hereunder at BSC's facilities. Healtheon agrees that it will not charge BSC (i) any support expenses, such as rent, phone, computing, office expenses for those IT

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Healtheon Management Fees: The management fees for the remainder of 1999 will reflect a monthly management fee of [\*]. The parties will negotiate the management fee to be applied to the remaining term of this Agreement.

The parties shall mutually develop a budget for the total fees and expenses under this Service Exhibit and Healtheon shall make a reasonable attempt to complete the services under this Service Exhibit within this budget.

Ownership Rights. Except as otherwise provided in this Section 5, all work product created by Healtheon for BSC under this Service Exhibit ("IT Service Product") is the sole property of BSC. Healtheon acknowledges and agrees that BSC shall have all proprietary rights to all IT Service Product including, but not limited to, all technology of any nature whatsoever, all notes, records, drawings, designs, inventions, improvements, developments, discoveries, and any copyrightable material, and all patentable inventions, conceived, made or discovered by Healtheon employees under this Service Exhibit, solely or in collaboration with others, in the performance of the Services performed under this Service Exhibit, including any derivative works of any of the foregoing. Healtheon acknowledges and agrees that BSC shall have all proprietary rights in and to the IT Service Product, including, without limitation, all copyrights, patents and trade secret rights, all moral rights, all contract and licensing rights, and all claims and causes of action of any kind with respect to any of the foregoing, whether now known or hereafter to become known, and that BSC shall have the sole and exclusive right to use, modify and exploit the IT Service Product in any manner that BSC may choose. Notwithstanding the foregoing, IT Service Product shall not include, and Healtheon shall have sole ownership of all right, title, and interest in and to, all enhancements, modifications, improvements, and derivative works of the Healtheon Platform Software, the Developed Applications, and the Additional Applications (excluding those Additional Applications owned by BSC), created by Healtheon employees in their performance under this Service Exhibit, or created by or for BSC ("Healtheon Improvements"), and all intellectual property rights therein. Healtheon agrees that the software currently under development by Dr. Ed Zalta for BSC is solely owned by BSC. Subject to the terms and conditions of the Agreement, the licenses granted to BSC under Section 5.2 of the Agreement shall apply to Healtheon Improvements of the Healtheon Platform Software, and the licenses granted to BSC under Section 5.1 the Agreement shall apply to Healtheon Improvements of the Developed Applications. Healtheon shall not use or provide to third parties any Healtheon Improvements of the Developed Applications.

[\*]CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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ATTACHMENT A-1
THIRD PARTY-TECHNOLOGY AND SOFTWARE

SERVER TECHNOLOGY AND SOFTWARE

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	<table> <caption></caption></table>			
	HOST NAMES	DESCRIPTIONS	os	IP ADDRESS
	<s> IRVINEFP</s>	<c> CPQ 1500, Tower P133</c>	<c> NT4.0 SP5</c>	<c> 192.168.200.5 192.168.201.5</c>
	IRVINE2FP	CPQ 1500, Tower P133	Ent NT4.0 SP5	192.168.201.15
	IRVINESECURE	CPQ 850r PII 200	NT4.0 SP5	192.168.200.16 192.168.201.16
	IRVINE1	CPQ 1500, Tower P133	Novell 312	
	IRVINE2	CPQ 1500, Tower P133	Novell 312	
	BEECH	AST Tower	Novell 312	
	BEECHSAA	AST Desktop	Novell 312	
	GATEWAY3	CPQ Deskpro 575	NT4.0 SP5	192.168.200.56
	NOTES11	CPQ 2500r P200	NT4.0 SP5	192.168.200.4 192.168.201.4
-	NOTES22	CPQ 2500r P200	NT4.0 SP3	192.168.200.9
	NOTES33	CPQ 850r PII 200	NT4.0 SP3	192.168.200.7 192.168.201.7
	FRONTSTREET	CPQ 3000r (2) PIII 500	NT4.0 SP5	192.168.199.24
	ELMSTREET	CPQ 3000r (2) PIII 500	Ent NT4.0 SP5	192.168.199.22
	PINESTREET	CPQ 3000r (2) PIII 500	Ent NT4.0 SP5	192.168.199.23
	STATESTREET	CPQ 5500 (4) PIII 500 Xeon	Ent NT4.0 SP5	192.168.199.26
	CAPITALSTREET	CPQ 5500 (4) PIII 500 Xeon	Ent NT4.0 SP5	192.168.199:27
	MAINSTREET1	CPQ 2500r (2) P200	NT4.0 SP5	192.168.201.20
	MAINSTREETEXCON	CPQ 1600r P300	NT4.0 SP5	192.168.201.21
	EXCSERV	CPQ 2500r P200	NT4.0 SP5	172.16.10.25
	ARCSERV	Dell PII 200	NT4.0 SP5	172.16.10.250
	CAPPSERV		Novell 411	

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CASESERV	CPQ 2500r P200	Novell 411	
CITRIX	CPQ Prolinea 800 PII 200	NT3.51 SP5	
SQLSERV	CPQ 2500r P200	NT4.0 SP5	172.16.10.24
INETSERV	CPQ Prolinea	NT4.0 SP5	208.145.144.33
COMMSERV	CPQ Prolinea	Novell 411	
POLKSTREET	CPQ 1500, Tower P133	NT4.0 SP5	10.101.2.49
LAKESTREET	CPQ 2500r P200	NT4.0 SP5	10.251.171.36
PEACHSTREET	CPQ 2500r P200	NT4.0 SP5	10.251.171.68
WOODSTREET			

 CPQ 1500, Tower P133 | NT4.0 SP5 | 192.168.111.5 ||  | Page 17 |  |  |
18			
	CPQ 1500, Tower P133	NT4.0 SP5	192.168.103.5
BCHPR2	AS/400 9406/530	os/400	192.168.201.10
BCHDV1	AS/400 9406/500	CS/400	192.168.201.11
CAPPRICE	AS/400 9406/530	os/400	192.168.200.12
DMACHINE	AS/400 9406/500	os/400	192.168.200.13
WEBTOHOST	AS/400 720	OS/400	192.168.200.3

# VOICE TECHNOLOGY AND SOFTWARE

</TABLE>

BSC - TECHNOLOGY VOICE SYSTEMS Northern Telecom PBX 61C Northern Telecom Meridian Mail CCR - ACD Scripting System MAX - ACD Reporting System

TAMPA, FLORIDA - VOICE SYSTEMS Norstar PBX System StarTalk Voice Mail System

EDISON, NEW JERSEY VOICE SYSTEMS Norstar PBX System StarTalk Voice Mail System

MACARTHUR VOICE MAIL SYSTEMS Lucent PBX - G3si Intuity Voice Mail System CMS ACD System

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, SEC EDGAK SUOMISSION 0000720144-00-004227 . WESTERN REGION - 5000 BIRCH STREET Lucent PBX - VS Intuity Voice Mail System CENTRAL REGION - OAKBROOK, ILLINOIS Lucent PBX - VS Intuity Voice Mail System EASTERN REGION - ATLANTA, GEORGIA Lucent PBX - VS Intuity Voice Mail System ADDITIONAL TECHNOLOGY AND SOFTWARE OS/400 OV/400 **JDEdwards** CA-PRMS Hawkeye PerZip TurnOver Page 18 <PAGE> PeekPlus Novell IntranetWare MS NT MS Exchange MS Professional Office Suite MS Project MS PowerPoint MS Windows MS Outlook MS Internet Explorer MS Visual Interdev MS IIS Visio Visual Basic SQL Server HahtSite MapInfo MapMarker MapInfo MapXsite GeoAccess FoxPro Netscape Navigator Lotus Notes Crystal Reports Case Manager Assistant (CMA) Paradox WinFrame ArcServ Adobe Photoshop PCAnywhere QuarkXpress GWI Help! Fixed Asset System Page 19 http://www.sec.gov/Archives/edgar/data/1088917/0000950144-00-004229-index.html 05/12/2003

\* PEC EDAW 2001111221011 0000370144-00-004573

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# SERVICE EXHIBIT B PROVIDERWORKS APPLICATION DEVELOPMENT WORK

This Service Exhibit B is subject to and incorporates the terms of the Master Services, Development and License Agreement (the "Agreement") dated November \_\_\_\_\_, 1999 between Healtheon Corporation ("Healtheon") and Beech Street Corporation ("BSC").

- Development Work. Healtheon shall design, develop, test, and complete Healtheon's ProviderWorks Application incorporating BSC's Repricing Configuration. A "Repricing Configuration" for a particular entity means a configuration of the application and associated database that is determined by such entity's claim reimbursement schedules, and the repricing contracts between such entity and its affiliated providers and payers. The specifications for the ProviderWorks Application to be developed hereunder are described in Attachment B-1 ("Specifications"), which is attached hereto for reference. The parties shall jointly develop a mutually agreeable detailed project plan, which shall be described in Attachment B-2 ("Project Plan"), which is attached hereto for reference. The Project Plan shall describe, in a degree of detail reasonably satisfactory to the parties, all tasks and responsibilities required for the successful and timely completion of the development and delivery of the ProviderWorks Application, including the projected costs. The ProviderWorks Application incorporating BSC's Repricing Configuration shall be deemed a "Developed Application" for purposes of the Agreement.
- 2. Project Managers. The Project Managers shall coordinate the development of the ProviderWorks Application. In addition, the Project Managers shall be responsible for the development of the Project Plan, coordinating their respective personnel and resources to satisfy their respective responsibilities, administering Change Requests, and arranging for the transmission and receipt of any deliverables, information and periodic status reports as required under the Project Plan. From time to time during the term of this Agreement, each party may replace its Project Manager with another person having equivalent authority by providing written notice to the other party.
- 3. Change Requests. From time to time prior to the completion of the Development Work hereunder, BSC may propose changes to the Project Plan and/or Specifications ("Change Requests"). Such Change Requests shall be submitted in writing. Healtheon shall review the Change Request and advise BSC whether Healtheon's assessment of and response to the Change Request will require payment of fees by BSC to Healtheon. If a Change Request does not, in Healtheon's sole opinion, require Healtheon's expenditure of materially more time and effort, Healtheon shall agree to the change at no additional charge, but may require adjustment of the time schedules. If such Change Request does require, in Healtheon's sole opinion, Healtheon's expenditure of materially more time and effort, Healtheon will provide BSC a cost estimate for implementing the change and shall advise BSC of the impact on the ProviderWorks Application. No such changes, however, shall become effective until a written amendment specifying the change or changes is executed by authorized representatives of both parties.
- 4. Development Team. Healtheon shall provide an engineering team staffed with up to forty engineers until the completion of the Development Work in accordance with the Project Plan. In the event that the Project Plan require additional personnel resources, the parties will revise the staffing commitments hereunder.

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- 5. System Testing and Final Acceptance.
- Testing. In accordance with the Project Plan, the parties will 5.1 mutually agree upon a plan for testing the ProviderWorks Application ("Test Plan"). Within fifteen (15) days following the completion of testing in accordance with the Test Plan, BSC will give notice of its acceptance or rejection of the ProviderWorks Application provided to BSC hereunder. BSC shall accept the ProviderWorks Application if it substantially meets the Specifications in all material respects. If BSC determines that the ProviderWorks Application does not substantially meet the Specifications in all material respects, then BSC shall notify Healtheon in writing of the non-compliances identified by BSC. If BSC provides Healtheon with a notice of non-compliance within such fifteen (15) day period, then within thirty (30) days after its receipt of such notice, Healtheon shall correct the non-compliance and document to BSC the corrective actions. Upon receiving such documentation of corrective action, BSC shall immediately retest the ProviderWorks Application in accordance with the Test Plan, and provide notice of acceptance or rejection as set forth above. The foregoing testing and acceptance cycle shall be repeated up to four (4) times before invocation of any other remedy in this Agreement by BSC. BSC shall have been deemed to accept the ProviderWorks Application upon (i) BSC's delivery to Healtheon of a written notice of acceptance, (ii) BSC's failure to provide notice of rejection or acceptance within fifteen (15) days following completion of testing under the Test Plan, or (iii) BSC's use of the ProviderWorks Application other than for testing purposes.
- 5.2 Rejection of ProviderWorks Application. Upon expiration of the testing and acceptance process described in Section 5.1 above, if the ProviderWorks Application fails to meet the Acceptance Criteria, BSC shall have the option of either (i) accepting the ProviderWorks Application as it is then currently implemented; or (ii) rejecting the ProviderWorks Application and terminating this Service Exhibit. THESE RIGHTS OF ACCEPTANCE AND REJECTION CONSTITUTE BSC'S SOLE REMEDY IN THE EVENT OF ANY FAILURE OF THE PROVIDERWORKS APPLICATION TO MEET THE ACCEPTANCE CRITERIA. In the event BSC rejects the ProviderWorks Application under this Section 5.2, the ProviderWorks Application shall not be licensed under Sections 5.1 and 5.3 in the Agreement, and BSC shall promptly return all copies thereof to Healtheon.
- 6. Ongoing Development. Following completion of the ProviderWorks Application under Section 1 above, Healtheon will continue to provide, upon BSC's request, services for the further development of the ProviderWorks Application on a time and materials basis.
- Revenue Sharing by Healtheon. Healtheon shall pay to BSC the Applicable Percentage (as defined in this Section 7) of Net Revenues (as defined below) with respect to ProviderWorks On-Line Services received from Healtheon's ProviderWorks customers. "Net Revenues" shall mean the revenues received by Healtheon from a Healtheon ProviderWorks customer for ProviderWorks On-Line Services less any amounts paid or owed by Healtheon to anyone on account of the revenues received, including but not limited to taxes, royalties, leased network fees, broker fees, commissions paid to outside third parties, subcontractor vendor fees and other such reasonable and customary fees as may apply from time to time. The "Applicable Percentage" with respect to Healtheon's ProviderWorks On-Line Services shall be [\*] percent ([\*]%) if the customer is a Qualified Healtheon Customer, or [\*] percent ([\*]%) otherwise. A customer will be designated as a "Qualified Healtheon Customer" if BSC generated the lead, participated in sales calls, demonstrations, and negotiations, and brought the

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sale by Healtheon to such customer to conclusion, such designation to be determined by the parties on a case-by-case basis. Healtheon's obligation under this Section 7 shall continue for the term of this Service Exhibit B for so long as BSC

[\*] CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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continues to use its best efforts to market the ProviderWorks On-Line Services, and to pay the Development Services fees due hereunder.

- 8. Limitation on Right to Modify. Nothwithstanding Section 5.1 of the Agreement, BSC may use the ProviderWorks Application solely in a BSC Repricing Configuration, and may not reconfigure the ProviderWorks Application for a third party Repricing Configuration.
- 9. Fees and Expenses. For Development Work performed hereunder, BSC will pay Healtheon development fees at a rate of \$[\*] per hour. The parties shall mutually develop a budget for the total fees and expenses under this Service Exhibit and Healtheon shall make a reasonable attempt to complete the Development Work within this budget.
- [\*] CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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ATTACHMENT B-1 SPECIFICATIONS

The parties shall mutually agree upon the ProviderWorks Specifications to be included in this Attachment B-1.

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ATTACHMENT B-2

PROJECT PLAN

Healtheon will provide the first draft of the Project Plan to BSC within ninety (90) days after the Effective Date.

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</TEXT>
</DOCUMENT>
</DOCUMENT>
</TYPE>EX-10.35

<SEQUENCE>4
</DESCRIPTION>SERVICES LICENSE AGREEMENT DATED OCTOBER 24, 1999
<TEXT>

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### RESEARCH AND DEVELOPMENT AGREEMENT

This Research and Development Agreement ("Agreement") is made this 30th day of October 2000, between Rohm and Haas Company, a Delaware corporation, having its principal office at 100 Independence Mall West, Philadelphia, Pennsylvania, 19106-2399, United States of America ("RandH") and AgraQuest, Inc., a Delaware corporation, having its principal place office at 1530 Drew Avenue, Davis, California 95616, United States of America ("AQ").

### ARTICLE 1 BACKGROUND

- 1.1. AQ has conducted research in the areas of biopesticide microbials and biochemicals to develop environmentally friendly natural pesticide products. From this microbial and biochemical research initiative, AQ has identified a number of product leads.
- 1.2. RandH possesses considerable expertise in research, development, registration and commercialization of agricultural chemical products. Using this expertise, RandH is interested in assessing AQ's product leads to identify those materials which RandH and AQ, will develop, register and bring to market.
- 1.3. To advance these goals, RandH and AQ have determined to enter into a commercial relationship regarding the future development, registration and commercialization of AQ's product leads.

## ARTICLE 2 DEFINITIONS

- 2.1 "Actual Costs" means the out-of-pocket costs, including labor costs and indirect overhead expenses (head-count driven facilities and administrative allocation).
- 2.2. "Affiliate" means, in relation to a party to this Agreement, a body corporate which from time to time is directly or indirectly controlled by or in control of such party and, for these purposes, "control" shall

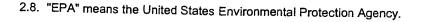
consist of the ownership of over fifty percent (50%) of the voting stock of a body corporate.

2.3 "AQ's Field" means use in the areas of Animal Health which is limited to therapeutics and pharmaceuticals for animal diseases, products for controlling internal and external parasites and pests, probiotics, animal feed additives, Human Health which is limited to pharmaceuticals, therapeutics, nutritional supplements and nutriceuticals and Aquaculture which is limited to growth enhancers, nutritional supplements and products for controlling external or internal parasites and diseases of fish, shellfish and mollusks.

[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406.

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- 2.4. "Biopesticide" means a biochemical or microbial pesticide as defined at 40 C.F.R. (S) 158.65.
- 2.5. "Confidential Information" means, as to either party and without limitation, the Technology Rights, and any other data, know-how, formulas, compositions, processes, documents, designs, sketches, photographs, plans, graphs, drawings, specifications, equipment, samples, reports, findings, inventions, ideas and information, including business information related to the Lead Candidates and the Project.
- 2.6 "Damages" means any and all losses, liabilities, obligations, costs, expenses, damages or judgments of any kind or nature whatsoever (including reasonable attorney's, accountant's and expert's fees, disbursements of counsel, and other costs and expenses incurred in pursuing or defending claims under Article 13).
- 2.7. "Effective Date" means the date first written above.



- 2.9. "Gated Process" means the research and development process set forth in Article 6 of this Agreement and as described in further detail in the Gated Process Template set forth at Exhibit D to this Agreement.
- 2.10. "Improvements" means any invention, improvement, modification, new application or enhancement whether patentable or not, relating solely to a specific Lead Candidate or Licensed Technology, but expressly excluding the combination of such Lead Candidate with any RandH product.
- 2.11. "Lead Candidates" means those product leads from AQ's biopesticide microbial and biochemical research and development (including any analogs and homologs, which may qualify as a Biopesticide) identified at Exhibit A, attached hereto and made a part hereof. Such Exhibit A may be updated from time to time as provided herein.
- 2.12. "Net Sales" means, for any given quarter, the net sales of a technical grade or formulated product containing a given Lead Candidate during such period, including products containing any Improvements, as such net sales are determined after deducting industry standard discounts, rebates, chargebacks, sales freight and taxes. With respect to RandH, Net Sales shall include the Net Sales to permitted sublicensees.
- 2.13. "Patent Prosecution" means, with respect to any Technology Right, the prosecution and maintenance (before the United States Patent and Trademark Office or the

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406.

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applicable counterpart agency in a foreign country) of any patent or patent application, or any divisions, continuations, extensions or

renewals relating to such Technology Right.

- 2.14. "Patent Rights" means all rights under any U.S. or foreign patent or patent application which may issue with claims directed to a Lead Candidate, a method to isolate or manufacture a Lead Candidate or a method to use a Lead Candidate, as the case may be, in each case together with any divisionals, continuations, continuations-in-part, reissues, reregistrations or extensions thereof.
- 2.15. "Project" means the activities of RandH and AQ to assess, develop, register and commercialize the Lead Candidates as Biopesticide products, including the Gated Process described in Article 6 of this Agreement.
- 2.16. "Registration" means approval by the EPA or European Union ("EU") or Japan of a microbial, a substance or mixture of substances as a Biopesticide pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA").
- 2.17. "Technology Rights" means any and all ideas, inventions, formulae, processes, trade secrets and substantial know-how, intellectual property, techniques, methods, specifications, practices, data and other forms of information relating to the processes, methods and techniques for manufacturing, formulating and using the Lead Candidates, whether patentable or not and whether or not reduced to practice, including Patent Rights.

### ARTICLE 3 REPRESENTATIONS, WARRANTIES AND COVENANTS OF AQ

AQ hereby represents, warrants and covenants to RandH as follows:

3.1	Corporate Power	and Authority
3.1	Corporate Power	and Authority

AQ has the corporate power and authority to execute and deliver this

Agreement, the Convertible Note Purchase Agreement, the Convertible Note and
perform its obligations hereunder and thereunder, and the execution, delivery

and performance of this Agreement, the Convertible Note Purchase Agreement, and the Convertible Note have been duly and validly authorized by AQ, and upon execution and delivery by AQ, this Agreement, the Convertible Note Purchase Agreement, and the Convertible Note will constitute valid and binding agreements of AQ enforceable against it in accordance with their respective terms.

3.2 No Conflict.

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

Neither the execution and delivery of this Agreement, the Convertible Note

Purchase Agreement, the Convertible Note, nor the consummation of the
transactions contemplated hereunder or thereunder, requires AQ to obtain any
permits, authorizations or consents from any governmental body or from any other
person, firm or corporation, and such execution, delivery and consummation will
not result in the breach of or give rise to any termination of any agreement or
contract to which AQ may be a party.

3.3 Compliance with Law.

AQ will conduct its activities and operations in material compliance with all applicable laws, statutes, rules or regulations.

3.4 Effort

During the term of this Agreement, AQ shall use commercially reasonable efforts to fulfill its obligation as set forth in this Agreement.

3.5 Patent Prosecution; Infringement.

AQ is obligated to, at AQ's expense, prepare and file one or more patent application(s) for any Lead Candidate(s) and Improvements and is obligated to pursue Patent Prosecution of such patent application(s) and patent(s) which issue from such application(s). AQ shall pursue any Patent Prosecution in a manner that it in good faith believes to be scientifically and commercially reasonable; provided, however, that (i) AQ shall determine in consultation with the Joint Project Team the timing and manner of such Patent Prosecution and the amount of resources, personnel, and effort, devoted by AQ to such Patent Prosecution, patent protection or the scope of the protection afforded by any allowed patent claim and (ii) provided that AQ diligently and in good faith pursues Patent Prosecution of a particular Lead Candidate, AQ shall have no liability or obligation to RandH for the failure to obtain any patent protection relating to any Lead Candidate or the scope of the protection afforded by any allowed patent claim. AQ shall pursue the prosecution of any actual or alleged infringement by a third party of any of the Licensed Technology (as defined in Section 9.1 below).

## ARTICLE 4 REPRESENTATIONS, WARRANTIES AND COVENANTS OF RANDH

RandH represents, warrants and covenants the following to AQ:

4.1 Corporate Power and Authority.	
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[***] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406.	
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RandH has the corporate power and authority to execute and deliver this

Agreement and the Convertible Note Purchase Agreement, and to perform its obligations hereunder and thereunder, and the execution, delivery and performance of this Agreement and the Convertible Note Purchase Agreement have been duly and validly authorized by RandH, and upon execution and delivery by RandH, this Agreement and the Convertible Note Purchase Agreement will constitute valid and binding agreements of RandH enforceable against it in accordance with their respective terms.

4.2 No Conflict.

Neither the execution and delivery of this Agreement or the Convertible

Note Purchase Agreement, nor the consummation of the transactions contemplated hereunder or thereunder, requires RandH to obtain any permits, authorizations or consents from any governmental body or from any other person, firm or corporation, and such execution, delivery and consummation will not result in the breach of or give rise to any termination of any agreement or contract to which RandH may be a party.

4.3 Source of Funds.

No payment to AQ hereunder will be made with government funds.

4.4. Effort.

During the term of this Agreement, RandH shall use commercially reasonable efforts to fulfill its obligations under this Agreement.

4.5. Compliance with Law.

RandH will conduct its activities and operations in material compliance with all applicable laws, statutes, rules or regulations.

4.6. Patent Prosecution; Infringement.

RandH shall cooperate with AQ's efforts regarding the Patent Prosecution, notify AQ of any possible claims of infringement of the Licensed Technology and cooperate with AQ in the prosecution of any actual or alleged infringement by a third party of any of the Licensed Technology.

### ARTICLE 5 CERTAIN OBLIGATIONS

5.1. Supply of Lead Candidates.

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

AQ will supply the needed quantities of Lead Candidates (as determined by the Joint Project Team) for entry into the Gated Process. Until such time as [\*\*\*] Lead Candidates are [\*\*\*].

- 5.2. Exclusivity; Reservation of Right.
- (a) AQ shall not work, collaborate or coordinate with any third party to develop a Lead Candidate or any analog or homolog of a Lead Candidate as a Biopesticide, unless such Lead Candidate (i) has been abandoned by RandH as provided at section 6.1(c) herein or (ii) is within AQ's Field. Any such work, collaboration or coordination shall be considered a material breach of this agreement.
- (b) Notwithstanding anything herein to the contrary, AQ reserves the right to conduct research and development in conjunction with third parties on analogs

and homologs of Lead Candidates which do not and will not qualify as Biopesticides.

5.3. Sale of Convertible Note.

Concurrently with the execution of this Agreement, AQ will sell to RandH and RandH will purchase from AQ, pursuant to a Convertible Note Purchase Agreement attached hereto as Exhibit B, a Convertible Note (as defined therein)

in the principal amount of five hundred thousand dollars (\$500,000) made within five (5) days of the Effective Date by wire transfer of immediately available funds to an account designated in writing by AQ. The entire outstanding principal balance of, and all accrued but unpaid interest on, the Convertible Note shall be converted automatically into fully paid nonassessable shares of the equity security (the "Next Financing Securities") sold by AQ in its next equity financing involving the receipt by AQ of at least \$3,000,000, including the amounts received on conversion of debt (the "Next Financing"). The number of shares of Next Financing Securities to be issued to RandH upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of the Convertible Note by (ii) the price per share of the Next Financing Securities multiplied by 1.2, rounded to the nearest whole share. The issuance of such shares upon such conversion shall be upon and subject to the same terms and conditions applicable to the Next Financing and, except as set forth in the preceding sentence, such shares shall have the same rights and preferences as the Next Financing Securities and such shares shall be upon and subject to terms and conditions no less favorable than any share issued by AQ prior to the Effective Date. If AQ does not complete a Next Financing within six months of the Effective Date, the Convertible Note shall be converted into shares of preferred stock of AQ (the "Next Equity Securities") at a purchase price to be determined by AQ's Board of Directors immediately prior to such conversion. Except as to purchase price, the Next Equity Securities will have the same rights and preferences as the Series E Preferred Stock.

5.4. Additional Investment.

During the Term, RandH may, [\*\*\*], purchase additional shares of AQ equity securities, subject to the approval of the Board of Directors of AQ.

# ARTICLE 6 GATED RESEARCH AND DEVELOPMENT FOR LEAD CANDIDATES

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406.

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6.1. The Gated Process and General Governing Principles for the Gated Process

- (a) RandH and AQ will assess, review, and develop the Lead Candidates through the Gated Process described below and as set forth in greater detail in the Gated Process Template at Exhibit D attached hereto and made
- a part hereof.
- (b) RandH, in its sole and exclusive discretion, will determine whether a particular Lead Candidate will move from one gate in the Gated Process to a subsequent Project Stage or gate.
- (c) RandH reserves the right to abandon a particular Lead Candidate at any time in the Gated Process. Subject to the following two sentences, a Lead Candidate shall be considered abandoned by RandH [\*\*\*]. If AQ does not receive written determination within sixty (60) days from the date of such request, such Lead Candidate shall be considered abandoned by RandH.
- 6.2. Project Stage 1.

(a) From time to time during the Term, RandH will evaluate the currently available data on the Lead Candidates and in its sole discretion select a Lead Candidate from Exhibit A for assessment in Project Stage 2 of the

Gated Process by written notification thereof to AQ; provided, however, that selection of the first Lead Candidate shall occur no later than the [\*\*\*] of the Effective Date.

(b) At the time that a Lead Candidate is selected to move to Project Stage 2, RandH shall pay AQ [\*\*\*] in immediately available funds to an account designated by AQ.

#### 6.3. Project Stage 2.

AQ will provide sufficient quantities of each Lead Candidate in order for RandH to evaluate the efficacy of such Lead Candidate in the laboratory. AQ will also provide a preliminary assessment for the novelty of the Lead Candidate, including dereplication with AQ's natural product database, and literature search of known chemistry and taxonomy.

### 6.4. Project Stage 3.

(a) Upon written notification by RandH to advance a Lead Candidate to Project Stage 3 and the concurrent advancement of [\*\*\*] to AQ for reimbursement of Actual Costs of the Pre-Development Activities, AQ will immediately commence the Pre-Development Activities. If at any time AQ becomes aware that the Actual Costs of such development activities for any individual Lead Candidate will

[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

exceed [\*\*\*], AQ shall notify RandH and obtain prior written approval from RandH to continue with the activities for such Lead Candidate. "Pre-Development Activities" means those activities identified as such in Project Stage 3 of the Gated Process Template.

- (b) Upon request by RandH and as a part of AQ's obligation pursuant to the Gated Process, AQ will conduct fractionation/purification and characterization (structure elucidation) to determine the active component molecules of the particular Lead Candidate. If these analyses demonstrate that the molecules are:
  - (i) lipophilic compounds, RandH will pay [\*\*\*] to AQ;
  - (ii) water soluble compounds, RandH will pay [\*\*\*] to AQ.

Any payments made pursuant to this Section 6.4(b) and 6.4(c) shall be made in immediately available funds to an account designated by AQ within thirty (30) days of written notification thereto by AQ.

(c) AQ will develop an analytical method suitable for meeting Registration requirements for the Lead Candidate in major market countries as determined by the Joint Project Team. RandH will pay a total of [\*\*\*] upon completion of such analytical method.

### 6.5. Project Stage 4.

(a) If AQ exercises its right of first refusal and undertakes the Commercial Manufacture of a Lead Candidate pursuant to Section 9.2(a) below, AQ in accordance with Project Stage 4 will conduct final process development on such Lead Candidate and manufacture [\*\*\*]-batches of such Lead Candidate to support Registration of the Lead Candidate. RandH will reimburse AQ for reasonable costs and expenses incurred in the process development under Project Stage 4 and manufacture of the [\*\*\*] batches of the Lead Candidate within [\*\*\*] days of submission of an invoice therefore.

- (b) RandH, at RandH's expense, will prepare and file with EPA an application for Registration and petition for tolerance or exemption from tolerance, if required, of the Lead Candidate. AQ shall have the right to review such application for Registration prior to filing. Upon submission of the application for Registration and petition, if required, as a Biopesticide to EPA or Japan or the EU, RandH shall pay AQ [\*\*\*].
- (c) Upon issuance by EPA of a Biopesticide Registration by EPA or Japan or the EU for the Lead Candidate, RandH shall pay to AQ [\*\*\*].

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- (d) RandH may request AQ to continue process optimization research for a Lead Candidate prior to commercialization, but after the [\*\*\*] analysis and submission for Registration. If such request is made by RandH, RandH will reimburse AQ for reasonable costs and expenses incurred in this optimization.
- 6.6. Special Payment to AQ. AQ shall receive a one time, lump sum payment of

[\*\*\*] of RandH's Net Sales for each Lead Candidate for which Registration is obtained for sales of such registered Lead Candidate(s) made during the fifth after the first year, in which a commercial sale occurs, and such lump sum payment will be made during the first quarter of in the year following.

6.7. Audit; Inspection of Records. Each party, including a permitted
-----sublicensee, shall keep full and accurate books and records of its

sublicensee, shall keep full and accurate books and records of its Actual Costs, Net Sales, and any other expenses or disbursements relating to this Agreement. Each party shall permit the other party, at its own

expense, to examine such books and records at any reasonable time.

### ARTICLE 7 JOINT PROJECT TEAM

7.1. Composition and Duties of Team.

The parties will establish a multifunctional team (the "Joint Project
Team") which will meet as needed at a mutually agreeable location to review and
direct the Project. Specifically, the Joint Project Team shall have among its
principal duties to review the status of Lead Candidates in the Gated Process
and review and discuss all draft and final data, studies and reports generated
through the Gated Process. At a minimum, the Joint Project Team will meet [***].
The Joint Project Team will be consultative in nature and, except as otherwise
set forth herein, all decisions regarding the Project will remain in the sole
and exclusive discretion of RandH.
7.2. Obligations of the Parties.

Each party to this Agreement working through the Joint Project Team will have the responsibility and obligation to supply appropriate personnel and all relevant data and other information needed to implement and accomplish the objectives of the Project.

# ARTICLE 8 PROPRIETARY RIGHTS, RIGHTS TO STUDIES, REGISTRATIONS, REGISTRATION DATA AND TRADEMARKS

8.1. Proprietary Rights.			
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[\*\*\*] Confidential information has been omitted and filed separately with the

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shall have access to all filings and all information and data relevant thereto.

8.4. RandH Trademarks.

RandH will obtain and maintain trademarks for the Lead Candidates as RandH sees fit in RandH's sole discretion and at its own expense. RandH will retain sole and exclusive ownership of such trademarks at all times. Nothing in this Agreement shall be construed as conferring on AQ the right to use in advertising, publicity or other promotional activities any name, trademark or

tradename of RandH or its existing products.

8.5. AQ Trademarks.

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

Nothing in this Agreement shall be construed as conferring on RandH the right to use in advertising, publicity or other promotional activities any name, trademark or tradename of AQ or its existing products.

### ARTICLE 9 LICENSE AND MANUFACTURING RIGHTS

9.1. License Grant.

AQ hereby grants an exclusive, worldwide, non-cancellable-right and license in and to the Technology Rights to make, use, offer for sale, import, export and distribute any and all Lead Candidates of products embodying a Lead Candidate for all uses except in AQ's Field (the "Licensed Technology"). Such license includes the right to sublicense; provided, however, that such sublicense (i) is subject to any restrictions set forth in this Agreement and

Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

Except as expressly provided to the contrary herein, as between the parties, all proprietary rights, title, and interest with respect to the Lead Candidates, including the Technology Rights and Improvements as set forth in Section 10.1 shall be and remain solely with AQ.

8.2. RandH Data.

All data and studies obtained, conducted or paid for by RandH for each individual Lead Candidate shall remain the exclusive property of RandH; provided, however, that notwithstanding anything else in this Agreement, AQ shall have access to all filings and all information and data relevant thereto for use by AQ in AQ's Field. If AQ uses such data or study in AQ's Field, AQ shall pay RandH [\*\*\*] of the Actual Costs incurred by RandH in the generation of such data or study within thirty (30) days of receipt of supporting documentation therefor. The parties agree however that AQ, with prior written approval from RandH, may use the data or studies without payment to RandH solely for the purpose of providing information to its current or prospective investors, and such approval shall not unreasonably withheld or delayed.

Notwithstanding the foregoing, if for any reason and at any time during the Gated Process described in Article 6, RandH determines to abandon a Lead Candidate as set forth in Section 6.1(c) of this Agreement, RandH will provide AQ with a copy of all data and studies generated by or on behalf of RandH in the Gated Process up to the date of RandH's notice of abandonment. However, if AQ at any time receives an economic benefit from the commercial sale of such abandoned Lead Candidate, AQ will [\*\*\*].

RandH shall be entitled to submit all regulatory filings in its name and shall own all such filings and Registrations, and subject to Section 8.2, AQ

(ii) prior to such sublicense, RandH provides written notification to AQ of its intent to effect such sublicense and a copy of such sublicensing agreement. The license described herein shall be in effect until such time as the Lead Candidate that is the subject of the license is abandoned as set forth in Section 6.1(c) or until such time as the latest of any patent relating to such Lead Candidate expires, at which time RandH shall have a [\*\*\*].

#### 9.2. Commercial Manufacture.

- (a) "Commercial Manufacture" means the manufacture of a Lead Candidate for the purpose of commercial sale of such Lead Candidate, whether in its technical form or in a product formulation.
- (b) RandH hereby grants AQ the right of first refusal to the Commercial Manufacture of the Lead Candidates by AQ at a facility owned or leased and operated by AQ ( "AQ's Manufacturing Right"); provided, however, that AQ must advise RandH of its decision to exercise AQ's Manufacturing Right within thirty (30) days of RandHs determination to advance a Lead Candidate to Project Stage 4. If AQ exercises AQ's Manufacturing Right, the Total Costs (as defined in Section 9.3(a)) shall be paid by RandH to AQ within thirty (30) days of submission of an invoice for such costs and expenses. AQ represents and warrants that if AQ exercises AQ's Manufacturing Right, AQ will manufacture the Lead Candidate at the lowest commercially reasonable cost possible.
- (c) If AQ decides to exercise AQ's Manufacturing Right, RandH and AQ agree to negotiate in good faith a Supply Agreement for such Lead Candidate.
- (d) If AQ decides not to exercise AQ's Manufacturing Right (i) RandH has [\*\*\*] to Commercial Manufacture of the Lead Candidate; (ii) AQ will provide RandH with any and all data and information it possesses pertaining to the Lead Candidate to be manufactured, including but not limited to all information about the Commercial Manufacture of such Lead Candidate and; (iii) AQ will provide any advice and consultation reasonably requested by RandH pertaining to the Commercial

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

Manufacture of such Lead Candidate. The parties agree that the information and advice provided pursuant to this Section 9.2(d) constitutes "Confidential Information" and all process information and rights remain the property of AQ.

9.3. Total Gross Margin Split.

(a) If AQ exercises AQ's Manufacturing Right and the parties enter into a Supply Agreement as set forth in Section 9.2(c), RandH will pay to AQ [\*\*\*], which shall be defined as the difference between (i) Net Sales and (ii) Total Costs. Total Costs shall mean the fully allocated costs associated with the Commercial Manufacture by AQ of Lead Candidates, including but not limited to labor, fermentation, recovery, formulation and packaging expenses, raw materials, taxes, direct depreciation and the allocable portion of utilities.

- (b) With respect to a Lead Candidate manufactured pursuant to Section 9.2(d), RandH shall pay to AQ a royalty of [\*\*\*] on RandH's Net Sales of such Lead Candidate.
- (c) Any payments made pursuant to this Section 9.3 shall be made by RandH in immediately available funds to an account designated by AQ within thirty (30) days of the end of RandH's fiscal quarter.

ARTICLE 10
INVENTIONS, IMPROVEMENTS OR NEW APPLICATIONS

7	U.	7.	ву	AQ
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AQ shall promptly inform RandH in writing of any Improvements made by AQ. Such Improvements shall be the sole property of AQ; provided, however, that such improvements shall be included within the meaning of the "Licensed Technology" licensed to RandH hereunder.

10.2 By RandH.

RandH shall promptly inform AQ in writing of any Improvements, whether patentable or not, made by RandH relating solely to a specific Lead Candidate or Licensed Technology. Such Improvements shall be the sole property of RandH; provided, however, that RandH hereby grants to AQ an exclusive (except as to RandH), royalty-free, worldwide, non-cancellable right and license, with the right to sublicense, to make, use, sell, offer for sale, import, export and distribute such Improvements in AQ's Field.

10.3. Joint Improvements.

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Any Improvements, whether patentable or not, made jointly by the parties shall be jointly owned by RandH and AQ ("Joint Improvements"). The parties will mutually agree in good faith which party will be responsible for development and Patent Prosecution of such Joint Improvement.

## ARTICLE 11 CONFIDENTIALITY

11.1 Scope. During the period of this Agreement and for ten (10) years

thereafter, RandH and AQ agree: (a) not to disclose to any third party, except as specifically allowed by this Agreement, any Confidential Information, (b) to limit disclosure of Confidential Information within its own organization to individuals whose duties justify the need to know such information and who are legally obligated to comply with the terms of this Agreement.

- (a) To the extent practical, Confidential Information shall be disclosed in tangible form and marked "Confidential". Information disclosed in non-tangible form, such as orally or by visual inspection, shall not be considered confidential unless the disclosing party confirms in writing the fact and general nature of the disclosure within one (1) month after it is made.
- (b) The recipient of Confidential Information shall be under no obligation with respect to any information which: (i) at the time of disclosure is available to the public (ii) after disclosure becomes available to the public through no fault of the recipient, provided that the obligation of the recipient shall cease only after the date on which such information has become available to the public (iii) the recipient can demonstrate through tangible evidence was in its possession before receipt from the disclosing party (iv) is disclosed to the recipient without restriction on disclosure by a third party who has the lawful right to disclose such information. Confidential Information shall not be deemed to be within the foregoing exceptions merely because it is (i) specific and embraced by more general information in the public domain or the recipient's possession or (ii) a combination which can be pieced together to reconstruct the Confidential Information from multiple sources, none of which shows the whole combination, its principle of operation, or method of use.

### ARTICLE 12 TERM AND TERMINATION

12.1.	Term.	_			
				-	-

The term of this Agreement shall be for a period of [\*\*\*] from the

Effective Date (the "Term"); provided, however, that for any Lead Candidate(s) that has proceeded beyond Gate 2 of the Gated Process Template, the terms and conditions of this Agreement shall remain in effect solely with respect to such Lead Candidate(s) until such time as (i) RandH

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has abandoned such Lead Candidate(s) as set forth in Section 6.1(c); (ii) a Biopesticide Registration for such Lead Candidate is issued by EPA or EU.

#### 12.2. Material Breach.

Should either RandH or AQ, at any time during the term of this Agreement, commit a material breach of any provision hereunder, and fail to rectify such breach within sixty (60) days from receipt of written notice from the other party, such other party may terminate this Agreement by notice in writing to the breaching party provided that such notifying party is not in material breach of this Agreement. Failure to make any payment under this Agreement when due shall constitute a material breach of the Agreement. Upon termination, provision for clearance of unsold stocks and related issues would be made in good faith between the parties.

### 12.3. Proceedings in Bankruptcy.

Should either party be adjudicated bankrupt or petition for or consent to any relief under any bankruptcy, reorganization, receivership, liquidation, compromise or arrangement or any moratorium statute whether now or hereinafter in effect, or should either party make arrassignment for the benefit of its creditors, or petition for the appointment of a receiver, liquidator, trustee or custodian for all or a substantial part of its assets, or should a receiver,

liquidator, trustee or custodian be appointed for all or a substantial part of such party's assets, the other party to this Agreement shall have the right to immediately terminate this Agreement. Notwithstanding any proceedings in bankruptcy, it is the express intent of the parties that each party shall retain any and all rights granted to such party in Articles 9 and 10 of this Agreement.

12.4 Survival.

Termination or expiration of this Agreement shall be without prejudice to any accrued rights or obligations of either party. Notwithstanding any provision in this Agreement, the provisions of Articles 8, 9, 10 and 11 shall survive any termination of this Agreement.

### ARTICLE 13 INDEMNIFICATION

13.1 Indemnification. Subject to Section 13(c) below:

(a) RandH hereby agrees to defend, indemnify and hold harmless AQ and each of its officers, directors, shareholders, employees, agents, representatives, attorneys, or advisors from and against any Damages arising out of or resulting from (i) RandH's failure to perform any of its obligations hereunder, (ii) any

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breach of or inaccuracy in any representation or warranty made by RandH herein, (iii) the use or commercialization by RandH (or its sublicensees and assignees) of the Licensed Technology, or (iv) the conduct of RandH's business.

- (b) AQ agrees to defend, indemnify and hold harmless RandH and each of its officers, directors, shareholders, employees, agents, representatives, attorneys, or advisors from and against any Damages arising out of or resulting from (i) AQ's failure to perform any of its obligations hereunder or (ii) any breach of or inaccuracy in any representation or warranty made by AQ herein and (iii) the conduct of AQ's business.
- (c) LIMITATIONS ON LIABILITY. EXCEPT TO THE EXTENT SET FORTH ABOVE (WITH

RESPECT TO DAMAGES ASSERTED BY THIRD PARTIES), IN NO EVENT SHALL EITHER

PARTY (OR ITS AGENTS, EMPLOYEES, REPRESENTATIVES, OFFICERS, DIRECTORS, SHAREHOLDERS, ATTORNEYS OR ADVISORS) BE LIABLE TO THE OTHER PARTY (OR ITS

AGENTS, REPRESENTATIVES, OFFICERS, DIRECTORS OR SHAREHOLDERS) OR ANY
THIRD PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL

DAMAGES RESULTING FROM THE USE, OR INABILITY TO USE, THE LICENSED
TECHNOLOGY, THE COMMERCIALIZATION OF THE LICENSED TECHNOLOGY OR
OTHERWISE

ARISING OUT OF THIS AGREEMENT.

### ARTICLE 14 MISCELLANEOUS

14.1. Governing Law.

This Agreement shall be governed by the laws of the state of Delaware.

14.2. Assignment.

RandH and AQ shall have the right to assign this Agreement without consent of the other party; provided, however, that the assigning party will use its best efforts to provide the earliest notification possible to the non-

assigning party.

14.3. Notices.

All notices, requests or consents required or permitted under this

Agreement shall be made in writing and shall be given to the other party by
personal delivery, registered or certified mail (with return receipt), overnight
air courier (with receipt signature) or facsimile transmission (with
"answerback" confirmation of transmission), sent to such party's address or
telecopy numbers set forth below, or such other addresses or telecopy numbers of
which

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the parties have given notice pursuant to this section 14.3. Each such notice, request or consent shall be deemed effective upon the date of actual receipt, receipt signature or confirmation of transmission, as applicable.

If to RandH:

Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19106-2399 USA

Attn: Dr. James B. Ryan Phone: (215) 641-7397 Facsimile: (215) 619-1614

If to AQ;

AgraQuest, Inc. 1530 Drew Avenue Davis, California, 95616 Attn: Dr. Pamela Marrone

Phone: (530) 750-0150 Facsimile: (530) 750-0153

### 14.4. Entire Agreement.

This Agreement constitutes the entire agreement of the parties with respect to the subject matter herein, supersedes all prior agreements with respect thereto, and may be amended only in writing signed by both parties.

#### 14.5. Severability.

If a court or regulatory authority of competent jurisdiction determines that one or more of the paragraphs or provisions of this Agreement are or may be invalid or unenforceable such decision shall not affect the remainder of the Agreement.

#### 14.6. Force Majeure.

The parties shall not be liable for any delay in or failure of performance hereunder due to any contingency beyond its reasonable control including but not limited to an act of God, war, mobilization, insurrection, rebellion, civil commotion, riot, act of extremist or public enemy, sabotage, labor dispute, lockout, strike explosion, fire, flood, storm, accident, drought, equipment failure, power failure, shortage of cars, delay of carrier, embargo, law,

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ordinance, rule or regulation, whether valid or invalid, including priority requisition, allocation, or price control.

14.7. Waiver.

Failure by either party hereto to exercise or enforce any rights conferred upon it by this Agreement shall not be deemed to be a waiver of any such rights or operate so as to bar the exercise or enforcement thereof or of any other rights at any subsequent time or times.

14.8. Status of the Parties.

Nothing in this Agreement shall be construed as to constitute a partnership or joint venture between the parties or authorize either to represent the other party or contract any liability on behalf of the other party.

14.9. Dispute Resolution; Arbitration.

The parties failure to comply with the terms of the license grant in Sections 9.1, 10.1 or 10.2 shall constitute a material breach of this Agreement for which the parties respectively will be entitled to injunctive relief from a court of competent jurisdiction. In the event of a dispute between the parties as to any matter arising in connection with this Agreement, such matter shall be referred to the Vice President, Agricultural Chemicals Business Unit Director at RandH and Chief Executive Officer at AQ for resolution. If the dispute cannot be settled amicably through negotiation by these individuals, then the parties agree in good faith to submit the dispute to mediation in accordance with the Center for Public Resources Model Procedure for Mediation of Business Disputes. If the dispute cannot be settled through mediation, the parties agree to submit the dispute to binding arbitration in accordance with Title 9 of the United

States Code and the Commercial Arbitration Rules of the American Arbitration Association (the "Association"). If the parties are unable to agree upon a single arbitrator, the arbitrator shall be a single, independent arbitrator selected by the Association. Arbitration shall take place at a location mutually agreeable to the parties. The fees and expenses of the mediator and arbitrator shall be paid equally by the parties to such mediation or arbitration.

14.10 Joint Press Release.

Upon execution of this Agreement or as soon as practicable thereafter, the parties will issue a joint press release, the text of which shall be mutually acceptable to the parties.

Agreed to by:

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[\*\*\*] Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to 17 C.F.R. Section 230.406. <PAGE>

AGRAQUEST, INC.

**ROHM AND HAAS COMPANY** 

By: /s/ Pamela G. Marrone

By: /s/ Carlos A. Estevez

Name: Dr. Pam Marrone

Name: Carlos A. Estevez

Title: President & CEO

Title: Vice-President and World Wide

Agricultural .

Chemicals Business Unit Director

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EXHIBIT 10.32

CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. \* INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST THAT IS FILED SEPARATELY WITH THE COMMISSION.

COLLABORATION AGREEMENT

BY AND BETWEEN

HOECHST MARION ROUSSEL, INC.

AND

AMYLIN PHARMACEUTICALS, INC.

DATED AS OF MARCH 31, 1997

ALT 00327

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### COLLABORATION AGREEMENT

COLLABORATION AGREEMENT (the "Agreement") entered into as of the 31st day of March, 1997 by and between AMYLIN PHARMACEUTICALS, INC., a Delaware corporation ("Amylin"), and HOECHST MARION ROUSSEL, INC., a Delaware corporation ("HMR"), effective only upon HMR's exercise of the HMR Option as provided for in Section 4.1 of the License Agreement (as defined below) (the "Effective Date"). Amylin and HMR are sometimes referred to herein individually as a "Party" and together as the "Parties".

#### WITNESSETH:

WHEREAS, HMR is a leading multinational health care company with a broad product portfolio of drugs for the treatment of human diseases;

WHEREAS, Amylin is a leading biotechnology company that has expertise and experience in the research and development of compounds for use in treating metabolic and other disorders;

WHEREAS, Amylin and HMR have entered into that certain License and Option Agreement effective as of March 31, 1997 (the "License Agreement"), with respect to the HMR Compounds (as defined in the License Agreement); and

WHEREAS, the Parties desire to collaborate with respect to the Research, Development and Commercialization (as such terms are defined below) of one or more HMR Compounds on the terms set forth in this Agreement.

NOW, THEREFORE, in consideration of the following premises and the mutual covenants and agreements contained herein, the Parties agree as follows:

#### ARTICLE I

#### DEFINITIONS

Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the License Agreement. For purposes of this Agreement, the following terms shall have the meanings specified below:

1.1 "ALLOWABLE EXPENSES" means those expenses incurred after the first commercial launch of a Collaboration Product which are generally consistent with a Commercialization Plan and Commercialization Budget and are specifically attributable to Collaboration Products in the Profit Sharing Territory, and shall consist of (i) Cost of Goods Sold, (ii) Marketing Expenses,

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- (iii) Distribution Expenses, (iv) Post-Launch Product R&D Expenses, (v) Collaboration Patent Expenses, and (vi) Currency Gains or Losses. Allowable Expenses shall exclude Development Expenses and Research Expenses, even if incurred after the first commercial launch of a Collaboration Product.
- 1.2 "AVERAGE NET SELLING PRICE" means total Net Sales of a Collaboration Product divided by the total units sold of such Collaboration Product, in both cases excluding sales and units involving government mandated or conceded discounts or bearing a Nominal Price.
- $_{1.3}$  "BREACHING PARTY" shall have the meaning set forth in Section  $_{12.2\,(a)}$  .
- 1.4 "COLLABORATION COMPOUND" means any HMR Compound which is, as of the Effective Date, or thereafter becomes, the subject of Research, Development or Commercialization under this Agreement.
- 1.5 "COLLABORATION PATENT EXPENSES" means the fees and expenses of outside counsel and payments to Third Parties incurred in connection with the preparation, filing, prosecution and maintenance of Amylin Patents, Joint Patents and HMR Patents after the Effective Date, including the costs of patent interference and opposition proceedings.
- 1.6 "COLLABORATION PRODUCT" means a product including or incorporating any form or dosage of a Collaboration Compound for use in the Field and as to which each Party has paid, is paying or is obligated to pay hereunder one-half of the Research and Development Expenses.
- 1.7 "COMMERCIALIZATION" shall mean all activities relating to the manufacture, marketing, distribution and sale of a Product, including, without limitations, Pre-Marketing, advertising, education, planning, marketing, distribution, market and product support pre-clinical studies, Phase IIIB Clinical Trials and Phase IV Clinical Trials and, subject to Section 9.7, sub-licensing of Collaboration Products.
- 1.8 "COMMERCIALIZATION BUDGET" shall have the meaning set forth in Section 5.5(a).
- 1.9 "COMMERCIALIZATION LIAISON OFFICER" shall have the meaning set forth in Section 3.10(b)
- $_{1.10}$  "COMMERCIALIZATION PLAN" shall have the meaning set forth in Section 5.5(a).
- 1.11 "COMPETITIVE PRODUCT INFRINGEMENT" shall have the meaning set forth in Section 9.1(a).
- 1.12 "CORE DOSSIER COUNTRIES" means the United States, Canada, Japan and the countries included in the European Union as of the Effective Date.

- 1.13 "COST OF GOODS SOLD" means the cost of Collaboration Product inventory sold and other manufacturing related costs incurred with respect to Collaboration Products in the Profit Sharing Territory during any relevant period, in each case excluding administration expenses. These costs shall be defined as the sum of the applicable expenditures incurred directly in bringing goods acquired and/or manufactured to their existing condition or location. Cost of Goods Sold shall be calculated in the manner set forth in Exhibit A.
- 1.14 "CURRENCY GAINS OR LOSSES" means gains or losses resulting from a change in exchange rates (in the case of unhedged transactions) and/or the gains or losses of related hedging transactions, in either case as associated with Net Sales of Collaboration Products, calculated in the manner set forth in Exhibit A.
- 1.15 "DEVELOPMENT" means all activities relating to obtaining Regulatory Approval of a Product, Product line extensions, alternative delivery systems and new indications therefor and all activities relating to developing the ability to manufacture the same. This includes preclinical testing, toxicology, formulation, bulk production, fill/finish, manufacturing process development, manufacturing and quality assurance technical support, clinical studies, regulatory affairs and outside counsel regulatory legal services.
- 1.16 "DISTRIBUTION EXPENSES" means the costs, excluding administration costs, incurred by a Party or for its account, specifically attributable to the distribution of a Collaboration Product in the Profit Sharing Territory, to be calculated in the manner set forth in Exhibit A.
- 1.17 "EFFECTIVE DATE" shall have the meaning set forth in the introduction to this Agreement.
- 1.18 "EQUALIZATION PAYMENT" shall mean the amount payable by one Party to the other to equalize the Operating Profit or Losses between the Parties as shown on Exhibit B. By way of example, in a total Operating Profits situation, if HMR has an Operating Profit of 40 and Amylin has an Operating Loss of 10, then the Equalization Payment made by HMR to Amylin will be 25. In a total Operating Losses situation, if HMR has an Operating Loss of 40 and Amylin has an Operating Loss of 10, the Equalization Payment made by Amylin to HMR will be 15.
- 1.19 "EX-MANUFACTURER SELLING PRICE" means the invoice price to wholesalers (or their equivalent) less all cash discounts taken for prompt cash payment for a Collaboration Product.
- 1.20 "EXCEPTED COMMERCIALIZATION MATTERS" shall have the meaning set forth in Section 5.1(b).

- 1.21 "EXCEPTED DEVELOPMENT MATTERS" shall have the meaning set forth in Section 4.1(b).
- 1.22 "FINANCIAL STATEMENT FORMAT" means the form of Financial Statement shown and described in Exhibit B.
- 1.23 "INDEPENDENT PRODUCT" means a product including or incorporating any form or dosage of an HMR Compound which is developed by a Party under Section 4.8(b) without the other Party paying one-half of all Research and Development Expenses.
- 1.24 "INITIAL RESEARCH AND DEVELOPMENT PLAN AND BUDGET" shall have the meaning set forth in Section 4.4(a).
- 1.25 "JOINT COMMERCIALIZATION COMMITTEE" OR "JCC" means the committee established pursuant to Section 3.7.
- 1.26 "JOINT DEVELOPMENT COMMITTEE" OR "JDC" means the committee established pursuant to Section 3.7.
- 1.27 "LAUNCH BUDGET" shall have the meaning set forth in Section 5.6(a).
- 1.28 "LAUNCH PLAN" shall have the meaning set forth in Section 5.6(a).
- 1.29 "LIAISON OFFICER" shall have the meaning set forth in Section 3.10(c).
- 1.30 "MANUFACTURING ATTRIBUTES" shall have the meaning set forth in Section 8.1.1(a).
- 1.31 "MARKETING EXPENSES" means the costs, excluding administration costs, which are generally consistent with a Commercialization Budget and Commercialization Plan and (i) are incurred after the first commercial launch of a Collaboration Product and are specifically attributable to the sale, promotion, and marketing of such Collaboration Product in the Profit Sharing Territory or (ii) are incurred after the first commercial launch of a Collaboration Product in a Major Market Country and are specifically attributable to preparation of the launch of such Collaboration Product in additional countries of the Profit Sharing Territory. Marketing Expenses shall be calculated in the manner set forth on Exhibit A.
- 1.32 "MATERIAL BREACH" shall have the meaning set forth in Section 12.2(g).
- 1.33 "NET SALES" means the amount invoiced by a Party or an Affiliate for sales of Products to a Third Party in the Profit Sharing Territory less: (i) discounts, including cash discounts, rebates and retroactive price reductions or allowances actually allowed or granted from the invoiced amount (as adjusted pursuant to Section 5.14), (ii) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, including recalls,

(iii) taxes (other than income taxes), duties or other governmental charges levied on or measured by the invoiced amount when included in billing, as adjusted for rebates and refunds, and (iv) provisions for uncollectible accounts determined in accordance with such Party's normal accounting procedures consistently applied within and across its pharmaceutical operating units.

1.34 "NET SUBLICENSE REVENUES" means all revenues or other consideration received from Third Parties as consideration for sublicensing of the manufacture, distribution, use or sale of Collaboration Products in the Profit Sharing Territory, less the expenses directly attributable to supplying goods and services to such sublicensees to enable their performance of the sublicenses.

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- $_{\rm 1.36}$  "NON-BREACHING PARTY" shall have the meaning set forth in Section 12.2(a).
- 1.37 "OPERATING PROFITS OR LOSSES" means the profits ("Operating Profits") or losses ("Operating Losses") resulting from the Commercialization of Collaboration Products in the Profit Sharing Territory and shall be equal to (i) Net Sales less Allowable Expenses plus (ii) Net Sublicense Revenues. A separate determination of Operating Profits or Losses shall be made for each Collaboration Product on a worldwide basis as outlined in Exhibit B. In the event multiple Collaboration Products are being marketed under this Agreement, the individual statements of Operating Profits or Losses shall also then be consolidated into a single statement of Operating Profits or Losses for purposes of overall accounting between the Parties.
- 1.38— "PHASE I CLINICAL TRIALS" shall have the meaning set forth in 21 CFR ss. 312.21(a).
- 1.39 "PHASE IIIB CLINICAL TRIALS" means product support clinical trials of a Collaboration Product (i.e., a clinical trial which the JDC determines is not required for receipt of Regulatory Approval but which may be useful in providing additional drug profile data) commenced before receipt of Regulatory Approval in the country where such trial is being conducted.
- 1.40 "PHASE IV CLINICAL TRIALS" means product support trials of a Collaboration Product commenced after receipt of Regulatory Approval in the country where such trial is being conducted.
- 1.41 "POST-LAUNCH PRODUCT R&D EXPENSES" means the costs of Phase IV Clinical Trials and ongoing product support (including manufacturing and quality assurance technical support, and laboratory and clinical efforts directed toward the further understanding of product
- \* CONFIDENTIAL TREATMENT REQUESTED

safety and efficacy) and medical affairs (including regulatory support necessary for product maintenance) which are specifically attributable to a Collaboration Product in the countries of the Profit Sharing Territory where such Collaboration Product has been launched, excluding administrative expenses and costs that are included within Costs of Goods Sold or Development Expenses. Post-Launch Product R&D Expenses shall be calculated in the manner set forth on Exhibit A.

- 1.42 "PRE-MARKETING" means all Commercialization activities undertaken prior to and in preparation for the launch of a Collaboration Product in the Profit Sharing Territory, consistent with a Commercialization Plan and prior to the first commercial launch of a Collaboration Product in a Major Market Country. Pre-Marketing shall include advertising, education, sales force training, Phase IIIB Clinical Trials, trademark selection, filing, prosecution and enforcement, and other activities included within the Commercialization Plan prior to the first commercial launch of a Collaboration Product in a Major Market Country. If a Collaboration Product is first launched in a country other than a Major Market Country, the expenses of marketing incurred in those countries where such Collaboration Product has been launched shall be included in Marketing Expenses, while the expenses of Pre-Marketing elsewhere in the world shall still be included in Pre-Marketing Expenses.
- 1.43 "PRE-MARKETING EXPENSES" means the costs, excluding Development Expenses, specifically attributable to the Pre-Marketing of a Collaboration Product. Pre-Marketing Expenses shall exclude administrative expenses.
- 1.44 "PRODUCTS" shall mean Collaboration Products, Royalty-Bearing Products and Independent Products, collectively.
- 1.45 "PROFIT SHARING TERRITORY" means the world except for those countries as to which Amylin has elected to withdraw from the sharing of expenses, profits and losses with respect to Collaboration Products pursuant to Section 5.7. The Profit Sharing Territory may be different for each Collaboration Product, based on the elections made by Amylin with respect to each such product in each country.
- 1.46 "REGULATORY FILINGS" shall have the meaning set forth in Section 4.6
- 1.47 "RESEARCH" means the scientific, technical and clinical activities undertaken to evaluate an HMR Compound for Development, including pharmacology, pharmacokinetics, toxicology, formulation, process development, manufacture of HMR Compounds (including manufacture of bulk drug substance and fill/finish) for preclinical studies and clinical trials, and clinical pharmacology.
- 1.48 "RESEARCH AND DEVELOPMENT BUDGET" shall have the meaning set forth in Section 4.4(a).

- 1.49 "RESEARCH AND DEVELOPMENT EXPENSES" means the expenses incurred by a Party or for its account which are generally consistent with a Research and Development Plan and Research and Development Budget and are specifically attributable to the Research and Development of a Collaboration Product (including royalties paid to a Third Party not otherwise recovered as a Cost of Goods Sold). Research and Development Expenses shall exclude administrative expenses.
- 1.50 "RESEARCH AND DEVELOPMENT LIAISON OFFICER" shall have the meaning set forth in Section 3.10(a).
- 1.51 "RESEARCH AND DEVELOPMENT PLAN" shall mean the Research and Development Plans referred to in Section 4.4(a).
- 1.52 "RESEARCH EXPENSES" means the expenses incurred by a Party or for its account specifically attributable to Research for a Collaboration Compound. Research Expenses shall exclude administrative expenses.
- 1.53 "ROYALTY-BEARING COUNTRY" shall have the meaning set forth in Section 5.7.
- 1.54 "ROYALTY-BEARING PRODUCT" means a Collaboration Product marketed directly or indirectly by HMR in a Royalty-Bearing Country under a royalty arrangement pursuant to Section 5.7.
- 1.55 "ROYALTY-BEARING SALES" means the amount invoiced for sales of a Royalty-Bearing Product, or (pursuant to Section 12.2) a Collaboration Product or (pursuant to Section 4.8(b)) an Independent Product by a Party or its permitted sublicensees to a Third Party, less (i) discounts, including cash discounts, or rebates, retroactive price reductions or allowances actually allowed or granted from the invoiced amount, (ii) credits or allowances actually granted upon claims, rejections or returns of such Products, including recalls, (iii) freight, postage, shipping and insurance charges paid for delivery of such Products, to the extent invoiced, (iv) taxes (other than income taxes), duties or other governmental charges levied on or measured by the invoiced amount when included in billing, as adjusted for rebates and refunds, and (v) provisions for uncollectible accounts determined in accordance with such Party's normal accounting procedures consistently applied within and across its pharmaceutical operating units.

In the event a Party is receiving royalties under this Agreement from any Product sold in the form of a combination product containing one or more active ingredients in addition to a Collaboration Compound, and if said combination product is not covered by a Patent owned or Controlled by the Party receiving royalties, Royalty-Bearing Sales for such combination product will be calculated by multiplying actual Royalty-Bearing Sales of such combination product by the fraction A/(A+B) where A is the invoice price of the Product if sold separately,

and B is the total invoice price of any other active component or components in the combination product, if sold separately. If, on a country-by-country basis, the other active component or components in the combination are not sold separately in said country, Royalty-Bearing Sales for the purpose of determining royalties of the combination product shall be calculated by multiplying actual Royalty-Bearing Sales of such combination product by the fraction A/C where A is the invoice price of the Product if sold separately, and C is the invoice price of the combination product. If, on a country-by-country basis, neither the Product nor the other active component or components of the combination product is sold separately in said country, Royalty-Bearing Sales for the purposes of determining royalties of the combination product shall be determined by the Parties in good faith. If the manufacture, use or sale of the combination product is itself covered by a Patent owned or Controlled by the Party receiving royalties (other than a Patent covering the manufacture, use or sale of said Collaboration Compound), the provisions of this paragraph shall not apply to sales of said combination product.

- 1.56 "SIMULTANEOUS FILINGS" shall have the meaning set forth below in Section 4.6.
- 1.57 "STEERING COMMITTEE" means the committee described in Section 3.1.

### ARTICLE II

## PRE-COLLABORATION EXPENSES

- 2.1 ALLOCATION OF PRE-COLLABORATION RESEARCH AND DEVELOPMENT EXPENSES. Within thirty (30) days after the Effective Date, the Parties shall apportion amongst themselves the Amylin Research and Development Expenses, HMR's Additional Research and Development Expenses and HMR's costs and expenses of developing the HMR Compounds prior to the effective date of the License Agreement, taking into account any reimbursements of the foregoing made by one Party to the other, so that such costs and expenses are borne equally by the Parties, as follows:
- (a) The Amylin Research and Development Expenses (whether or not reimbursed), minus any amount actually paid by HMR to reimburse Amylin on account of Amylin's Research and Development Expenses (collectively, the "Net Amylin Expenses"); shall be compared with
- (b) The sum of (i) any HMR Additional Research and Development . Expenses plus (ii) \*\*\*\*\*\*\*\*\*\*\*\* (representing a portion of the total costs incurred by HMR prior to the effective date of the License Agreement with respect to Research and Development of the HMR Compounds, the other portion to be reimbursed pursuant to Section 6.2 (b) of this Agreement) (collectively, the "Net HMR Expenses").
- \* CONFIDENTIAL TREATMENT REQUESTED

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2.2 PRE-COLLABORATION ALLOCATION PAYMENT. Within thirty (30) days following the thirty-day period referred to in Section 2.1, in the event the Net Amylin Expenses exceed the Net HMR Expenses, then HMR shall pay to Amylin one-half of the difference between the Net Amylin Expenses and the Net HMR Expenses. In the event the Net HMR Expenses exceed the Net Amylin Expenses, then Amylin shall pay to HMR one-half of the difference between the Net HMR Expenses and the Net Amylin Expenses.

### ARTICLE III

## MANAGEMENT OF PROGRAM

- 3.1 STEERING COMMITTEE. Within thirty (30) days after the Effective Date, the Parties shall form an executive committee for the management of their collaborative efforts (the "Steering Committee"). The Steering Committee shall be comprised of up to six members, with an equal number of members appointed by each Party. Each Party shall appoint and replace its own representatives on the Steering Committee. Members of the Steering Committee shall be composed of executive personnel of the Parties. One member of the Steering Committee selected by each party shall have substantial experience in pharmaceutical product research and development. One member of the Steering Committee selected by each party shall have substantial executive experience. Steering Committee members shall serve on such terms and conditions as shall be determined by the Party selecting such member, and may be removed or replaced at any time by such Party. An alternate member may serve temporarily in the absence of a permanent member.
  - 3.2 MEETINGS OF THE STEERING COMMITTEE. The Steering Committee:
- (a) shall hold meetings at such times and places as shall be determined by a majority vote of the entire membership of the Steering Committee, but in no event shall such meetings be held less frequently than once every six (6) months;
- (b) may conduct meetings in person or by telephone conference, provided that any decision made during a telephone conference meeting shall be evidenced by minutes signed by one of the members of the Steering Committee from each of the Parties;
  - (c) shall keep minutes reflecting actions taken at meetings;
- (d) may act without a meeting if prior to such action a written consent thereto is signed by all members of the Steering Committee then in office; and
- (e) may amend or expand upon the foregoing procedures for its internal operation by unanimous written consent of all members of the Steering Committee then in office.

- FUNCTIONS AND POWERS OF THE STEERING COMMITTEE. The activities rties under this Agreement shall be managed by the Steering Committee only to he extent set forth in this Agreement, including:
- manage and coordinate the long-range strategy and planni: for the Research, Development and Commercialization of HMR Compounds, includ: facilitation of the flow of Information with respect to Research, Develoge ent and Commercialization work being conducted for each Collaboration Produc:
- coordinate the activities of the Parties hereunder, includ: g long-range strategy and oversight of the Joint Development Committee (the "JCC") and the Joint Commercialization Committee (the "JCC") (as described below)
- attempt to settle disputes or disagreements that are (c) unresched as referenced herein;
- review and approve the Research and Development Budgets (d) submit ad to it by the JDC;
- review and approve the Commercialization Budgets and (e) Launch Budgets submitted to it by the JCC;
- review planned pricing and manufacturing decisions of the JCC, as provided herein;
- (g) review and approve a proposal by either Party (i) to stop a Phase I Clinical Trial or Phase II Clinical Trial of a Collaboration Product because of Safety, (ii) to stop a Phase III Clinical Trial of a Collaboration Product for any reason, or (iii) to terminate such Party's participation in Research and Development of a Collaboration Product under Section 4.8; and
- (h) perform such other functions as appropriate to further the purposes of this Agreement as mutually determined by the Parties.
- STEERING COMMITTEE ACTIONS. Except as otherwise provided in this Agreement, actions to be taken by the Steering Committee pursuant to the terms of this Agreement shall require the unanimous vote of the members of the Steering Committee. The following procedures will be followed by the Steering Committee with respect to Research, Development and Commercialization matters referred to it:
- If the Steering Committee cannot reach a unanimous decision with respect to any Research and/or Development matters referred to it for approval within sixty (60) days following receipt of such referral, the final decision on such matters shall be made by Amylin,

except as to Excepted Development Matters. If the Steering Committee cannot reach a unanimous decision with respect to any of the Excepted Development Matters referred to it by the JDC pursuant to Section 4.1(b), (1) the status quo shall be maintained with respect to Excepted Development Matters items (i) and (ii) in Section 4.1(b) and (2) as to Excepted Development Matter item (iii) in Section 4.1(b), the Phase III Clinical Trial shall be terminated if the Steering Committee does not reach a unanimous decision within ten (10) days.

- (b) If the Steering Committee cannot reach a unanimous decision with respect to approval of the Commercialization Budget or Launch Budget of a Collaboration Product pursuant to Article V, or any other Commercialization matters referred to it for approval, within sixty (60) days following receipt of such referral, the final decision on such matters shall be made by HMR, except as to Excepted Commercialization Matters, which shall be resolved as provided for in Section 5.1(b).
- (c) Except as provided for above in this Section 3.4, if the Steering Committee fails to reach unanimous agreement on a matter before it for decision within sixty (60) days following its receipt of the referral of the matter, such matter shall be referred to executive officers of the Parties pursuant to the dispute resolution procedures set forth in Section\* 12.2 of the License Agreement. The manner described in this Section 3.4 to resolve disputes regarding Excepted Development Matters and Excepted Commercialization Matters shall be the sole mechanism for resolving such matters under this Agreement. If either Amylin or HMR wishes to seek a non-binding opinion from a Third Party with respect to any issue before the Steering Committee for decision, it may do so at its own expense; provided, however, that if both Parties agree to seek such opinion, such expense shall be shared equally by the Parties.
- 3.5 ACCESS TO RECORDS. The Parties shall provide the Steering Committee and its authorized representatives with reasonable access during regular business hours to all records and documents in their possession relating to the Collaboration Compounds and the Collaboration Products which the Steering Committee may reasonably require in order to perform its obligations hereunder.
- 3.6 LIMITATIONS ON THE POWERS OF THE STEERING COMMITTEE. The Steering Committee shall have only such powers as are specifically delegated to it hereunder or as are specifically agreed to in writing by the Parties. Except as set forth in Section 3.3, the Steering Committee shall not be involved with the day-to-day management of the collaboration activities contemplated by this Agreement.
- 3.7 FORMATION OF THE JDC AND THE JCC AND APPOINTMENTS. The Parties shall form the JDC and the JCC within thirty (30) days after the Effective Date. For each of the JDC and the JCC, each Party shall appoint and replace its own representatives on such committees. Each such committee shall be comprised of equal numbers of members appointed by each Party (up to four (4) members for each Party per committee) of appropriately expert and experienced

individuals. Members of the Steering Committee shall not serve as members of the JDC or JCC, and the Parties shall use their best efforts to not appoint a person as a member of both the JDC and JCC. One of the members of the JDC appointed by Amylin will serve as the chairperson of the JDC. One of the members of the JCC appointed by HMR will serve as the chairperson of the JCC. Either Party may designate an alternate for a committee member to participate in the event one of that Party's regular committee members is unable to be present at a meeting.

- 3.8 MEETINGS OF THE JDC AND THE JCC. Meetings of the JDC or the JCC may be called by either Party on ten (10) working days prior written notice, unless such notice is waived by the Parties. Such committees may be convened, polled or consulted from time to time by means of telecommunication, video communication, or correspondence. Each of the JDC and the JCC will meet at least once every four (4) month period following the Effective Date, at sites to be designated by the chairpersons of such committees.
- 3.9 AGENDAS. Each Party will provide proposed agenda items to the committee chairpersons, together with appropriate information, at least five (5) working days in advance of each meeting of the Steering Committee, JDC or JCC. The committee chairpersons will then deliver an agenda for the meeting to each member of the committee at least three (3) working days in advance of the committee meeting.

### 3.10 LIAISON OFFICERS.

- individual as Research and Development Liaison Officer, who will facilitate communication and coordination of activities relating to Research and Development between the Parties and provide support and guidance to the JDC and the Research and Development teams. Amylin will make available an office and secretarial services to the Research and Development Liaison Officer, and will provide reasonable access to Amylin technical staff, management, and documentation relevant to Collaboration Products. The Research and Development Liaison Officer is expected to attend project team meetings and JDC meetings. The Research and Development Liaison Officer also will have reasonable access to Steering Committee members from each Party.
- experienced individual as Commercialization Liaison Officer, who will facilitate communication and coordination of Commercialization activities between the Parties. HMR will make available to the Commercialization Liaison Officer an office and secretarial services and will provide reasonable access to marketing, sales, planning and other relevant HMR personnel assigned to work on Collaboration Products and to plans, market research, and other documentation relevant to Commercialization of Collaboration Products. The Commercialization Liaison Officer is expected to attend relevant product team meetings and JCC meetings. The Commercialization Liaison Officer also will have reasonable access to Steering Committee members from each Party.

- an employee of HMR and the Commercialization Liaison Officer will remain an employee of Amylin (the Research and Development Liaison Officer and the Commercialization Liaison Officer are referred to collectively herein as the "Liaison Officers"). Each Liaison Officer is expected to spend between "Liaison Officers" one-quarter and three-quarters of his or her working time at the premises of the Party who is not his or her employer in order to perform his or her liaison function effectively.
- (d) HMR and Amylin will propose, within thirty (30) days after formation of the JDC and JCC, respectively, candidates to serve as Liaison Officers to the chairpersons of the JDC and JCC, respectively, who shall approve the respective Liaison Officers within thirty (30) days following receipt of each such proposed candidate. Such Liaison Officers may be replaced from time to time by the Party employing them. Any such replacement must be approved by the chairperson of the JDC or JCC, as the case may be.

### 3.11 ACCOUNTING.

- (a) For the purposes of determining all costs and expenses hereunder, any cost or expense allocated by either Party to a particular category for a particular Collaboration Product shall not also be allocated to another category for such Collaboration Product, and any cost or expense allocated to a particular Collaboration Product in a particular country shall not be allocated to another Collaboration Product of such Party or the same Collaboration Product in a different country.
- Party agrees to determine Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and all other costs and expenses hereunder with respect to the Products using its standard accounting procedures, consistent with United States Generally Accepted Accounting Principles, to the extent practical, as if such Products were solely owned products of the Party. The Parties also recognize that such procedures may owned products of the Party. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and such other costs and expenses. The Parties Expenses, Pre-Marketing Expenses and such other costs and expenses. The Parties adjustments shall be made to compensate the affected Party in order to preserve the same economics as reflected under this Agreement under such Party's accounting procedures in effect as of the date on which the activity in question (for example, Research, Development, marketing or manufacturing) first commences under this Agreement. Where the change is or would be economically material to expense category. For purposes of this Section 3.11, "economically material" expense category. For purposes of this Section 3.11, "economically material" shall mean, before the first commercial launch of a Collaboration Product, a change which affects Research Expenses, Research and Development Expenses and/or Pre-Marketing Expenses by five percent

(5%) or more, and after the first commercial launch of a Collaboration Product, a change which affects Operating Profits or Losses by five percent (5%) or more.

### ARTICLE IV

### JOINT RESEARCH AND DEVELOPMENT

## 4.1 RESPONSIBILITIES OF THE JDC.

- (a) Following the Effective Date, the JDC shall oversee the Research and Development of Collaboration Compounds in order to obtain Regulatory Approvals, as set forth in this Article IV. The JDC will also (i) oversee the preparation of Research and Development Plans and Research and Development Budgets and submit such plans and budgets to the Steering Committee for review and budget approval, (ii) evaluate and designate Collaboration Compounds for Research and Development and (iii) facilitate the flow of Information with respect to Research and Development being conducted for each Collaboration Product. In addition, in connection with an approved Commercialization Budget and/or an approved Launch Budget, the JDC will oversee Phase IIIB Clinical Trials, and shall provide such support with respect to Phase IV Clinical Trials as may be reasonably requested by the JCC.
- vote of the members of the JDC. If the JDC is unable to obtain a majority affirmative vote as to any matter involving Research or Development, except for (i) increasing the Research and Development Budget (other than as provided for in the Initial Research and Development Plan and Budget in Section 4.4(a)), (ii) altering the Research and Development Plan in a manner which would (1) change indications for which a Collaboration Product is being developed, (2) conduct Development for less than North America and the European Union or (3) change or add a route of delivery or line extension of a Collaboration Product in Development or (iii) terminating a Phase III Clinical Trial prior to completion in accordance with its protocol (collectively, the "Excepted Development Matters"), the decision of Amylin will be final and determinative so long as such decision does not contradict or modify the terms of this Agreement. Such Excepted Development Matters shall be referred to the Steering Committee for consideration pursuant to Section 3.4 of this Agreement.
- (c) The JDC will have the power to form subcommittees with appropriate representation from Amylin, HMR and appropriate Third Parties; provided, however, that any Third Party member of a subcommittee must be approved by HMR.
- (d) During clinical trials for any Collaboration Products, the JDC and JCC shall work together to assure a smooth transition from Development of such Collaboration Products to Commercialization of such Collaboration Products, including, without limitation,

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product claims, product positioning, pre-launch medical education and communications programs. In addition, the JDC shall keep the JCC informed of proposed changes in the dosage form of Collaboration Products and the countries in which Phase III Clinical Trials are being conducted.

- Research and Development Party with respect to all Collaboration Products and, as a result, shall be obligated and responsible for carrying out Research and Development pursuant to each Research and Development Plan. Amylin will commence reporting to the JDC within sixty (60) days following the Effective Date. Amylin will report to the JDC at such times and in such manner as is reasonably determined by the JDC from time to time. HMR agrees to carry out such Research and Development tasks as are reasonably requested by Amylin and accepted by HMR. In addition, consideration shall be given to HMR to participate in other Research and Development activities, as mutually agreed upon by the Parties. All HMR Research and Development Expenses will be included in Research and Development Expenses to the account of HMR.
- 4.3 RIGHT TO ENGAGE THIRD PARTIES. In the course of its business, Amylin regularly uses Third Parties to perform certain Research and Development activities. Amylin will continue to do so during the course of this Agreement, and expenses relating to such Third Party Development will be included in Amylin's Research and Development Expenses.
- 4.4 RESEARCH AND DEVELOPMENT PLAN AND RESEARCH AND DEVELOPMENT BUDGET.
- (a) The Research and Development of each Collaboration Product shall be governed by a Research and Development Plan and a Research and Development Budget, which shall provide for Development in at least all Core Dossier Countries and, together with updates, shall be prepared by Amylin, after taking into consideration HMR's comments, for budget approval by the Steering Committee. The Parties shall agree upon and approve an Initial Research and Development Plan and Budget within sixty (60) days after the Effective Date. If the Parties are unable to agree on the Initial Research and Development Plan and Budget within such sixty (60) day period, then the Initial Research and Development Plan and Budget shall be referred to the Steering Committee for resolution by the Steering Committee.
- proposed overall program of Research and Development Plan shall describe the proposed overall program of Research and Development for the subject Collaboration Product in each applicable country, including preclinical studies, toxicology, formulation, process development, clinical studies and regulatory plans and other elements of obtaining Regulatory Approval in each applicable country. HMR shall provide such guidance as Amylin reasonably requests regarding local Drug Approval Application submission requirements. The Research and Development Plan shall include a summary of estimated Research and Development Expenses of the program expected during the Research and Development process through obtaining Regulatory Approval

for each proposed indication and route of delivery, and shall also include a detailed Research and Development Budget for all Research and Development activities proposed for the following twelve (12) months.

- Development Budget shall be updated annually by Amylin, after taking into account HMR's comments, and shall be submitted by October 1 of each calendar year to the Steering Committee for review and for Research and Development Budget approval. The Steering Committee shall provide comments on each such Budget approval. The Steering Committee shall provide comments on each such updated Research and Development Plan and Research and Development Budget within thirty (30) days following its receipt of such plan and budget. Within ninety (90) days following its receipt of such plan and budget, the Steering Committee shall either approve the Research and Development Budget submitted by the JDC or approve a modified Research and Development Budget prepared by the Steering Committee consistent with the objectives for the Collaboration Products and the aims of the collaboration contemplated by this Agreement. If the Steering Committee fails to approve any budget increase in the Research and Development Committee fails to approve any budget increase in the Research and Development Research and Development Plan, the Research and Development Budget and the Research and Development Plan shall remain at its previously approved level or previous unmodified form.
- 4.5 DEVELOPMENT EFFORTS. Each Party agrees to exert the efforts necessary and reasonable to execute and substantially carry out the Research and Development Plan within the Research and Development Budget and to cooperate with the other Party in carrying out the Research and Development Plan.
- Development Plan, Amylin shall be responsible for preparing and filing all filings with the regulatory authorities with respect to HMR Compounds in each country in the Profit Sharing Territory ("Regulatory Filings"), including, but not limited to, Drug Approval Applications, and seeking Regulatory Approvals for Collaboration Products in the Profit Sharing Territory, including preparation of Collaboration Products in the Profit Sharing Territory, including preparation of all reports necessary as part of a Drug Approval Application. All such Drug Approval Applications shall be filed jointly in the names of Amylin and HMR if Approval Applications shall be filed jointly in the names of Amylin and HMR if permitted by the regulatory agency. If a joint filing is not permitted, simultaneous filings of identical Drug Approval Applications, one in Amylin's name and one in HMR's name, shall be made ("Simultaneous Filings"). If neither of the preceding filing scenarios is permitted by a regulatory agency, the Drug Approval Application in such case shall be filed in the name of Amylin, and a copy of such Drug Approval Application shall be simultaneously provided to HMR together with written notice from the regulatory agency that neither joint together with written notice from the regulatory agency that neither joint filings nor Simultaneous Filings are permitted in such jurisdiction. Amylin shall be responsible for prosecuting all such Drug Approval Applications, including any such Drug Approval Applications filed in HMR's name. In the event a Drug Approval Application is filed in the name of a single Party, the other Party shall have the right of cross reference. The Parties shall consult and Regulatory Approvals. Upon receipt of

each Regulatory Approval, Amylin shall promptly transfer ownership of the corresponding Drug Approval Application and Regulatory Approval to HMR, provided HMR is the marketing Party in the country wherein Regulatory Approval is obtained, and shall promptly notify the appropriate regulatory agency of such transfer of ownership. Transfer of sole ownership shall occur earlier in time if necessary for negotiating pricing approvals pursuant to Section 5.11. In the event HMR's right to market any Collaboration Products under this Agreement event HMR's right to market any Collaboration Products under this Agreement terminates for any reason, HMR shall promptly transfer any and all of its ownership rights in the corresponding Drug Approval Application and Regulatory ownership rights in the corresponding Drug Approval Applications being Approvals to Amylin. In connection with all Drug Approval Applications being Approvated by Amylin hereunder, each Party agrees to provide the other Party with a copy (which may be wholly or partly in electronic form) of all fillings to regulatory agencies it makes on its behalf or on the other Party's behalf hereunder.

## 4.7 COSTS OF DEVELOPMENT.

- (a) All Research and Development Expenses of Collaboration Products under this Agreement shall be shared equally by the Parties.
- (b) HMR shall advance to Amylin, on the next to last.

  business day of each calendar quarter ending subsequent to the Effective Date,
  HMR's share of the budgeted Research and Development Expenses for the following
  quarter, based on the most recently approved Research and Development Budget.
- Development Expenses incurred by it in accordance with procedures to be agreed upon between the Parties. Subsequent to the Effective Date, Amylin and HMR shall report quarterly to each other on their Research and Development Expenses, with such reports to be submitted within twenty (20) days after the end of each calendar quarter and within thirty (30) days after the end of each calendar. The Parties shall seek to resolve any questions related to such accounting reports within sixty (60) days following receipt of such reports. If the Parties are unable to resolve any disputes regarding such accounting reports within such sixty (60) day period, such dispute will be referred to the Steering Committee for resolution pursuant to Section 3.4.
- (d) Any differences between the actual expenses incurred in a particular quarter and the budgeted expenses for such quarter upon which HMR's advance payment was made to Amylin shall be applied as an adjustment to the following quarter's payment due from HMR as follows:
  - (i) in the event actual expenses exceed budgeted expenses for a particular quarter, the amount of the difference shall be added to the amount due under HMR's next quarterly advance payment of budgeted Research and Development Expenses; and

- (ii) in the event actual expenses are less the budgeted expenses for a particular quarter, the amount of the diffeshall be subtracted from the amount due under HMR's next quarterly advance payment of budgeted Research and Development Expenses.
- (e) Notwithstanding the provisions of Section 4.7 (d), Amylin shall be solely responsible for any Research and Development Expenses exceeding, during a calendar year, one hundred five percent (105%) of the most recently approved Research and Development Budget for such year, and such overage, if any, shall be paid by Amylin to HMR within ten (10) days after the amount of such overage is determined, unless the overage is (i) the result of actions of such overage is determined, unless the expense), (ii) is approved by the Steering Committee or (iii) is the result of the requirements of regulatory authorities (in which cases the Parties shall share the expense equally). If actual costs and expenses for a given calendar year are less than or equal to 5% below budgeted costs and expenses for such year, then such amount will be carried forward into the next calendar year's budget. If actual costs and expenses for such year, then the Parties will mutually determine the portion of such amount in year, then the Parties will mutually determine the portion of such amount in excess of 5%, if any, that will be carried forward into the next calendar year's budget.
- 4.8 ELECTION BY A PARTY TO TERMINATE ITS PARTICIPATION IN THE DEVELOPMENT OF A COLLABORATION COMPOUND OR COLLABORATION PRODUCT FOR SAFETY OR TOLERABILITY REASONS.
- (a) In the event material issues regarding the Safety or Tolerability of a Collaboration Compound or Collaboration Product arise during the Development thereof, each Party shall have the right to terminate its participation in worldwide Development of such Collaboration Compound or Collaboration Product as provided below in Section 4.8 (b). A Party's decision to terminate its participation in Development of a particular Collaboration Compound or Collaboration Product shall be in its own discretion.
- (b) In the event one Party's participation in Development of a Collaboration Compound or Collaboration Product is terminated pursuant to this Section 4.8, then (i) such termination shall be effective thirty (30) days following the date of receipt of written notice by the non-terminating Party of the terminating Party's decision to terminate its participation, (ii) the terminating Party shall not be responsible for any Research and Development Expenses related to such Collaboration Compound or Collaboration Product after the date the termination is effective, (iii) the non-terminating Party may thereafter proceed independently with research, development and/or commercialization of the

compound or product in question as an Independent Product, either alone or in conjunction with Third Parties and (iv) the terminating Party shall, to the extent not previously granted under this Agreement or the License Agreement, (1) grant exclusive licenses (even as to the granting Party) under Amylin Patents or HMR Patents, as applicable, Joint Patents and know-how Controlled by such Party to the non-terminating Party for continued research, development and/or commercialization of the compound or product in question, (2) shall transfer any related Drug Approval Applications or Regulatory Approvals (including transfer of all relevant data and information relevant to Regulatory Authorities) to the non-terminating party, and (3) otherwise cooperate to enable the non-terminating Party under this Section 4.8 to continue said research, development and/or commercialization. In the event a termination of participation in Development of a Collaboration Compound or Collaboration Product occurs under this Section 4.8, (i) ten (10) years from the first commercial sale of such Independent Product in such country and (ii) the expiration of the last to expire of any issued patents covering such Independent Product in any relevant country; provided, however, that such Collaboration Compound or Collaboration Product may not be so independently developed or commercialized for any indication for which a Collaboration Product or Royalty-Bearing Product is being (i) Developed, (ii) Commercialized, or (iii) Developed and/or Commercialized, in all cases in at least two Major Market Countries at the time the termination under this Section 4.8(b) became effective for any Collaboration Compound or Collaboration Product. Royalty payments, if any, due under this Section 4.8(b) shall be paid in accordance with the provisions of Section 6.6.

- (c) The rights set forth in this Section 4.8 to terminate participation in Development of a particular Collaboration Compound or Collaboration Product for Safety or Tolerability reasons shall be separate from, and in addition to, the right to terminate this Agreement pursuant to Article

### ARTICLE V

## COMMERCIALIZATION

## 5.1 RESPONSIBILITIES OF THE JCC.

(a) The purpose of the JCC shall be to (i) oversee the Commercialization of Collaboration Products in the Profit-Sharing Territory, including the planning, annual budgeting, commercial manufacturing, marketing, sales and distribution and sublicensing of Collaboration

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Products, (ii) monitor, review and comment on costs incurred by the Parties in the commercial manufacture, marketing, sale and distribution of Collaboration Products, (iii) review and comment on the Commercialization Plans and Launch Plans and the selection of trademarks for Collaboration Products, (iv) receive and provide to the Parties all sales, pricing, and financial reports pertaining to Pre-Marketing and Commercialization of Collaboration Products, (v) recommend to the JDC the principal indications and delivery routes for all Collaboration Products, (vi) review and comment on HMR's pricing recommendations prior to submission of such to the Steering Committee pursuant to Section 5.11, (vii) review and comment on HMR's manufacturing recommendations prior to submission of such to the Steering Committee pursuant to Section 8.1, and (viii) facilitate the flow of Information with respect to the Commercialization of each Collaboration Product. Subject to the provisions of Section 5.1(b) regarding Excepted Commercialization Matters, HMR shall make the final decision on all matters relating to the Commercialization of any Collaboration Product, including all day to day decisions.

- (b) Decisions of the JCC shall require a majority vote of all members of the JCC. If the JCC is unable to obtain a majority affirmative vote as to any matter involving Commercialization, the decision of HMR will be final and determinative, so long as such decision does not contradict or modify the terms of this Agreement, except with regard to (i) a decision to recall a Collaboration Product, which shall be decided pursuant to Section 5.12, (ii) a dispute related to pricing of a Collaboration Product, which shall be referred to the executive officers of the Parties pursuant to Section 5.11, (iii) a dispute related to manufacturing of a Collaboration Product, which shall be referred to the executive officers of the Parties pursuant to Article XII of the License Agreement, or (iv) a Third Party promotion support arrangement for a Collaboration Product which also involves the promotion support of a non-Collaboration Product(s), which must be approved by the Steering Committee pursuant to Section 5.3(a) (collectively, the "Excepted Commercialization Matters").
- (c) The JCC will have the power to form subcommittees with appropriate representation from Amylin, HMR and appropriate Third Parties; provided, however, that any Third Party members of such a subcommittee must be approved by Amylin.
- (d) During clinical trials for any Collaboration Products, the JCC shall coordinate with the JDC to assure a smooth transition from Development to Commercialization.
- (e) The JCC shall not be involved with the commercialization of (i) Independent Products or (ii) Royalty-Bearing Products in any Royalty-Bearing Countries.

## 5.2 HMR AS LEAD MARKETING PARTY.

(a) HMR will be the lead marketing party with respect to all Collaboration Products and, as a result, shall be obligated and responsible for carrying out Commercialization pursuant to each Commercialization Plan. HMR will assemble its product team and commence

reporting to the JCC within sixty (60) days following the Effective Date. Amylin agrees to carry out the Commercialization tasks referred to in Section 5.2(b) and such other Commercialization tasks as are reasonably requested by HMR and accepted by Amylin.

- (b) It is recognized that the Parties bring particular strengths to the ongoing Commercialization of Collaboration Products. HMR will assign to Amylin a role in Commercialization functions and activities, both during Development and following Collaboration Product launch, as follows:
  - (i) it is anticipated by the Parties that from the Effective Date throughout the marketing of Collaboration Products, Amylin will provide members for the HMR product teams, participating in the development of all strategies and performing activities relating to the following marketing functions as part of the Commercialization Plans and Launch Plans in the Core Dossier Countries:

Medical Symposia
 Scientific Exhibits
 Opinion Leader Program Development
 Medical Education Program Development;

- (ii) furthermore, in preparation for, but at least twelve (12) months prior to, product launch of the first Collaboration Product hereunder in the first Core Dossier Country, Amylin will provide a small (not to exceed one hundred (100) persons) dedicated field force of experienced, scientifically competent "Medical Liaison Officers"; and
- (iii) Amylin's activities will be performed in accordance with each approved Commercialization Plan and Commercialization Budget and each approved Launch Plan and Launch Budget. All other marketing activities that have not been assigned to Amylin will be the responsibility of HMR, unless determined otherwise by the JCC

## 5.3 RIGHT TO ENGAGE THIRD PARTIES.

(a) If HMR determines that it needs promotion support in the Profit Sharing Territory and Amylin does not provide it, or HMR determines Amylin is not reasonably capable of providing it, then HMR may contract for additional promotion support from a Third Party. In such event, the Parties will consult prior to the engagement of a Third Party. The costs of engaging such Third Party will be a Royalty Expense (as defined in Exhibit A). Any other use of a Third Party, such as the sublicensing of a Third Party with respect to co-marketing and/or co-promotion in the Profit Sharing Territory, must be approved by the Steering Committee as described in Section 3.4, except to the extent such arrangements either directly or indirectly also

involve the marketing, promotion, co-marketing and/or co-promotion of non-Collaboration Products. To the extent any non-cash consideration is conveyed to either Party as part of any arrangement under this Section 5.3, the other Party shall be made whole.

- (b) In the event that HMR decides not to market a Collaboration Product in a country, the Parties will consider whether it is desirable to license a Third Party to market in such country, and only if both Parties so agree, the Parties, through HMR with full participation by Amylin, shall attempt to license such rights to a Third Party. Royalties received under this provision, if any, shall be included in Net Sublicense Revenues.
- 5.4 COMMERCIALIZATION EFFORTS. Each Party agrees to exert the efforts necessary and reasonable to execute and substantially carry out the Commercialization Plans and Launch Plans within the Commercialization Budgets and Launch Budgets and to cooperate with each other in carrying out the Commercialization Plans. In addition, with regard to the determination of all pricing, sampling and discount strategies for Collaboration Products, HMR shall use a similar and no less rigorous approach as that used by it in determining such strategies for its own pharmaceutical products of comparable market potential.

## 5.5 COMMERCIALIZATION PLAN AND COMMERCIALIZATION BUDGET.

- HMR shall develop a commercialization plan (the "Commercialization Plan") for each Collaboration Product, which shall include but not be limited to (i) global demographics and market dynamics, Major Market Country market strategies, estimated country launch dates, a worldwide sales and expense forecast (including at least three (3) years of estimated sales and expenses, manufacturing plans and expected product profile based upon the Research and Development Plan, (ii) a market plan (including pricing strategies pertaining to discounts, samples and Nominal Price sales) for the United States, which will serve as a strategic reference for other market plans for countries such as Germany, the United Kingdom, France and Japan (it being understood that such market plans will evolve over time and shall be similar to existing market plans developed at such time by HMR for pharmaceutical products with comparable market potential), and (iii) a commercialization budget ("Commercialization Budget") for each Collaboration Product for all applicable countries so determined by HMR (but at a minimum, the countries covered by the then current Research and Development Plan), including the Third Parties to be utilized and the arrangements with them that have been or are proposed to be agreed upon. Each Commercialization Budget shall include a budget of the expenses expected to be incurred in connection with performing the Commercialization Plan, including Pre-Marketing Expenses and Allowable Expenses in each applicable country.
- (b) The first Commercialization Plan shall be in the form of an initial outline and the first Commercialization Budget shall be in the form of an estimated budget. The JCC shall submit such outline of the first Commercialization Plan and such estimated Commercialization Budget to the Steering Committee for review and approval no later than six

(6) months following the Effective Date. It is understood that such outline and estimate may contain open issues and identify areas wherein more information is needed to complete the outline and estimated budget and to prepare a more complete Commercialization Plan and Commercialization Budget. Thereafter, by October 1 of each subsequent year, HMR, after taking into consideration Amylin's comments, will prepare a Commercialization Plan for submission by the JCC to the Steering Committee for review and a Commercialization Budget for submission by the JCC to the Steering Committee for review and approval. Notwithstanding anything in this Agreement to the contrary, the Commercialization Budget shall be approved by the Steering Committee no later than October 31 of each year. For any subsequent Collaboration Products, HMR shall prepare and the JCC shall submit an outline of an initial Commercialization Plan for each such Collaboration Product to the Steering Committee for review and an estimated Commercialization Budget for review and approval no later than six (6) months after any Collaboration Compound is designated a Collaboration Product. Each such Commercialization Plan and Commercialization Budget shall be updated and refined on each subsequent October 1 as described above in connection with Collaboration Compounds. Any significant change in any Commercialization Plan or Commercialization Budget during the course of the year will be communicated promptly to the JCC. In addition, HMR shall provide an update of each Commercialization Plan and Commercialization Budget to the JCC in a manner consistent (with respect to timing and content) with such updates as are reported internally by HMR on its existing pharmaceutical products of comparable market potential.

### 5.6 LAUNCH PLAN.

- (a) Each Commercialization Plan shall be updated, in advance of the launch of the applicable Collaboration Product in each country as the JCC determines is appropriate, to include a Launch Plan and Launch Budget for such launch and the twelve (12) month period following the launch date for such Collaboration Product. Each such Launch Plan and Launch Budget shall be developed by HMR, after taking into consideration Amylin's comments, and presented to the JCC for Launch Plan and Launch Budget review and approval and to the Steering Committee for Launch Budget approval, with HMR having the final decision at the JCC and Steering Committee as described in Section 3.4. The Steering Committee shall have sixty (60) days to review and approve such Launch Budget. If the Steering Committee is unable to approve the Launch Budget within such sixty (60) day period, the Launch Budget shall be submitted to the Parties' executives as provided for in Article XII of the License Agreement.
- (b) It is understood by the Parties that determining a date for Regulatory Approval and thus a launch date is difficult. The failure to accurately estimate the launch date shall not constitute a breach hereunder. As a result of this uncertainty, the JDC shall estimate for each country a realistic date for Regulatory Approval, and the JCC will use this estimated date to submit its Launch Plan and Launch Budget at least twelve (12) months prior to the estimated Regulatory Approval date, to the Steering Committee. By October 1 of each calendar year thereafter, if not yet executed, each Launch Plan and Launch Budget for each Collaboration

Product shall be updated by HMR and the updated Launch Budget shall be s by the JCC for approval by the Steering Committee.

- (c) Each Launch Plan shall include (i) updated marker sales forecasts in units and estimated revenues of Collaboration Product estimated resource requirements and (iii) such other matters deemed approby HMR.
- (d) Each Launch Budget shall include a breakdown of individual Allowable Expense items expected to be incurred in connection with performing the applicable Launch Plan. It is understood that there will not necessarily be a separate Launch Plan and Launch Budget for each country in which a Collaboration Product launch is planned, but that estimated launch dates, Launch Budgets and Launch Plans for each country in which a launch is planned may be incorporated into one or more comprehensive Launch Plans and Launch Budgets.
  - 5.7 ELECTION BY AMYLIN OF ROYALTY-BEARING COUNTRIES.
- (b) Subject to Sections 7.3, 11.2 and 11.3, the Commercialization of Royalty- Bearing Products shall be conducted independently by HMR.
- 5.8 ADVERTISING AND EDUCATION. HMR, after consultation with the JCC, will assign to the Parties, their Affiliates or any Third Party the preparation of advertising and education materials. Such materials shall be subject to prior review and comment by Amylin and HMR, which review and comment by Amylin and HMR shall be completed within thirty (30) days after receipt of such materials by Amylin and HMR. With respect to written and visual promotional or educational materials, to the extent such materials identify or otherwise make reference to either of the Parties, Amylin and HMR shall both be presented and described with equal prominence, as permitted by the applicable laws and regulations of each country in which such materials are to be presented. All product labeling, documentary information, promotional

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material and oral presentations (where practical) regarding the detailing and promoting of Collaboration Products shall display the names and logos of Amylin and HMR with equal prominence. All advertising and education and training materials for use in a country must also be approved in advance by the Party holding the relevant Drug Approval Application or responsible for the Regulatory Approval for such country, as necessary to ensure such Party's compliance with all applicable Regulatory Approvals. Such approval or disapproval shall be given by the Party within thirty (30) days after receipt of such advertising and education and training materials.

- Pre-Marketing Expenses; provided, however, that HMR will fund all Pre-Marketing Expenses for the first Collaboration Product. Amylin's 50% share of such Pre-Marketing Expenses for the first Collaboration Product shall be reimbursed by Amylin to HMR from its share of Operating Profits as provided in Section 6.2(b). In this regard, a written accounting of Pre-Marketing Expenses incurred by Amylin within a Commercialization Plan and Budget shall be submitted by Amylin to HMR within twenty (20) days of the end of each calendar quarter and within thirty (30) days of the end of each calendar year in which such expenses were incurred. HMR will repay Amylin within thirty (30) days of its receipt of such written accounting. Notwithstanding anything in this Agreement to the contrary, in the event that greater than 50% of the voting stock or substantially all of the assets of Amylin are acquired by (i) an entity with a market capitalization equal to or in excess of \$2.5 billion in publicly traded stock or (ii) a privately held entity with annual sales in excess of \$1 billion, then HMR's obligation to fund all Pre-Marketing expenses for the first Collaboration Product pursuant to this Section 5.9 shall terminate and be of no further effect.
- 5.10 TRAINING PROGRAM. HMR will develop adequate training programs for personnel involved in the Commercialization of Collaboration Products and/or Royalty-Bearing Products. Amylin shall play an appropriate role, as determined by the JCC, in the preparation of such training materials and conduct of training; provided, however, that Amylin shall not be involved in the preparation of training materials or the conduct of training with respect to Royalty-Bearing Products in a Royalty-Bearing Country or HMR's Independent Products. HMR shall submit to Amylin for its review all training materials, which review shall be completed within thirty (30) days of receipt of such materials by Amylin. The Parties agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy. Training shall be carried out at a time which is determined by HMR, and which is prior to but reasonably near the date on which Regulatory Approval is expected. The costs of transporting, housing and maintaining personnel to be trained, and the preparation of materials, shall be deemed to be Pre-Marketing Expenses or Marketing Expenses, as the case may be.
- 5.11 PRICING, PRICING APPROVALS AND PRODUCT DISTRIBUTION. If Amylin does not agree with the recommended price proposed by HMR with respect to a Collaboration Product, it may, within ninety (90) days following receipt of such recommended price from HMR, prepare

its own analysis of the market potential and recommended price for such Collaboration Product and present such analysis and recommendation to Steering Committee. If the Steering Committee is unable to agree on the for such Collaboration Product within sixty (60) days after receipt of and, if applicable, Amylin pricing recommendations, whichever is late analyses and recommendations of both Parties will be referred to a jo executive review panel composed of the Chief Executive Officer of Amylin — HMR's Chief Operating Officer. If this joint executive review panel is unable to agree on a price after reviewing the submissions from Amylin and HMR within thirty (30) days following receipt of such recommendations, then HMR shall set the applicable prices, which shall be somewhere between the prices proposed by each Party. The above described mechanism shall be the sole method for resolving disputes as to price(s) and shall not be subject to dispute resolution pursuant to Article XII of the License Agreement. HMR shall obtain for Collaboration Products such pricing approvals as may be required by, and arrange for distribution of each Collaboration Product in, each applicable country of the Profit Sharing Territory.

- 5.12 PRODUCT RECALLS. As an exception to the general authority of HMR under this Article V, if HMR commences an internal product quality investigation, it shall promptly notify and consult with Amylin regarding such investigation. Further, if either Party believes that a recall of a Collaboration Product is necessary, such Party shall notify and consult with the other Party within two (2) working days of its determination, and both Parties shall cooperate to allow such recall to occur under the direction of the Steering Committee. In the event of a dispute about whether to recall a Collaboration Product, such recall shall occur.
- 5.13 TAX CONSIDERATION. Either Party may take advantage of tax considerations which benefit it and not the other Party. In the event that a Party takes advantage of a tax consideration which benefits it and not the other Party takes advantage of a tax consideration which benefits it and not the other Party, no compensation to the other Party is required unless such affects the other Party's Operating Profits or Losses negatively, in which case compensation shall be provided to the other Party to make it whole. To the extent such negative impact on one Party's Operating Profits or Losses results from the manufacture of a Collaboration Product, such impact shall be addressed in the manner described in Section 8.1.
- 5.14 DISCOUNTED SALES. It is possible that Collaboration Products could be included as part of a multiple product offering to customers by HMR, and, at times, discounts may be offered independently. In the event that any Collaboration Products are offered along with other HMR products, the effect of the potential discounts may not impact the Average Net Selling Price below \*\*\*\* of the Ex-Manufacturer Selling Price in any given country. In the event that planned or executed discounting activities related to any Collaboration Product (pursuant to which such Collaboration Product is sold by HMR in combination with one or more non-Collaboration Products in any given country) as measured on a quarterly basis will reduce the Average Net Selling Price below \*\*\*\* of the Ex-Manufacturer Selling Price in any given country, HMR shall present an analysis of such discounting forecasts and activities to the JCC for review and comment. Such analysis will include all appropriate information for such Collaboration Product
- \* CONFIDENTIAL TREATMENT REQUESTED

### 6.2 PAYMENT.

- Subject to Section 6.2(b), within twenty (20) days of (a) the end of each of the first three calendar quarters and within thirty (30) days of the end of the fourth calendar quarter of each year following the launch of each Collaboration Product in a country, Amylin shall report to HMR and the JCC as outlined in Exhibit B, its revenues and individual Allowable Expense items (with appropriate supporting information) involved in the computation of Operating Profits or Losses and recognized during such quarter with respect to each such Collaboration Product. Within ten (10) days after receipt of such report, HMR shall provide for each Collaboration Product one worldwide consolidated Financial Statement and individual Financial Statements for each country in the Profit Sharing Territory to the JCC, and the JCC shall promptly direct the remittance between the Parties of an Equalization Payment with respect to each Collaboration Product. The reports and Equalization Payments for the fourth quarter of the fiscal year may include reconciliations and year-end adjustments with respect to previous quarters. The payment required by this Section 6.2(a), together with interest accrued from the end of each calendar quarter (to be paid at the commercial paper rate for high grade unsecured notes sold through dealers, as quoted in the Wall Street Journal on the last day of each such quarter), shall be made in any event within thirty (30) days of the due date of the receipt of reports described in the first sentence of this Section 6.2(a).
- 6.3 TERM. The Parties shall share Operating Profits or Losses hereunder with respect to each Collaboration Product in each Profit Sharing Territory until each such Collaboration Product is permanently withdrawn from and is no longer being sold anywhere in the relevant Profit-Sharing Territory.

## 6.4 ROYALTY-BEARING PRODUCTS.

(a) HMR shall pay to Amylin the applicable running royalty, as set forth in Section 5.7(a), on Royalty-Bearing Sales for Royalty-Bearing Products, if any.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

- royalties to be paid to Amylin on Royalty-Bearing Sales for Royalty-Bearing Products shall be paid in accordance with the provisions of Section 6.6, on a country-by-country basis, from the date of the first commercial sale of each Royalty-Bearing Product in a particular country until the later of (i) ten (10) years from the first commercial sale in such country or (ii) the last to expire of any (1) Amylin Patents or (2) HMR Patents or Joint Patents, as applicable, which covers use or sale of the Royalty-Bearing Product in such country, subject to the following:

Notwithstanding anything in this Section 6.4 to the contrary, the aggregate reduction of royalties set forth in Subsections (i) and (ii) of this Section 6.4 (b) and in Section 9.4 of this Agreement shall not reduce the net royalty amount payable—under this Section 6.4 by more than

- (c) HMR may discontinue Commercialization of a Royalty-Bearing Product at any time in its sole discretion.
- 6.5 SALES BY SUBLICENSEES. In the event HMR grants licenses or sublicenses to others to make or sell Royalty-Bearing Products, or in the event either Party grants licences or sublicenses to others to make or sell Independent Products, such licenses or sublicenses shall include an obligation for the licensee or sublicensee to account for and report its Royalty-Bearing Sales of such Royalty-Bearing Products and/or Independent Products on the same basis as if such sales were Royalty-Bearing Sales by the Party, and such Party shall pay royalties to the other Party as if the Royalty-Bearing Sales of the sublicensee were Royalty-Bearing Sales of the Party granting the license or sublicense.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

- ROYALTY PAYMENTS AND REPORTS. A report summarizing the Royalty-Bearing Sales of any Royalty-Bearing Products and/or Independent Products during the relevant quarter shall be delivered to the receiving Party within twenty (20) days following the end of each calendar quarter and within thirty (30) days following the end of each calendar year for which royalties are due from the selling Party. Royalty payments under this Agreement shall be made to the receiving Party or its designee quarterly within thirty (30) days following the due date for the report as set forth in the first sentence of this Section 6.6.
- 6.7 TAXES. The Party receiving royalties shall pay any and all taxes levied on account of royalties it receives under this Agreement. If laws or regulations require that taxes be withheld, the Party paying royalties will (i) deduct those taxes from the remittable royalty, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of payment to the other Party within thirty (30) days following such payment.
- 6.8 BLOCKED CURRENCY. In each country where the local currency is blocked and cannot be removed from the country, at the election of the selling Party, royalties or the other Party's share of Operating Profits or Losses accrued in that country shall be paid to the appropriate Party in the country in local currency by deposit in a local bank designated by the receiving Party.
- 6.9 PAYMENTS TO OR REPORTS BY AFFILIATES. Any payment required under any provision of this Agreement to be made to either Party or any report required to be made by any Party shall be made to or by an Affiliate of that Party if designated by that Party as the appropriate recipient or reporting entity.
- 6.10 NO OVERLAPPING ROYALTIES. Notwithstanding any other provision of this Agreement to the contrary, in no event shall any royalty payment provided for under any Section of this Agreement be paid with respect to any sale of an Independent Product or Royalty-Bearing Product to the extent a royalty-payment has been paid pursuant to any other Section of this Agreement with respect to such sale; provided, however, that in the event of such overlapping royalty provisions, the highest royalty rate provided for such sale in this Agreement shall be the applicable royalty rate for such sale.

### ARTICLE VII

### LICENSES

- 7.1 LICENSES TO HMR TO CONDUCT RESEARCH AND DEVELOPMENT.
- (a) Subject to the terms of this Article VII, Amylin grants to HMR an exclusive (except as to Amylin) paid-up, worldwide license under the Amylin Patents, Amylin

Data and Amylin Know-how to conduct Research and Development with respect to Collaboration Products and Royalty-Bearing Products in accordance with the terms of this Agreement and an exclusive (even as to Amylin) paid-up, worldwide license to conduct Research and Development with respect to Independent Products in accordance with the terms of this Agreement.

- (b) A list of the Amylin Patents identified as of the Effective Date is attached hereto as Exhibit C. Amylin shall promptly notify HMR, and such Exhibit C shall be expanded from time to time, to reflect any changes to Amylin Patents, any Amylin Patents hereafter identified and/or to include any other Amylin Patents.
- 7.2 LICENSES TO HMR TO CONDUCT COMMERCIALIZATION. Subject to the terms of this Article VII, Amylin grants to HMR an exclusive (except as to Amylin) worldwide license under the Amylin Patents, Amylin Data and Amylin Know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Collaboration Products and Royalty-Bearing Products in accordance with the terms of this Agreement and an exclusive (even as to Amylin) worldwide license under the Amylin Patents, Amylin Data and Amylin know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Independent Products in accordance with the terms of this Agreement. Such licenses with respect to Royalty-Bearing Products and Independent Products shall be subject to royalty payments as provided in Sections 5.7 and 4.8, respectively.
- 7.3 LICENSE TO AMYLIN TO CONDUCT COMMERCIALIZATION. Subject to the terms of this Article VII, HMR grants to Amylin an exclusive (even as to HMR) worldwide license under the HMR Patents, HMR Data and HMR Know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Independent Products in accordance with the terms of this Agreement. Such license shall be subject to royalty payments as provided in Section 4.8.
- 7.4 SUBLICENSING. During the term of this Agreement, neither Party may grant sublicenses of Joint Patents or Patents owned or Controlled by the other Party except with the express prior written approval of the other Party; provided, however, that (i) either Party may proceed with distribution and sale of a Collaboration Product through its usual and customary distributors performing their usual and customary distribution activities for such Party in accordance with this Agreement without the other Party's prior written approval of any necessary sublicenses in connection therewith, and (ii) in the case of Royalty-Bearing Products or Independent Products, the Party having a license with respect to such Products shall have a right to sublicense under such license with respect to such Products without approval of the other Party.

## 7.5 THIRD PARTY TECHNOLOGY.

- (a) The licenses granted under Sections 7.1, 7.2 and 7.3 may include sublicenses of Third Party technology. Any royalty amounts payable to Third Parties in connection with sales of Products shall be considered a Royalty Expense (as defined in Exhibit A) with respect to the sale of Collaboration Products and in any event shall be offset against any royalty amount owed with respect to the sale of Royalty-Bearing Products and Independent Products, as provided under Section 6.4(b)(ii).
- (b) The licenses granted under Sections 7.1, 7.2 and 7.3, to the extent they include sublicenses of Third Party technology, shall be subject to the terms and conditions of the license agreement pursuant to which the sublicense is granted.
- becomes aware of technology of a Third Party that would be valuable to the Development or Commercialization of Collaboration Products, the JDC will determine whether such technology should be brought into the collaboration contemplated by this Agreement and the cost of acquiring such technology shall be borne equally by the Parties. In the event that such acquired technology results in the payment of Third Party royalties, such royalties shall be a Royalty Expense with respect to the sale of Collaboration Products, and offset against any royalty owed with respect to the sale of Royalty-Bearing Products and Independent Products, as provided under Section 6.4(b)(ii).

## ARTICLE VIII

## MANUFACTURE AND SUPPLY

- 8-1 MANUFACTURE AND SUPPLY DURING DEVELOPMENT. Amylin will be responsible for manufacture of Collaboration Products for use during the Development of Collaboration Products. Payments to Third Party manufacturers for such manufacture of Collaboration Products and related costs will be included in Research and Development Expenses for purposes of Article IV. As used in this Article VIII, "manufacture" shall mean manufacture of Collaboration Products in bulk form or finished form.
- 8.2 MANUFACTURE AND SUPPLY DURING COMMERCIALIZATION. HMR shall be responsible for arranging for the commercial manufacture of Collaboration Products in such a manner as to achieve and maintain a substantially competitive Cost of Goods Sold and to assure quality control and quality assurance as stringent as such quality control and quality assurance standards used by HMR in the manufacture of its other pharmaceutical products of comparable market potential, continuity and security of supply, compliance with cGMP, compliance with all applicable regulatory requirements, and other terms and conditions of supply which best serve the interests of the collaboration contemplated by this Agreement. Such manufacturer(s) may

include either or both of the Parties as well as Third Parties. To enable the transfer of manufacturing to Amylin in situations under this Agreement where HMR is obligated to do so, with respect to all contracts entered into by HMR with a Third Party relating to the manufacture of Collaboration Products, HMR shall use commercially reasonable efforts to include a provision permitting the assignment of such contract to Amylin on the same terms for at least three (3) years. In selecting one or more manufacturers, the goals set forth in the first sentence of this paragraph shall take precedence over the consideration of whether one Party or the other then has unused or excess manufacturing capacity. Any selection of manufacturers for Commercialization shall be subject to the rights of any Third Parties existing at the time such determination is made.

(b) To the extent the Steering Committee decides that HMR or Amylin, as the case may be, should manufacture such Collaboration Product and the "make versus buy" analysis described in Section 8.2(a) shows one or more of the alternative manufacturers with quality control and quality assurance standards and Manufacturing Attributes reasonably acceptable to both Parties to be less expensive, the Steering Committee shall determine whether HMR or Amylin, as the case may be, should increase the Equalization Payment due to the other Party or decrease the Equalization Payment due from the other Party, as the case may be, each quarter by half the amount of such difference to make the other Party whole.

- (c) To the extent HMR or Amylin, as the case may be, manufactures such Collaboration Product pursuant to this Section 8.2, then at least once every three (3) years, the Party performing the manufacturing shall present to the JCC a review and analysis of the manufacturing cost elements identified in Section 8.2(a) to determine if the then current manufacturing arrangements are substantially competitive with other manufacturing alternatives at such time. Following such review and analysis, no change will be made to the Equalization Payment adjustment as described in Section 8.2(b).
- 8.3 QUALITY CONTROL, QUALITY ASSURANCE, ETC. During the term of this Agreement, HMR shall have day to day responsibility for commercial manufacturing and formulation issues related to product safety and regulatory compliance. Amylin shall provide technical support reasonably required by HMR or Third Parties for such manufacture of Collaboration Products.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

of providing on-going post-launch technical support shall be an The cos: Expense under Post-Launch Product R & D Expenses (as defined in Allowat . Regardless of the parties selected to manufacture the Collaboration Exhibit each of the Parties shall have rights of inspection and audit as Product. or reasonable to enable it to comply with its internal quality control necessa y assurance and reporting obligations, including those imposed by and qua authorities. In addition, before a final commitment is made to any regulat Parties or to any Third Party regarding manufacturing plant decisions, Party c ies shall have the right to perform plant quality assurance audits. both Pa

- PROVISIONS FOR THE MANUFACTURE OF COLLABORATION PRODUCTS. If a manufacturing and supplying the Collaboration Products pursuant to Party i .2, such Party shall be entitled to recover as an Allowable Expense Section y's Cost of Goods Sold for Collaboration Products so supplied, upon the such Pa uch Collaboration Products according to its standard accounting is consistently applied within and across its pharmaceutical operating proced: matching revenues with costs of products sold for pharmaceutical units 1 with a comparable market potential. In the event a Party would obtain a product it from such manufacture of Collaboration Products in a particular tax ber ion, such tax benefit shall be treated as described in Section 5.13. jurisd:
- TECHNOLOGY TRANSFER IN EVENT OF TERMINATION BY HMR. In the event n termination by HMR of this Agreement, HMR is manufacturing in whole that, ' t one or more Collaboration Products or Royalty-Bearing Products under or in cle VIII, then HMR shall continue to provide for such manufacture of this A. aboration Products and Royalty-Bearing Products to the extent provided such C notice of such termination, from the time notice of such termination is prior until such time as Amylin is able to secure an equivalent alternative provid ring source, in the event that Amylin is unable to secure such an manufa ve source during the notice period. To this end, as of the effective altern such termination, all Third Party manufacturing contracts that are date o e shall be assigned to Amylin, and the cost charged to Amylin by HMR assign. of the internal manufacturing activities to be continued by HMR pursuant for an Section 8.5 for the production of Collaboration Products and to thi Bearing Products shall be the same as HMR's cost during the time that Royalt ement was in effect; provided, however, that HMR may receive a profit the Ag internal manufacturing activities relating to such Products at a rate of for it \*\*\*\* upon Amylin's request, HMR shall provide such technical assistance and Furthe licenses on a royalty free basis as may reasonably be requested to know-h such technology needed by Amylin to commence or continue manufacture of transf ation Products and Royalty-Bearing Products. Collab
- \* CONF ENTIAL TREATMENT REQUESTED

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Such technical assistance shall be provided at HMR's cost, which cost shall be reimbursed by Amylin within thirty (30) days after receipt of an invoice for such cost by Amylin.

### ARTICLE IX

# ENFORCEMENT OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

## 9.1 GENERAL ENFORCEMENT RIGHTS.

With respect to infringement of any of the Amylin Patents or any of the Joint Patents by a Third Party through the manufacture, import, use, sale or offer for sale of a product competitive with a Collaboration Product being Developed or Commercialized under this Agreement, except as provided in Section 9.5(a) ("Competitive Product Infringement"), Amylin shall have the right to institute, prosecute and control any action or proceeding with respect to such infringement (with HMR having the right to participate in such action and be represented if it so desires by counsel of its own selection) and, if necessary, HMR agrees to be joined as a party plaintiff and to give Amylin reasonable assistance and any needed authority to control, file and prosecute such action. Amylin's and, if any, HMR's costs related to patent enforcement (including internal costs and expenses specifically attributable to said patent enforcement) and related recoveries with respect to Competitive Product Infringement shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. With respect to infringement of any of the HMR Patents by a Third Party through Competitive Product Infringement, HMR shall have the right to institute, prosecute and control any action or proceeding with respect to such infringement (with Amylin having the right to participate in such action and be represented if it so desires by counsel of its own selection) and, if necessary, Amylin agrees to be joined as a party plaintiff and to give HMR reasonable assistance and any needed authority to control, file and prosecute such action. The Parties shall consult with each other regarding the institution, prosecution and control of any action or proceeding with respect to any infringement of any of the HMR Patents, other than Competitive Product Infringement. In the absence of agreement with respect to such infringement, each Party may proceed in such manner as the law permits. HMR's and, if any, Amylin's costs related to patent enforcement (including internal costs and expenses coedifically attributable to acid attack of the second sec expenses specifically attributable to said patent enforcement) and related recoveries with respect to Competitive Product Infringement shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. In this regard, if it is believed in good faith that any Amylin Patents, HMR Patents, or Joint Patents are infringed by a Third Party through the manufacture, import, use, sale or offer for sale of a product competitive with a Collaboration Product the Party first having knowledge of such infringement shall promptly notify the other Party in writing thereof, which notice shall set forth the facts of such infringement in reasonable detail. If Amylin or HMR, as the case may be, fails to institute and prosecute an action or proceeding to abate the infringement within a period of ninety (90) days after receiving written notice or otherwise having knowledge of the infringement, then the other

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Party shall have the right, but not the obligation, to bring and prosecute any such action and the Party which failed to bring such action agrees to be joined as a party plaintiff and to give the Party bringing such action reasonable assistance and all authority to control, file and prosecute the suit as may be necessary; provided, however, that the Party which failed to bring such action shall have the right to participate in such action and to be represented in any such action by counsel of its choice. The Parties' costs of patent enforcement (including internal costs and expenses specifically attributable to said patent enforcement) and related recoveries with respect to actions brought under this paragraph shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. Any recovery of damages and costs in such action referred to in this Section 9.1(a) shall be apportioned between the Parties as follows: (i) the Party bringing suit shall first recover from any such award an amount equal to the cost and expense incurred by such Party and (ii) the remainder, if any, shall be divided equally by the Parties.

- (b) No settlement or consent judgment or other voluntary final disposition of suit under this Section 9.1 may be entered into without the joint consent of Amylin and HMR.
- DEFENSE AND SETTLEMENT OF THIRD PARTY CLAIMS AGAINST COLLABORATION PRODUCTS. If a Third Party asserts that a patent or other right owned by it is infringed by the manufacture, import, use, sale or offer for sale of any Collaboration Product, the Party first obtaining knowledge of such a claim shall immediately provide the other Party notice of such claim and the related facts in reasonable detail. In such event, the Steering Committee shall determine how best to control the defense of any such claim. In the event the Parties cannot agree on the defense of any such claim, such defense shall be controlled by HMR; provided, however that Amylin shall have the right to participate in such defense and to be represented in any such action by counsel of its selection at its sole discretion. The entity (whether Amylin and HMR, or HMR only) that controls the defense of a given claim with respect to a Collaboration Product, shall also have the right to control settlement of such claim; provided further, however, that no settlement shall be entered into without the written consent of the other Party. If there is no agreement between the Parties as to any proposed settlement, then the dispute shall be decided by the Steering Committee and if the Steering Committee is unable to decide the dispute, the matter will be resolved pursuant to the dispute resolution provisions of Article XII of the License Agreement. If the dispute is not resolved pursuant to Article XII of the License Agreement, then the case may not be settled.
- 9.3 ALLOCATION OF EXPENSES. The expenses of patent defense, settlement and judgments pursuant to Section 9.2 with respect to Collaboration Products shall be a shared expense of the Parties, except as otherwise expressly provided for in Section 9.2. Such costs which are incurred after the designation of a Collaboration Product for Development but prior to Regulatory Approval shall be borne in the same manner as if such costs were Development Expenses. Such costs which are incurred following launch of the subject Collaboration Product in a Major Market Country shall be an Allowable Expense, reimbursed to the Party incurring such expense.

- 9.4 SETTLEMENT OF THIRD PARTY CLAIMS FOR ROYALTY-BEARING PRODUCTS AND INDEPENDENT PRODUCTS; ROYALTY REDUCTION.
- (a) If a Third Party asserts that a patent or other right owned by it is infringed by any Royalty-Bearing Product, and as a result of settlement procedures or litigation under this Section 9.4, HMR is required to pay the Third Party a royalty or make any payment of any kind for the right to sell a Royalty-Bearing Product in a particular country, the royalty rate for such Royalty-Bearing Product shall be adjusted as recited in Section 6.4(b).
- (b) If a Third Party asserts that a patent or other right owned by it is infringed by any Independent Product, and as a result of settlement procedures or litigation under this Section 9.4), either Party is required to pay the Third Party a royalty or make any payment of any kind for the right to sell an Independent Product in a particular country, the royalty rate for such Independent Product shall be adjusted as recited in Section 6.4(b).
- 9.5 INFRINGEMENT BY THIRD PARTIES WITH RESPECT TO ROYALTY-BEARING PRODUCTS OR INDEPENDENT PRODUCTS.
- If any Amylin Patent is infringed by a Third Party in (a) any country in connection with the manufacture, import, use, sale or offer for sale of a product competitive with one or more Royalty-Bearing Products or Independent Products being marketed by HMR in such country, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail. Amylin shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement of the Amylin Patent, by counsel of its own choice, and HMR shall have the right to participate in such action and to be represented by counsel of its own choice. If Amylin fails to bring an action or proceeding within a period of ninety (90) days after having knowledge of that infringement, HMR shall have the right to bring and control any such action by counsel of its own choice, and Amylin shall have the right to participate in such action and to the represented by counsel of its own choice. be represented by counsel of its own choice. If one Party brings any such action or proceeding, the second Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and authority to control, file and prosecute the suit as necessary. The costs and expenses of the Party bringing suit under this Section 9.5(a) (including the internal costs and expenses specifically attributable to said suit) shall be reimbursed first out of any \*\*\*\*\*\*\* to HMR if Amylin institutes and controls such suit. However, if HMR institutes and controls such suit, any damage recovery shall be treated as Royalty-Bearing Sales and Amylin shall receive a portion of such damages equal to the applicable royalty rate (expressed as a percentage) payable to Amylin on said Royalty-Bearing Sales and all remaining damages shall be distributed to HMR.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

- If any HMR Patent or Joint Patent is infringed by a (b) Third Party in any country in connection with the manufacture, import, use, sale or offer for sale of a product competitive with one or more Royalty-Bearing Products being marketed by HMR, or with one or more Independent Products being marketed by Amylin in such country, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail. HMR shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement of the HMR Patent or Joint Patent, by counsel of its own choice, and Amylin shall have the right to be represented in that action by counsel of its own choice. If HMR fails to bring an action or proceeding within a period of ninety (90) days after having knowledge of that infringement, Amylin shall have the right to bring and control any such action by counsel of its own choice, and HMR shall have the right to participate in such action and be represented by counsel of its own choice. If one Party brings any such action or proceeding, the second Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and all authority to file and prosecute the suit as may be necessary. The costs and expenses of the Party bringing suit under this Section 9.5(b) (including the internal costs and expenses specifically attributable to said suit) shall be reimbursed first out of any damages or other monetary awards any damage recovery shall be treated as Royalty-Bearing Sales and HMR shall receive a portion of such damages equal to the applicable royalty rate (expressed as a percentage) payable to HMR on said Royalty-Bearing Sales and all remaining damages shall be distributed to Amylin.
- (c) No settlement or consent judgment or other voluntary final disposition of a suit under this Section 9.5 may be entered into without the joint consent-of Amylin and HMR.
- (d) Notwithstanding the provisions of Section 9.1 and this Section 9.5, neither Party shall file and prosecute an action for infringement of a Patent for which the other Party has the primary responsibility to file and prosecute such action, and pursuant to which that other Party having primary responsibility has commenced and is prosecuting at least one such action for infringement of said Patent, without the agreement of that other Party.
- 9.6 COLLABORATION PATENT EXPENSES. Prior to the first commercial sale of a Collaboration Product, Collaboration Patent Expenses shall be borne equally by the Parties. Within thirty (30) days following the end of each calendar quarter, each Party shall deliver a report outlining its Collaboration Patent Expenses for such quarter. Within forty-five (45) days following the end of each such quarter, the Party incurring less than one-half of the aggregate combined total of such reported Collaboration Patent Expense during the quarter shall reimburse the other Party an amount sufficient to equalize each Party's one-half share of such combined

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

Collaboration Patent Expenses. Following the first commercial sale of a Collaboration Product, Collaboration Patent Expenses will be treated as an Allowable Expense.

9.7 ASSIGNMENT OF JOINT PATENTS. Neither Party may assign its rights under any Joint Patent except with the prior written consent of the other Party; provided, however, that either Party may assign such rights without consent to an Affiliate or other permitted assignee under this Agreement in connection with a merger or similar reorganization or the sale of all or substantially all of its assets, as provided in Section 15.1(b).

### 9.8 TRADEMARKS.

PRODUCT TRADEMARKS. The JCC shall oversee the selection, 9.8.1 prosecution of applications for, and maintenance of, trademarks in the applicable country for each Collaboration Product and shall designate which of the Parties shall be responsible for the related work. Under the supervision of the JCC, the Parties shall work together and seek to agree on the selection of trademarks for Collaboration Products for use in those countries where the subject trademarked product is to be marketed, whether as a Collaboration Product or as a Royalty-Bearing Product. In the event that the Parties cannot agree on a trademark for any Collaboration Product as a result of said joint selection efforts, HMR shall have the right to present three qualified trademarks that have been identified by the Parties to Amylin, and Amylin shall have the right to refuse any two such trademarks. The remaining trademark shall be the selected trademark for the subject Collaboration Product and shall be owned jointly by Amylin and HMR. To the extent expenses are incurred hereunder prior to the first commercial sale of the applicable Collaboration Product, such expense shall be treated as a Pre-Marketing Expense and thereafter, such expenses shall be treated as Allowable Expenses. Collaboration Products shall be sold under at least one trademark owned jointly by HMR and Amylin. All uses of a jointly owned trademark(s) to identify a Collaboration Product, whether sold as a Collaboration Product or as a Royalty-Bearing Product, shall comply with all applicable laws and regulations, and those laws and regulations particularly applying to the proper use and designation of trademarks in the countries of the Profit Sharing Territory or in Royalty-Bearing Countries, as applicable. Jointly owned trademark(s) shall be used only pursuant to the terms of this Agreement to identify Collaboration Products or Royalty-Bearing Products, and shall not be used by either Party to identify any other products. All jointly-owned trademarks shall be registered by HMR in the names of Amylin and HMR as joint owners in all countries where said marks will be used.

9.8.2 INFRINGEMENT OF TRADEMARKS. HMR shall take all reasonable and appropriate steps to protect, defend and maintain each jointly owned trademark for use by the Parties in connection with a Collaboration Product or Royalty-Bearing Product, and all registrations therefor, and each Party shall notify the other Party promptly upon learning of any actual, alleged or threatened infringement of a jointly-owned trademark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offenses. Upon learning of such offenses HMR shall have the right but not the obligation to, in consultation with Amylin,

institute and control an appropriate action or proceeding to halt the offense. Amylin shall have the right to participate fully in all such actions or proceedings.

9.8.3 COSTS OF DEFENSE. All of the unrecovered costs, expenses and legal fees (including internal costs, expenses and legal fees) in bringing, maintaining and prosecuting any action to maintain, protect or defend a trademark (or registration therefor) covering (i) a Collaboration Product shall be an Allowable Expense in the applicable country or (ii) a Royalty-Bearing Product shall be a deduction from Royalty-Bearing Sales, and any recovery shall be Net Sublicense Revenue in that country.

# ARTICLE X

# REPRESENTATIONS AND WARRANTIES

Each of the Parties hereby represents and warrants to the other Party as follows:

- (a) This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a any agreement, it is bound, nor violate any law or regulation of any court, Party or by which it is bound, nor violate any law or regulation over it.
- (b) Such Party has not, and during the term of the Agreement will not, grant any right to any Third Party relating to its respective Patents and know-how in the Field which would conflict with the rights granted to the other Party hereunder.

# ARTICLE XI

# INFORMATION AND REPORTS

COMMERCIALIZATION. HMR and Amylin will disclose and make available to each other all preclinical, clinical, regulatory, commercial marketing, promotion, pricing, sales and other Information, including copies of all preclinical and clinical reports, known by HMR or Amylin directly concerning Collaboration Compounds or Collaboration Products at any time during the term of this Agreement. All significant Information will be disclosed to the other Party promptly after it is learned or its significance is appreciated. Each Party shall own and maintain its own database of clinical trial data accumulated from all clinical trials of Collaboration Products for which it was responsible and of adverse drug event information for all Collaboration Products. At the option of the requesting information for all Collaboration Products. At the option of the requesting information Party, such data shall be provided in a computer readable format by the providing Party, to the extent available, which shall also assist in the transfer and validation of such data to the receiving Party. Without limitation of the foregoing, each Party shall supply to

the other the Information required by the other Party and requested by it (either as a routine practice or as a specific request) for purposes of compliance with regulatory requirements.

- 11.2 COMPLAINTS. Each Party shall maintain a record of all complaints it receives with respect to any Collaboration Product or Royalty-Bearing Product in accordance with its own established record keeping procedures for pharmaceutical products of comparable market potential. Each Party shall notify the other of any such complaint received by it in sufficient detail and within five (5) business days after receipt, and in any event in sufficient time to allow the responsible Party to comply with any and all regulatory requirements imposed upon it in any country.
- of a Drug Approval Application may be required to submit information and file reports to various governmental agencies on (i) Collaboration Products and Royalty-Bearing Products under clinical investigation, (ii) Collaboration Products and Royalty-Bearing Products proposed for marketing or (iii) marketed Collaboration Products and Royalty-Bearing Products. Information must be Collaboration Products and Royalty-Bearing Products. Information must be submitted at the time of initial filing for investigational use in humans and at the time of a request for market approval of a new Collaboration Product and Royalty-Bearing Product. In addition, supplemental information must be provided on Collaboration Products and Royalty-Bearing Products at periodic intervals and adverse drug experiences must be reported at more frequent intervals depending on the severity of the experience. Consequently, each Party agrees to:
- (a) provide to the other Party for initial and/or periodic submission to government agencies significant information on the Collaboration Product and Royalty-Bearing Product from preclinical laboratory, animal toxicology and pharmacology studies, as well as adverse drug experience reports from clinical trials and commercial experiences with the Collaboration Product and Royalty-Bearing Product;
- (b) in connection with investigational Collaboration

  Products and Royalty-Bearing Products, report to the other Party within

  twenty-four (24) days of the initial receipt of a report of any unexpected or

  serious experience with the drug, if required for either Party to comply with

  regulatory requirements; and
- (c) in connection with marketed Collaboration Products and Royalty-Bearing Products, report to the other Party within five (5) working days of the initial receipt of a report of any adverse experience with the drug that is serious and unexpected or sooner if required for either Party to comply with regulatory requirements. "Serious" adverse experience means any experience that suggests a significant hazard, contraindication, side effect or precaution, or any experience that is fatal or life threatening, is permanently disabling, requires or prolongs inpatient hospitalization, or is a congenital anomaly, cancer or overdose. "Unexpected" adverse experience means an adverse experience not identified in nature, specificity, severity or

frequency in the current investigator brochure or the U.S. labeling for the drug. Each Party also agrees that if it contracts with a Third Party for research to be performed by such Third Party on a Product, that Party agrees to require such Third Party to report to the contracting Party the information set forth in subsections (a), (b), and (c) of this Section 11.3

complete and accurate records which are relevant to revenues, costs, expenses and payments under this Agreement, and such records shall be open during reasonable business hours for a period of five (5) years from creation of individual records for examination at the other Party's expense and not more often than once each year by a certified public accountant selected by the other Party for the sole purpose of verifying for the inspecting Party the correctness of calculations and classifications of such revenues, costs, expenses or payments made under this Agreement. In the absence of material discrepancies (in excess of 5%) in any request for reimbursement resulting from such audit, the accounting expense shall be paid by the Party requesting the audit. If material discrepancies do result, the audited Party shall bear the accounting expense. Any records or accounting information received from the other Party shall be confidential information.

# ARTICLE XII

# TERM AND TERMINATION

12.1 TERM. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the date on which the Parties are no longer developing, marketing or selling in any country (i) a Royalty-Bearing Product or an Independent Product for which, in either case, royalties are or may be owed by one Party to the other Party, or (ii) a Collaboration Product.

# 12.2 TERMINATION FOR MATERIAL BREACH.

- (a) Subject to the provisions of this Section 12.2, if either Party (the "Breaching Party?) shall have committed a Material Breach (as defined below) and such Material Breach shall remain uncured and shall be continuing for a period of ninety (90) days following receipt of written notice thereof by the other Party (the "Non-Breaching Party"), then, in addition to any and all other rights and remedies that may be available, the Non-Breaching Party and la have the right to terminate this Agreement effective upon the expiration of such ninety (90) day period. Any such written notice of alleged Material Breach by the Non-Breaching Party shall include a reasonably detailed description of all relevant facts and circumstances demonstrating, supporting and/or relating to each such alleged Material Breach by the Breaching Party.
- (b) If the Breaching Party, upon written notice delivered to the Non-Breaching Party prior to the expiration of such ninety (90) day period, shall assert in good faith that any

such alleged Material Breach described in the Non-Breaching Party's notice, whether in payment of moneys or otherwise, was not a Material Breach, or was excused by reason of material failure of performance by the other Party or Third Parties or by reason of Force Majeure (as defined in Section 15.4), or shall otherwise in good faith dispute such alleged Material Breach, then the Parties shall continue to perform under this Agreement, subject to all of its terms and conditions, and the matter shall be resolved pursuant to the dispute resolution provisions of Article XII of the License Agreement. In such event, the Non-Breaching Party shall not be entitled to terminate this Agreement pursuant to this Section 12.2 unless and until (i) it shall be determined pursuant to the dispute resolution provisions of Article XII of the License Agreement that the Breaching Party has committed a Material Breach and (ii) such Material Breach has not been cured prior to such determination. To the extent that it is determined pursuant to a final and non-appealable decision under the dispute resolution provisions of Article XII of the License Agreement that the Breaching Party did commit a Material Breach and failed to cure the same within the period provided for in clause (ii) of this Section 12.2(b), then the Non-Breaching Party may immediately terminate this Agreement and, in addition to all damages determined pursuant to the dispute resolution provisions of Article XII of the License Agreement to be due and owing from the Breaching Party to the Non-Breaching Party under this Agreement, the Breaching Party shall be liable for the Non-Breaching Party's reasonable attorney's fees incurred in connection with resolving such matter.

- (c) If the Non-Breaching Party terminates this Agreement pursuant to the provisions of Sections 12.2(a) and (b), then the following provisions shall apply:
  - extent not already granted in this Agreement or the License Agreement, an exclusive (even as to the Breaching Party but subject to rights of Third Parties that are not Affiliates of the Breaching Party that pre-existed or accrued prior to such termination) worldwide right and license, with the right to grant sublicenses, to all HMR Patents or Amylin Patents, as applicable, of the Breaching Party and all of the Breaching Party's interest in jointly owned trademarks pursuant to Breaching Party's interest in jointly owned trademarks pursuant to Section 9.8.1, to make, have made, import, use, sell, offer for sale and have sold Collaboration Products, Royalty-Bearing Products and Independent Products, subject to the royalty obligations set forth below in Section 12.2(c)(ii), and shall have the exclusive right (but not the obligation) to enforce the Patents against Competitive Product Infringement and the exclusive right (but not the obligation) to enforce the trademark rights against infringers;

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

(iii) the provisions of Sections 6.4(b) and 6.5 through 6.10 shall apply with respect to royalties payable under this Section 12.2.

- (d) In the event of termination of this Agreement pursuant to this Section 12.2, the Breaching Party shall use its best efforts to cause the transfer of all INDs, Drug Approval Applications and Regulatory Approvals related to Collaboration Compounds, Collaboration Products, Royalty-Bearing related to Independent Products to the Non-Breaching Party, and take such products and Independent Products to the Non-Breaching Party, as assignments and documents as other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the Non-Breaching Party.

Further, upon Amylin's request, HMR shall provide such technical assistance and know-how licenses on a royalty free basis as may reasonably be requested to transfer such technology as is needed by Amylin to commence or continue commercial manufacture of Collaboration Products and Royalty-Bearing Products. Such technical assistance shall be provided at HMR's direct cost, which cost such technical assistance shall be provided at HMR's direct cost, which cost shall be reimbursed within thirty (30) days upon receipt of an invoice from HMR shall be reimbursed within thirty (30) days upon receipt of an invoice from HMR shall or its designee. In the event that any technology needed by Amylin to commence or continue commercial manufacture of Collaboration Products and Royalty-Bearing Products is covered by one or more HMR Patents, Amylin shall receive a fully paid-up, royalty-free, non-exclusive worldwide license to practice any and all such HMR Patents for the purposes contemplated in this Section 12.2(e) together with the right to grant sublicenses.

(f) Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation.

- shall mean the breach or failure to perform, in a material respect, a Party's material obligations under this Agreement. Without limiting the foregoing and by way of example only, the term "Material Breach" shall be deemed to include the failure of any Party in a material respect to meet such Party's payment or non-compete obligations. In no event shall a failure to gain Regulatory Approval for a Collaboration Product or to meet timelines or budgets specified in any Research and Development Plan, Research and Development Budget, Commercialization Plan, Commercialization Budget, Launch Plan or Launch Budget, in and of itself, be deemed to constitute a Material Breach, unless such failure is a result of acts and events or conduct that is otherwise a Material Breach.
- (h) The provisions of this Section 12.2 shall survive termination of this Agreement.
  - 12.3 TERMINATION WITHOUT A MATERIAL BREACH.
- (a) Each Party shall have a continuing right to terminate this Agreement for any reason, effective upon six (6) month advance written notice to the other Party, subject to this Section 12.3.
- (b) If either Party terminates pursuant to this Section 12.3, it shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement. In addition, as a result of such termination:
  - (i) all licenses and rights granted by the non-terminating Party to the terminating Party hereunder shall terminate;
    - Agreement or the License Agreement, the non-terminating Party shall receive an exclusive (even as to the terminating Party but subject to rights of Third Parties that are not Affiliates of the terminating Party that pre-existed or accrued prior to such termination) worldwide right and license, with the right to grant sublicenses, to all Patents of the terminating Party to import, use, sell, offer for sale and have sold Products for use in the Field, subject to the applicable royalty obligations set forth in Section 12.3(c) below, and shall have the right (but not the obligation) to enforce the Patents against Competitive (but not the obligation) applicable to the terminating Party's Patents in the event that the terminating Party does not or will not so enforce the Patents) and the exclusive right (but not the obligation) to enforce the trademark rights against infringers;

- all Confidential Information supplied by the non-terminating Party to the terminating Party shall be destroyed by the terminating Party; provided, however, the terminating Party may retain one copy of such information solely for legal archive purposes;
- if HMR is the terminating Party, HMR shall be (iv) obligated under Section 8.5 to the extent provided therein;
- the terminating Party shall cooperate in the transfer of all INDs, Drug Approval Applications and Regulatory Approvals related to Collaboration Compounds and the Products, to the non-terminating Party, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the non-terminating Party;
- the terminating Party shall not exploit or commercialize Joint Patents or jointly-owned trademarks in competition with the non-terminating Party's commercialization of the HMR Compounds.
- (c) The terminating Party under this Section 12.3 shall be entitled to a royalty of 6% of worldwide Royalty-Bearing Sales of products incorporating HMR Compounds, which royalty shall be paid in accordance with the provisions of Sections 6.5 through 6.10 of this Agreement.
- SURVIVING RIGHTS. The rights and obligations set forth in this Agreement shall extend beyond the term or termination of the Agreement only to the extent expressly provided for herein, or the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows:
- 12.4.1 In the event of expiration of this Agreement pursuant to Section 12.1, the following provisions shall survive: Article I (to the extent applicable to the interpretation of other surviving clauses), Sections 11.4, 12.4 and 12.5, and Articles XIII, XIV and XV.
- 12.4.2 In the event of termination of this Agreement pursuant to Section 12.2, the following provisions shall survive: Article I (to the extent applicable to the interpretation of other surviving clauses), Sections 4.8(b), 5.7(a), 6.4(b), 6.5 - 6.10, 7.4(a) and (b), 9.7, 11.2 - 11.4, 12.2, 12.4, 12.5, 13.1, 13.2 (solely with respect to acts or events occurring prior to such termination for which indemnity may be sought thereunder) and 13.3, and Articles XIV and XV.
- 12.4.3 In the event of termination of this Agreement pursuant to Section 12.3 the following provisions shall survive: Article I (to the extent applicable to the interpretation of

other surviving clauses), Sections 6.4(b), 6.5-6.10, 8.4, 9.7, 11.2 - 11.4, 12.3 - 12.5, 13.1, 13.2 (solely with respect to acts or events occurring prior to such termination for which indemnity may be sought thereunder) and 13.3, and Articles XIV and XV.

12.5 ACCRUED RIGHTS, SURVIVING OBLIGATIONS. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration, including damages arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of the Agreement.

# ARTICLE XIII

#### INDEMNIFICATION

- 13.1 INDEMNIFICATION FOR ROYALTY-BEARING PRODUCTS. With respect to Royalty-Bearing Products (determined on a country-by-country basis):
- (a) HMR hereby agrees to save, defend and hold Amylin and its agents and employees harmless from and against any and all suits, claims, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, "Losses"), resulting directly from the manufacture, use, handling, storage, sale or other disposition of Royalty-Bearing Products by HMR, its agents or sublicensees except to the extent such Losses result from the negligence or willful misconduct of Amylin, its agents or sublicenses.
- (b) In the event that Amylin is seeking indemnification under Section 13.1(a), it shall inform HMR of a claim for Losses as soon as reasonably practicable after it receives notice of such claim, shall permit HMR to assume direction and control of the defense of such claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of HMR) in the defense of the claim.
- 13.2 INDEMNIFICATION FOR COLLABORATION PRODUCTS. With respect to Collaboration Products:
- other Party and its agents and employees harmless from and against any and all Losses resulting directly or indirectly from the manufacture, use, handling, storage, sale or other disposition of Collaboration Products by the indemnifying Party, its agents or sublicensees, but only to the extent such Losses result from the negligence or willful misconduct of the indemnifying Party or its employees and agents and do not also result from the negligence or willful misconduct of the Party seeking indemnification. Any other Losses from claims resulting directly or indirectly from the

manufacture, use, handling, storage, sale or other disposition of Collaboration Products shall be included as an Allowable Expense of either Party at the time such claim is finally determined, whether by judgment, award, decree or settlement.

- (b) In the event that either Party receives notice of a claim with respect to a Collaboration Product, such Party shall inform the other Party as soon as reasonably practicable. The Parties shall confer how to respond to the claim and how to handle the claim in an efficient manner.
- 13.3 INDEMNIFICATION FOR INDEPENDENT PRODUCTS. With respect to Independent Products:
- (a) Each Party hereby agrees to save, defend and hold the other Party and its agents and employees harmless from and against any and all Losses resulting directly or indirectly from the manufacture, use, handling, storage, sale or other disposition of Independent Products by the indemnifying Party, its agents or sublicensees, but only to the extent such Losses result from the negligence or willful misconduct of the indemnifying Party or its employees and agents and do not also result from the negligence or willful misconduct of the Party seeking indemnification.
- (b) In the event that either Party receives notice of a claim with respect to an Independent Product, such Party shall inform the other Party as soon as reasonably practicable. The Parties shall confer how to respond to the claim and how to handle the claim in an efficient manner.

# ARTICLE XIV

#### DISPUTE RESOLUTION

The dispute resolution procedures of Article-XII of the License Agreement shall be applicable to any dispute, controversy or claim arising—out of or related to this Agreement, including, without limitation, the validity, construction, enforceability or performance hereof, and such procedures are incorporated herein by this reference.

# ARTICLE XV

# MISCELLANEOUS

#### 15.1 ASSIGNMENT.

(a) Either Party may assign any of its rights or obligations under this Agreement in any country to any Affiliates; provided, however, that such assignment shall not

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relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement.

- (b) Either Party may assign its rights or obligations under this Agreement or its ownership interest in Joint Patents to a non-Affiliate only as provided in Section 9.7, or in connection with a merger or similar reorganization or the sale of all or substantially all of its assets, or otherwise with the prior written consent of the other Party. This Agreement shall survive any such merger or reorganization of either Party with or into, or such sale of assets to, another party and no consent for such merger, reorganization or sale shall be required hereunder; provided, however, that in the event of such merger, reorganization or sale, no intellectual property rights of the acquiring corporation shall be included in the technology licensed hereunder.
- (c) This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.
- Either Party may assign its rights and obligations under this Agreement to an entity or entities (e.g., partnership or corporation) that are specifically formed for financial purposes and that finance Research, Development or Commercialization performed by such Party pursuant to this Agreement; provided, however, that such assignment shall not relieve the assigning Party of responsibility for performance of its obligations under this Agreement.
- 15.3 CONSENTS NOT UNREASONABLY WITHHELD. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.
- 15.4 FORCE MAJEURE. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.
- 15.5 INCORPORATION OF LICENSE AGREEMENT PROVISIONS; CONFLICTING PROVISIONS. Upon the Effective Date of this Agreement, the terms and conditions of the License Agreement are hereby incorporated by reference into this Agreement, except the provisions of the License Agreement that are superseded by the provisions of this Agreement, as set forth in Section 4.2 of

the License Agreement. Further, in the event that any term or provision of this Agreement is in conflict with a term or provision of the License Agreement, the term or provision of this Agreement shall prevail and shall be the operative term or provision.

- FURTHER ACTIONS. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- NO TRADEMARK RIGHTS. Except as otherwise provided herein or otherwise agreed to in writing by the Parties, no right, express or implied, is granted by this Agreement to use in any manner the name "Amylin," "HMR" or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.
- NOTICES. All notices hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, however, that notices of a change of address shall be effective only upon receipt thereof):

IF TO AMYLIN, ADDRESSED TO:

AMYLIN PHARMACEUTICALS, INC. 9373 Towne Centre Drive

San Diego, CA 92121

Attention: Office of the General Counsel

Telephone: (619) 552-2200 Telecopy: (619) 552-2212

IF TO HMR, ADDRESSED TO:

HOECHST MARION ROUSSEL, INC. Building B, Route 202-206

P.O. Box 6800

Bridgewater, New Jersey 08807-0800 Attention: Vice President, General Counsel,

Global Development Telephone: (908) 231-2000 Telecopy: (908) 231-2243

WAIVER. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights, or their failure to exercise any remedy, shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

- Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.
- 15.11 AMBIGUITIES. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 15.12 GOVERNING LAW. This Agreement shall be governed by and interpreted under the laws of the State of Delaware as applied to contracts entered into and performed entirely in Delaware by Delaware residents.
- 15.13 HEADINGS. The section and paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of said sections or paragraphs.
- 15.14 COUNTERPARTS. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- attached hereto and all documents delivered concurrently herewith, together with the License Agreement, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understanding between the Parties. There are no covenants, promises, agreements, warranties, between the Parties. There are no covenants, promises, agreements, warranties, the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

AMYLIN PHARMACEUTICALS, INC.

HOECHST MARION ROUSSEL, INC.

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By: /s/ Maurizio Denaro

By: /s/ Thomas Hofstaetter

Name: Maurizio Denaro Title: Executive Vice President, Chief Technical Officer Name: Thomas Hofstaetter Title: Senior Vice President, Business Development

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EXHIBIT A DETERMINATION OF CERTAIN ACCOUNTING TERMS

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#### EXHIBIT A

#### DETERMINATION OF CERTAIN ACCOUNTING TERMS

As a supplement to the definitions provided in Article 1 of this Agreement, the following accounting terms shall be further specified as follows. As used herein, the term "operating unit" shall mean the smallest operating unit in which an operating profit and loss statement is prepared for management accounting purposes in the Party's normal accounting procedures, consistently applied within and across its operating units.

#### COST OF GOODS SOLD

Cost of Goods Sold shall be equal to the Standard Cost of each unit of Collaboration Product sold plus Other Costs Not In Standard incurred during the period, subject to limitation as provided in Item C below.

- A. "STANDARD COST" shall include the following:
- 1) Material Cost shall mean the prices paid for raw material components and purchased Finished Goods which are purchased from outside vendors as well as any freight and duty where applicable.

Standard Material Cost includes the quantity of the components included in the Bill of Material times the purchase price and the waste factor (i.e., scrap percentage) included in the Bill of Materials. It also includes the normal costed Quality Assurance sample quantity which is included in the Bill of Materials. Raw Material prices shall be adjusted on an annual basis by Purchasing.

- 2) Direct Labor Costs shall mean the standard labor hours required for an operation according to the Standard Operating Procedures for such Collaboration Product multiplied by the Direct Labor Rate for work centers within the relevant manufacturing operating unit.
- 3) Overhead Costs shall mean other costs associated with the operating unit(s) manufacturing a Collaboration Product, provided, however, that such Overhead Costs shall exclude costs associated with unused manufacturing capacity and any administrative costs other than indirect labor of the Manufacturing Department specifically attributable to the Collaboration Product in question. Overhead Costs shall include expenses associated with Quality Assurance, Manufacturing and Engineering associated with the operating unit(s) manufacturing a Collaboration Product and shall include Depreciation and Property Taxes associated with the plant(s) manufacturing a Collaboration Product. These costs shall be allocated to each product line in such operating unit(s) or plant(s), whichever is applicable, based on specific criteria consistent with the standard operating procedures for each product and work center overhead rates of the Party performing the work determined and allocated in a manner consistently applied within and across its operating units (except as specifically provided in Item C below).

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# 4) Manufacturing Variances shall include:

(a) Purchase Price Variance shall mean the difference between the actual price paid the vendor versus the standard cost of such material, times the quantity received.

(b) Spending Variance shall mean the difference between actual department spending and the budgeted spending included in Standard Cost for the relevant manufacturing operating unit.

(c) Absorption volume variances shall mean the difference between actual product hours earned (or units produced) and the hours budgeted for the period (or projected production units used) in the development of Standard Costs times the standard labor and overhead content of those units.

(d) Material usage shall mean the difference between the actual quantity of component raw materials or work-in-process used in the production of work-in-process or finished goods versus the standard quantity included in the Bill of Materials times the standard cost of the component or work-in-process item.

. (e) Rework shall mean the additional standard cost of components or work-in-process items used to turn rejected inventory into usable inventory. No labor or overhead rate is assigned to rework orders, only the additional value of the inventory which is issued to the other. Additionally, no production/absorption credit is generated for rework orders since the credit was already generated the first time the production occurred.

# B. "OTHER COSTS NOT IN STANDARD" shall include:

- Scrap Expense shall mean the total standard cost of inventory which is physically destroyed or transferred to Rejected Inventory awaiting disposition. Total Cost means total inventory value which includes material, labor and overhead.
- 2) Inventory revaluation shall mean under FIFO Inventory Valuation the difference between the prior year's ending inventory at the prior year's standard cost plus or minus the year-end full absorption adjustment (see below) versus the same inventory at the new year's standard cost.
- 3) Full Absorption Adjustment -- Under FIFO Inventory Valuation the monthly adjustment which is made to adjust inventories from standard to actual cost. This involves reserving a period of the Manufacturing Variances, beginning with the current month and going back according to the number of month's supply of inventory on hand at the end of each month or annually as the case may be.
- 4) Excess and Obsolete Inventory Adjustments -- The P&L impact of adjusting the reserves for excess and obsolete inventory up and down based upon a quarterly analysis or

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annually as the case may be.

- 5) Loss on Returns Expense -- These are expenses (similar to sales returns and allowances) which are incurred as a result of issuing reasonable sales credits to customers at standard cost. This is the offset to reversing the standard cost of sales when the sale is negated.
- 6) No Charge Shipments -- Those expenses associated with shipping replacement product to customers at no charge. This is the offset to relieving inventory at standard cost when the product is shipped.
- C. EXCLUDED COSTS. Notwithstanding the foregoing, Cost of Goods Sold shall exclude administrative costs other than indirect manufacturing labor specifically attributable to the Collaboration Product being manufactured and shall exclude allocation of unused capacity costs.

#### MARKETING EXPENSES

Marketing Expenses shall be the sum of Selling Expenses, Marketing Management, Market and Consumer Research, Advertising, Trade Promotion, Consumer Promotion, and Education Expenses, each of which is specified below.

- A. "SELLING EXPENSES" shall include the following costs directly associated with the efforts of field sales representatives with respect to Collaboration Products: field sales force; field sales offices; home offices staffs directly involved in the management of and the performance of the selling functions; payments to Third Parties under co-promotion agreements approved by the Steering Committee. Reasonable field samples shall normally be charged to Trade Promotion, but if sales management has direct decision making authority for the distribution of field sales samples, it may be appropriate to charge these costs to Selling Expenses. The costs of detailing sales calls shall be allocated on a weighted average basis based on what detail position the involved Collaboration Product is assigned at an accounting charge rate consistently applied within and across its operating units and which is no less favorable to the collaboration than the internal charge rate used by HMR for its own internal cost accounting purposes for products other than Collaboration Products (excluding internal profit margins and markups).
- B. "MARKETING MANAGEMENT" shall include Product Management and Sales Promotion Management direct expenses. This shall include costs associated with developing overall sales and marketing strategies and planning for Collaboration Products. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement shall be included in this category.
- C. "MARKET AND CONSUMER RESEARCH" shall include direct expenses for Market and Consumer Research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of existing, new or proposed Collaboration Products such as market share services (e.g., IMS data), special research testing and focus groups.

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- D. "ADVERTISING" shall include all direct media costs associated with Collaboration Product advertising as follows: production expense/artwork including set up; design and art work for an advertisement; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.
- E. "TRADE PROMOTION" shall include reasonable allowances given to retailers, brokers, distributors, hospital buying groups, etc. for purchasing, promoting, and distribution of Collaboration Products. This shall include purchasing, advertising, new distribution, and display allowances as well as free goods, wholesale allowances and reasonable field sales samples. To the extent multiple products are involved and some of such products are not Collaboration Products then such allowances shall be allocated on a pro rata basis based upon net sales of each respective product by such operating unit during the most recent quarter.
- F. "CONSUMER PROMOTION" shall include the direct expenses associated with programs to promote Collaboration Products directly to the end user. This category shall include direct expenses associated with promoting products directly to the professional community such as professional samples, professional literature, promotional material costs, patient aids and detailing aids. To the extent multiple products are involved and some of such products are not Collaboration Products then such allowances shall be allocated on a pro rata basis based upon net sales of each respective product by such operating unit during the most recent quarter.
- G. "EDUCATION" shall include direct expenses associated with professional education with respect to Collaboration Products through any means not covered above, including articles appearing in journals, newspapers, magazines or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards and opinion leader development activities.
- H. "ROYALTY EXPENSES" shall mean royalties or other compensation payable to a Third Party under patents and/or technology rights of such Third Party to conduct Commercialization pursuant to the Collaboration Agreement.

# 3. DISTRIBUTION EXPENSES

Distribution Expenses shall be the sum of Stock and Shipping Expenses and Transportation Expenses, each as specified below.

- A. "STOCK AND SHIPPING" shall include the portion of distribution costs for the warehousing of Collaboration Product finished goods from the point of completion of production to the time the goods are turned over to a carrier for delivery as follows: order filling/assembly functions; reasonable order billing and customer service functions; reasonable portion of company owned/leased facilities relating to warehousing of finished products; storage of products at public warehouses.
- B. "TRANSPORTATION" shall include the portion of distribution costs relating to moving Collaboration Product goods from a warehouse to the customer as follows: outbound

4.

transportation costs; costs of moving goods from a manufacturing point to a warehouse at another location from which it is ultimately to be distributed to a customer.

4. POST-LAUNCH PRODUCT R&D EXPENSES

Post-Launch Product R&D Expenses shall include certain research and development costs incurred by a Party in relation to a Collaboration Product after the first commercial launch and shall exclude administrative expenses. Such post-launch research and development costs shall include:

- A. Phase IV Clinical Trials.
- B. Ongoing product support (as defined in Section 1.45 of the Collaboration Agreement).
- C. Ongoing medical affairs (as defined in Section 1.45 of the Collaboration Agreement).
  - D. Preclinical research.

~ C !>~

- E. Contract R&D costs performed by others for a particular project that have no alternative future uses in other R&D projects or otherwise.
- F. Fees and expenses of outside counsel in respect of regulatory affairs unrelated to obtaining Regulatory Approvals.
  - CURRENCY GAINS OR LOSSES

Currency Gains or Losses shall include the following:

- from a change in exchange rates between the functional currency and the currency in which the transaction is denominated. The transaction gain or loss is determined by measuring the increase or decrease in the functional currency cash flow due to the changes in the exchange rate from the date of the transaction to the settlement date. The difference between the functional currency amount calculated using the current exchange rate at the transaction date and the amount calculated using the currency exchange rate at the settlement date is the transaction gain or loss. Transaction gains or losses on unsettled foreign currency transactions are also reported in this manner. When there is a balance sheet date between the transaction date and settlement date, the gain or loss on the unsettled balance shall be measured using the current exchange rate at the balance sheet date.
- B. HEDGED TRANSACTIONS. For purposes of this collaboration, neither Party shall buy or sell forward, directly or indirectly, foreign currencies in amounts greater than those which can reasonably be expected to be received or paid, as the case may be, over the relevant time period.

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If a Party enters into a hedged transaction, the gain or loss realized from the hedge must be included in the underlying transaction. If the currency transaction gain or loss has been included in Net Sales, Costs of Goods Sold, etc., it shall not be included in this category.

6.

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EXHIBIT B

FINANCIAL STATEMENT FORMAT

ALT\_00391

# EXHIBIT B

# FINANCIAL STATEMENT FORMAT (CASE A - OPERATING PROFIT)

	HMR	Amylin	Total	* Net Sales
Gross Sales	****	***	***	***
Less:		****		
Discounts	****	****	****	****
Credits & Allowances	****	****	****	****
Taxes & Duties	****	****	****	****
Provisions for Uncollectible Accounts	****	****	****	****
Net Sales	****			****
Cost of Goods Sold:				
Standard Material Cost	***	****	***	****
Standard Direct Labor Costs	***	****	****	****
Standard Overhead Costs	****	****	****	***
Standard Manufacturing Variances	****	****	****	***
Scrap Expense	****	****	****	****
Inventory Revaluation	****	****	****	****
Full Absorption Adjustment	***	****	****	****
Excess & Obsolete Inventory Adjustments	****	****	****	****
Loss on Returns Expense	****	****	****	****
No Charge Shipments	****	****	****	****
Total Cost of Goods Sold	****	****	****	****
Gross Profit	****	****	****	****
Manhahira Ermanası			_	-
Marketing Expenses: Selling Expenses	****	****	****	****
Marketing Management	****	****	. ****	****
Market & Consumer Research	****	****	***	***
Advertising	****	****	****	****
Trade Promotion	****	****	. ****	****
Consumer Promotion	****	****	****	****
Education	****	****	****	***
Royalty Expense	****	****	****	****
Total Marketing Expenses	***	****	****	****
Distribution Expenses:				
Stock & Shipping	****	****	****	****
Transportation	****	****	****	****
Total Distribution Expenses	****	****	****	****

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B (CONT.)

# FINANCIAL STATEMENT FORMAT (CASE A- OPERATING PROFIT)

	HMR	Amylin	Total	Net Sales
Post-Launch Product R&D Expenses:				
Phase IV Clinical Trials	****	****	****	****
Product Support	****	***	****	****
Medical Affairs	****	****	****	****
Preclinical Research	****	****	****	****
Other Contract R&D.	****	****	****	****
Total Post-Launch Product R&D Expenses	****	****	****	****
Patent Expenses	****	****	****	****
Currency Gains (Losses):				
Unhedged Transactions	****	****	****	****
Hedged Transactions	****	****	****	****
Total Currency Gains (Losses)	****	****	****	****
Net Sublicense Revenues	****	****	****	****
Operating Profits (Losses)	****	****	****	****
Equalization Receipt (Payment)	****	****	****	****
Balance After Equalization	****	****	****	****

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B

# FINANCIAL STATEMENT FORMAT (CASE B - OPERATING LOSSES)

•	HMR	Amylin	Total	* Net Sales
Gross Sales	****	****	****	
	****	****	****	
Less: Discounts	****	****	****	
Credits & Allowances	****	***	****	
Taxes & Duties	****	****	****	
Provisions for Uncollectible Accounts	****	****	****	•
Net Sales	****	****	****	****
Cost of Goods Sold:				
Standard Material Cost	****	****	****	****
Standard Direct Labor Costs	****	****	****	****
Standard Overhead Costs	****	****	****	****
Standard Manufacturing Variances	****	****	****	****
Scrap Expense	***	****	***	****
Inventory Revaluation	****	****	****	****
Full Absorption Adjustment	****	***	****	****
Excess & Obsolete Inventory Adjustments	****	****	****	****
Loss on Returns Expense	****	***	****	****
No Charge Shipments	***	****	****	****
Total Cost of Goods Sold	****	****	****	***
Gross Profit	****	****	****	****
Marketing Expenses:				•
Selling Expenses	***	****	****	****
Marketing Management	***	***	****	***
Market & Consumer Research	***	****	****	****
Advertising	***	****	****	****
Trade Promotion	. ****	****	_# * * *	****
Consumer Promotion	***	****	****	****
Education	****	****	****	****
Royalty Expense	***	****	****	****
Total Marketing Expenses	****	****	****	****
Distribution Expenses:		****	****	****
Stock & Shipping	****	****	****	****
Transportation	***	****	****	****
Total Distribution Expenses	****	****	****	****

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B (CONT.) FINANCIAL STATEMENT FORMAT (CASE B- OPERATING LOSSES)

	HMR	Amylin	Total	ł Net Sales
Post-Launch Product R&D Expenses:				
Phase IV Clinical Trials	****	****	****	****
Product Support	****	****	****	****
Medical Affairs	***	****	****	****
Preclinical Research	****	****	****	****
Other Contract R&D	****	****	****	****
Total Post-Launch Product R&D Expenses	****	****	****	****
Patent Expenses	****,	****	****	****
Currency Gains (Losses):				
Unhedged Transactions	***	****	****	****
Hedged Transactions	****	****	****	****
Total Currency Gains (Losses)	****	****	****	****
Net Sublicense Revenues	****	****	****	****
Operating Profits (Losses)	***	****	****	****
Equalization Receipt (Payment)	****	****	****	****
Balance After Equalization	****	****	****	****

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT C LIST OF AMYLIN PATENTS

NONE.

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EXHIBIT 10.32

CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTIONS 200.80(b)(4), 200.83 AND 230.406. \* INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST THAT IS FILED SEPARATELY WITH THE COMMISSION.

COLLABORATION AGREEMENT

BY AND BETWEEN

HOECHST MARION ROUSSEL, INC.

AND

AMYLIN PHARMACEUTICALS, INC.

DATED AS OF MARCH 31, 1997

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# COLLABORATION AGREEMENT

COLLABORATION AGREEMENT (the "Agreement") entered into as of the 31st day of March, 1997 by and between AMYLIN PHARMACEUTICALS, INC., a Delaware corporation ("Amylin"), and HOECHST MARION ROUSSEL, INC., a Delaware corporation ("HMR"), effective only upon HMR's exercise of the HMR Option as provided for in Section 4.1 of the License Agreement (as defined below) (the "Effective Date"). Amylin and HMR are sometimes referred to herein individually as a "Party" and together as the "Parties".

# WITNESSETH:

WHEREAS, HMR is a leading multinational health care company with a broad product portfolio of drugs for the treatment of human diseases;

WHEREAS, Amylin is a leading biotechnology company that has expertise and experience in the research and development of compounds for use in treating metabolic and other disorders;

WHEREAS, Amylin and HMR have entered into that certain License and Option Agreement effective as of March 31, 1997 (the "License Agreement"), with respect to the HMR Compounds (as defined in the License Agreement); and

WHEREAS, the Parties desire to collaborate with respect to the Research, Development and Commercialization (as such terms are defined below) of one or more HMR Compounds on the terms set forth in this Agreement.

NOW, THEREFORE, in consideration of the following premises and the mutual covenants and agreements contained herein, the Parties agree as follows:

# ARTICLE I

#### DEFINITIONS

Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the License Agreement. For purposes of this Agreement, the following terms shall have the meanings specified below:

1.1 "ALLOWABLE EXPENSES" means those expenses incurred after the first commercial launch of a Collaboration Product which are generally consistent with a Commercialization Plan and Commercialization Budget and are specifically attributable to Collaboration Products in the Profit Sharing Territory, and shall consist of (i) Cost of Goods Sold, (ii) Marketing Expenses,

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- (iii) Distribution Expenses, (iv) Post-Launch Product R&D Expenses, (v) Collaboration Patent Expenses, and (vi) Currency Gains or Losses. Allowable Expenses shall exclude Development Expenses and Research Expenses, even if incurred after the first commercial launch of a Collaboration Product.
- 1.2 "AVERAGE NET SELLING PRICE" means total Net Sales of a Collaboration Product divided by the total units sold of such Collaboration Product, in both cases excluding sales and units involving government mandated or conceded discounts or bearing a Nominal Price.
- $_{1.3}$  "BREACHING PARTY" shall have the meaning set forth in Section  $_{12.2\,(a)}$  .
- 1.4 "COLLABORATION COMPOUND" means any HMR Compound which is, as of the Effective Date, or thereafter becomes, the subject of Research, Development or Commercialization under this Agreement.
- 1.5 "COLLABORATION PATENT EXPENSES" means the fees and expenses of outside counsel and payments to Third Parties incurred in connection with the preparation, filing, prosecution and maintenance of Amylin Patents, Joint Patents and HMR Patents after the Effective Date, including the costs of patent interference and opposition proceedings.
- 1.6 "COLLABORATION PRODUCT" means a product including or incorporating any form or dosage of a Collaboration Compound for use in the Field and as to which each Party has paid, is paying or is obligated to pay hereunder one-half of the Research and Development Expenses.
- 1.7 "COMMERCIALIZATION" shall mean all activities relating to the manufacture, marketing, distribution and sale of a Product, including, without limitations, Pre-Marketing, advertising, education, planning, marketing, distribution, market and product support pre-clinical studies, Phase IIIB Clinical Trials and Phase IV Clinical Trials and, subject to Section 9.7, sub-licensing of Collaboration Products.
- 1.8 "COMMERCIALIZATION BUDGET" shall have the meaning set forth in Section 5.5(a).
- 1.9 "COMMERCIALIZATION LIAISON OFFICER" shall have the meaning set forth in Section 3.10(b)
- 1.10 "COMMERCIALIZATION PLAN" shall have the meaning set forth in Section 5.5(a).
- 1.11 "COMPETITIVE PRODUCT INFRINGEMENT" shall have the meaning set forth in Section 9.1(a).
- 1.12 "CORE DOSSIER COUNTRIES" means the United States, Canada, Japan and the countries included in the European Union as of the Effective Date.

- 1.13 "COST OF GOODS SOLD" means the cost of Collaboration Product inventory sold and other manufacturing related costs incurred with respect to Collaboration Products in the Profit Sharing Territory during any relevant period, in each case excluding administration expenses. These costs shall be defined as the sum of the applicable expenditures incurred directly in bringing goods acquired and/or manufactured to their existing condition or location. Cost of Goods Sold shall be calculated in the manner set forth in Exhibit A.
- 1.14 "CURRENCY GAINS OR LOSSES" means gains or losses resulting from a change in exchange rates (in the case of unhedged transactions) and/or the gains or losses of related hedging transactions, in either case as associated with Net Sales of Collaboration Products, calculated in the manner set forth in Exhibit A.
- 1.15 "DEVELOPMENT" means all activities relating to obtaining Regulatory Approval of a Product, Product line extensions, alternative delivery systems and new indications therefor and all activities relating to developing the ability to manufacture the same. This includes preclinical testing, toxicology, formulation, bulk production, fill/finish, manufacturing process development, manufacturing and quality assurance technical support, clinical studies, regulatory affairs and outside counsel regulatory legal services.
- 1.16 "DISTRIBUTION EXPENSES" means the costs, excluding administration costs, incurred by a Party or for its account, specifically attributable to the distribution of a Collaboration Product in the Profit Sharing Territory, to be calculated in the manner set forth in Exhibit A.
- 1.17 "EFFECTIVE DATE" shall have the meaning set forth in the introduction to this Agreement.
- 1.18 "EQUALIZATION PAYMENT" shall mean the amount payable by one Party to the other to equalize the Operating Profit or Losses between the Parties as shown on Exhibit B. By way of example, in a total Operating Profits situation, if HMR has an Operating Profit of 40 and Amylin has an Operating Loss of 10, then the Equalization Payment made by HMR to Amylin will be 25. In a total Operating Losses situation, if HMR has an Operating Loss of 40 and Amylin has an Operating Loss of 10, the Equalization Payment made by Amylin to HMR will be 15.
- 1.19 "EX-MANUFACTURER SELLING PRICE" means the invoice price to wholesalers (or their equivalent) less all cash discounts taken for prompt cash payment for a Collaboration Product.
- 1.20 "EXCEPTED COMMERCIALIZATION MATTERS" shall have the meaning set forth in Section 5.1(b).

- 1.21 "EXCEPTED DEVELOPMENT MATTERS" shall have the meaning set forth in Section 4.1(b).
- 1.22 "FINANCIAL STATEMENT FORMAT" means the form of Financial Statement shown and described in Exhibit B.
- 1.23 "INDEPENDENT PRODUCT" means a product including or incorporating any form or dosage of an HMR Compound which is developed by a Party under Section 4.8(b) without the other Party paying one-half of all Research and Development Expenses.
- 1.24 "INITIAL RESEARCH AND DEVELOPMENT PLAN AND BUDGET" shall have the meaning set forth in Section 4.4(a).
- 1.25 "JOINT COMMERCIALIZATION COMMITTEE" OR "JCC" means the committee established pursuant to Section 3.7.
- 1.26 "JOINT DEVELOPMENT COMMITTEE" OR "JDC" means the committee established pursuant to Section 3.7.
- 1.27 "LAUNCH BUDGET" shall have the meaning set forth in Section 5.6(a).
- 1.28 "LAUNCH PLAN" shall have the meaning set forth in Section 5.6(a).
- 1.29 "LIAISON OFFICER" shall have the meaning set forth in Section  $3.10\,(\text{c})$ .
- 1.30 "MANUFACTURING ATTRIBUTES" shall have the meaning set forth in Section 8.1.1(a).
- 1.31 "MARKETING EXPENSES" means the costs, excluding administration costs, which are generally consistent with a Commercialization Budget and Commercialization Plan and (i) are incurred after the first commercial launch of a Collaboration Product and are specifically attributable to the sale, promotion, and marketing of such Collaboration Product in the Profit Sharing Territory or (ii) are incurred after the first commercial launch of a Collaboration Product in a Major Market Country and are specifically attributable to preparation of the launch of such Collaboration Product in additional countries of the Profit Sharing Territory. Marketing Expenses shall be calculated in the manner set forth on Exhibit A.
- 1.32 "MATERIAL BREACH" shall have the meaning set forth in Section 12.2(g).
- 1.33 "NET SALES" means the amount invoiced by a Party or an Affiliate for sales of Products to a Third Party in the Profit Sharing Territory less: (i) discounts, including cash discounts, rebates and retroactive price reductions or allowances actually allowed or granted from the invoiced amount (as adjusted pursuant to Section 5.14), (ii) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, including recalls,

(iii) taxes (other than income taxes), duties or other governmental charges levied on or measured by the invoiced amount when included in billing, as adjusted for rebates and refunds, and (iv) provisions for uncollectible accounts determined in accordance with such Party's normal accounting procedures consistently applied within and across its pharmaceutical operating units.

1.34 "NET SUBLICENSE REVENUES" means all revenues or other consideration received from Third Parties as consideration for sublicensing of the manufacture, distribution, use or sale of Collaboration Products in the Profit Sharing Territory, less the expenses directly attributable to supplying goods and services to such sublicensees to enable their performance of the sublicenses.

1.35	"NOMINAL E	PRICE"	means	*******
*****	*****	*****	*****	***********
******	*******	***		

- 1.36 "NON-BREACHING PARTY" shall have the meaning set forth in Section 12.2(a).
- 1.37 "OPERATING PROFITS OR LOSSES" means the profits ("Operating Profits") or losses ("Operating Losses") resulting from the Commercialization of Collaboration Products in the Profit Sharing Territory and shall be equal to (i) Net Sales less Allowable Expenses plus (ii) Net Sublicense Revenues. A separate determination of Operating Profits or Losses shall be made for each Collaboration Product on a worldwide basis as outlined in Exhibit B. In the event multiple Collaboration Products are being marketed under this Agreement, the individual statements of Operating Profits or Losses shall also then be consolidated into a single statement of Operating Profits or Losses for purposes of overall accounting between the Parties.
- 1.38— "PHASE I CLINICAL TRIALS" shall have the meaning set forth in 21 CFR ss. 312.21(a).
- 1.39 "PHASE IIIB CLINICAL TRIALS" means product support clinical trials of a Collaboration Product (i.e., a clinical trial which the JDC determines is not required for receipt of Regulatory Approval but which may be useful in providing additional drug profile data) commenced before receipt of Regulatory Approval in the country where such trial is being conducted.
- 1.40 "PHASE IV CLINICAL TRIALS" means product support trials of a Collaboration Product commenced after receipt of Regulatory Approval in the country where such trial is being conducted.
- 1.41 "POST-LAUNCH PRODUCT R&D EXPENSES" means the costs of Phase IV Clinical Trials and ongoing product support (including manufacturing and quality assurance technical support, and laboratory and clinical efforts directed toward the further understanding of product
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safety and efficacy) and medical affairs (including regulatory support necessary for product maintenance) which are specifically attributable to a Collaboration Product in the countries of the Profit Sharing Territory where such Collaboration Product has been launched, excluding administrative expenses and costs that are included within Costs of Goods Sold or Development Expenses. Post-Launch Product R&D Expenses shall be calculated in the manner set forth on Exhibit A.

- undertaken prior to and in preparation for the launch of a Collaboration Product in the Profit Sharing Territory, consistent with a Commercialization Plan and prior to the first commercial launch of a Collaboration Product in a Major Market Country. Pre-Marketing shall include advertising, education, sales force training, Phase IIIB Clinical Trials, trademark selection, filing, prosecution and enforcement, and other activities included within the Commercialization Plan prior to the first commercial launch of a Collaboration Product in a Major Market Country. If a Collaboration Product is first launched in a country other than a Major Market Country, the expenses of marketing incurred in those countries where such Collaboration Product has been launched shall be included in Marketing Expenses, while the expenses of Pre-Marketing elsewhere in the world shall still be included in Pre-Marketing Expenses.
- 1.43 "PRE-MARKETING EXPENSES" means the costs, excluding Development Expenses, specifically attributable to the Pre-Marketing of a Collaboration Product. Pre-Marketing Expenses shall exclude administrative expenses.
- 1.44 "PRODUCTS" shall mean Collaboration Products, Royalty-Bearing Products and Independent Products, collectively.
- 1.45 "PROFIT SHARING TERRITORY" means the world except for those countries as to which Amylin has elected to withdraw from the sharing of expenses, profits and losses with respect to Collaboration Products pursuant to Section 5.7. The Profit Sharing Territory may be different for each Collaboration Product, based on the elections made by Amylin with respect to each such product in each country.
- 1.46 "REGULATORY FILINGS" shall have the meaning set forth in Section 4.6
- 1.47 "RESEARCH" means the scientific, technical and clinical activities undertaken to evaluate an HMR Compound for Development, including pharmacology, pharmacokinetics, toxicology, formulation, process development, manufacture of HMR Compounds (including manufacture of bulk drug substance and fill/finish) for preclinical studies and clinical trials, and clinical pharmacology.
- 1.48 "RESEARCH AND DEVELOPMENT BUDGET" shall have the meaning set forth in Section 4.4(a).

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- 1.49 "RESEARCH AND DEVELOPMENT EXPENSES" means the expenses incurred by a Party or for its account which are generally consistent with a Research and Development Plan and Research and Development Budget and are specifically attributable to the Research and Development of a Collaboration Product (including royalties paid to a Third Party not otherwise recovered as a Cost of Goods Sold). Research and Development Expenses shall exclude administrative expenses.
- 1.50 "RESEARCH AND DEVELOPMENT LIAISON OFFICER" shall have the meaning set forth in Section 3.10(a).
- 1.51 "RESEARCH AND DEVELOPMENT PLAN" shall mean the Research and Development Plans referred to in Section 4.4(a).
- 1.52 "RESEARCH EXPENSES" means the expenses incurred by a Party or for its account specifically attributable to Research for a Collaboration Compound. Research Expenses shall exclude administrative expenses.
- 1.53 "ROYALTY-BEARING COUNTRY" shall have the meaning set forth in Section 5.7.
- 1.54 "ROYALTY-BEARING PRODUCT" means a Collaboration Product marketed directly or indirectly by HMR in a Royalty-Bearing Country under a royalty arrangement pursuant to Section 5.7.
- 1.55 "ROYALTY-BEARING SALES" means the amount invoiced for sales of a Royalty-Bearing Product, or (pursuant to Section 12.2) a Collaboration Product or (pursuant to Section 4.8(b)) an Independent Product by a Party or its permitted sublicensees to a Third Party, less (i) discounts, including cash discounts, or rebates, retroactive price reductions or allowances actually allowed or granted from the invoiced amount, (ii) credits or allowances actually granted upon claims, rejections or returns of such Products, including recalls, (iii) freight, postage, shipping and insurance charges paid for delivery of such Products, to the extent invoiced, (iv) taxes (other than income taxes), duties or other governmental charges levied on or measured by the invoiced amount when included in billing, as adjusted for rebates and refunds, and (v) provisions for uncollectible accounts determined in accordance with such Party's normal accounting procedures consistently applied within and across its pharmaceutical operating units.

In the event a Party is receiving royalties under this Agreement from any Product sold in the form of a combination product containing one or more active ingredients in addition to a Collaboration Compound, and if said combination product is not covered by a Patent owned or Controlled by the Party receiving royalties, Royalty-Bearing Sales for such combination product will be calculated by multiplying actual Royalty-Bearing Sales of such combination product by the fraction A/(A+B) where A is the invoice price of the Product if sold separately,

and B is the total invoice price of any other active component or components in the combination product, if sold separately. If, on a country-by-country basis, the other active component or components in the combination are not sold separately in said country, Royalty-Bearing Sales for the purpose of determining royalties of the combination product shall be calculated by multiplying actual Royalty-Bearing Sales of such combination product by the fraction A/C where A is the invoice price of the Product if sold separately, and C is the invoice price of the combination product. If, on a country-by-country basis, neither the Product nor the other active component or components of the combination product is sold separately in said country, Royalty-Bearing Sales for the purposes of determining royalties of the combination product shall be determined by the Parties in good faith. If the manufacture, use or sale of the combination product is itself covered by a Patent owned or Controlled by the Party receiving royalties (other than a Patent covering the manufacture, use or sale of said Collaboration Compound), the provisions of this paragraph shall not apply to sales of said combination product.

- 1.56 "SIMULTANEOUS FILINGS" shall have the meaning set forth below in Section 4.6.
- 1.57 "STEERING COMMITTEE" means the committee described in Section 3.1.

#### ARTICLE II

# PRE-COLLABORATION EXPENSES

- 2.1 ALLOCATION OF PRE-COLLABORATION RESEARCH AND DEVELOPMENT EXPENSES. Within thirty (30) days after the Effective Date, the Parties shall apportion amongst themselves the Amylin Research and Development Expenses, HMR's Additional Research and Development Expenses and HMR's costs and expenses of developing the HMR Compounds prior to the effective date of the License Agreement, taking into account any reimbursements of the foregoing made by one Party to the other, so that such costs and expenses are borne equally by the Parties, as follows:
- (a) The Amylin Research and Development Expenses (whether or not reimbursed), minus any amount actually paid by HMR to reimburse Amylin on account of Amylin's Research and Development Expenses (collectively, the "Net Amylin Expenses"); shall be compared with
- (b) The sum of (i) any HMR Additional Research and Development . Expenses plus (ii) \*\*\*\*\*\*\*\*\*\*\*\* (representing a portion of the total costs incurred by HMR prior to the effective date of the License Agreement with respect to Research and Development of the HMR Compounds, the other portion to be reimbursed pursuant to Section 6.2 (b) of this Agreement) (collectively, the "Net HMR Expenses").
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2.2 PRE-COLLABORATION ALLOCATION PAYMENT. Within thirty (30) days following the thirty-day period referred to in Section 2.1, in the event the Net Amylin Expenses exceed the Net HMR Expenses, then HMR shall pay to Amylin one-half of the difference between the Net Amylin Expenses and the Net HMR Expenses. In the event the Net HMR Expenses exceed the Net Amylin Expenses, then Amylin shall pay to HMR one-half of the difference between the Net HMR Expenses and the Net Amylin Expenses.

#### ARTICLE III

# MANAGEMENT OF PROGRAM

- 3.1 STEERING COMMITTEE. Within thirty (30) days after the Effective Date, the Parties shall form an executive committee for the management of their collaborative efforts (the "Steering Committee"). The Steering Committee shall be comprised of up to six members, with an equal number of members appointed by each Party. Each Party shall appoint and replace its own representatives on the Steering Committee. Members of the Steering Committee shall be composed of executive personnel of the Parties. One member of the Steering Committee selected by each party shall have substantial experience in pharmaceutical product research and development. One member of the Steering Committee selected by each party shall have substantial executive experience. Steering Committee members shall serve on such terms and conditions as shall be determined by the Party selecting such member, and may be removed or replaced at any time by such Party. An alternate member may serve temporarily in the absence of a permanent member.
  - 3.2 MEETINGS OF THE STEERING COMMITTEE. The Steering Committee:
- (a) shall hold meetings at such times and places as shall be determined by a majority vote of the entire membership of the Steering Committee, but in no event shall such meetings be held less frequently than once every six (6) months;
- (b) may conduct meetings in person or by telephone conference, provided that any decision made during a telephone conference meeting shall be evidenced by minutes signed by one of the members of the Steering Committee from each of the Parties;
  - (c) shall keep minutes reflecting actions taken at meetings;
- (d) may act without a meeting if prior to such action a written consent thereto is signed by all members of the Steering Committee then in office; and
- (e) may amend or expand upon the foregoing procedures for its internal operation by unanimous written consent of all members of the Steering Committee then in office.

- FUNCTIONS AND POWERS OF THE STEERING COMMITTEE. The activities rties under this Agreement shall be managed by the Steering Committee only to he extent set forth in this Agreement, including:
- manage and coordinate the long-range strategy and planni: for the Research, Development and Commercialization of HMR Compounds, includ: facilitation of the flow of Information with respect to Research, Develoge ent and Commercialization work being conducted for each Collaboration Produc:
- coordinate the activities of the Parties hereunder, includ: g long-range strategy and oversight of the Joint Development Committee (the "JCC") and the Joint Commercialization Committee (the "JCC") (as described below)
- attempt to settle disputes or disagreements that are (c) unresched as referenced herein;
- review and approve the Research and Development Budgets (d) submit ad to it by the JDC;
- review and approve the Commercialization Budgets and (e) Launch Budgets submitted to it by the JCC;
- review planned pricing and manufacturing decisions of the JCC, as provided herein;
- (g) review and approve a proposal by either Party (i) to stop a Phase I Clinical Trial or Phase II Clinical Trial of a Collaboration Product because of Safety, (ii) to stop a Phase III Clinical Trial of a Collaboration Product for any reason, or (iii) to terminate such Party's participation in Research and Development of a Collaboration Product under Section 4.8; and
- (h) perform such other functions as appropriate to further the purposes of this Agreement as mutually determined by the Parties.
- STEERING COMMITTEE ACTIONS. Except as otherwise provided in this Agreement, actions to be taken by the Steering Committee pursuant to the terms of this Agreement shall require the unanimous vote of the members of the Steering Committee. The following procedures will be followed by the Steering Committee with respect to Research, Development and Commercialization matters referred to it:
- If the Steering Committee cannot reach a unanimous decision with respect to any Research and/or Development matters referred to it for approval within sixty (60) days following receipt of such referral, the final decision on such matters shall be made by Amylin,

except as to Excepted Development Matters. If the Steering Committee cannot reach a unanimous decision with respect to any of the Excepted Development Matters referred to it by the JDC pursuant to Section 4.1(b), (1) the status quo shall be maintained with respect to Excepted Development Matters items (i) and (ii) in Section 4.1(b) and (2) as to Excepted Development Matter item (iii) in Section 4.1(b), the Phase III Clinical Trial shall be terminated if the Steering Committee does not reach a unanimous decision within ten (10) days.

- (b) If the Steering Committee cannot reach a unanimous decision with respect to approval of the Commercialization Budget or Launch Budget of a Collaboration Product pursuant to Article V, or any other Commercialization matters referred to it for approval, within sixty (60) days following receipt of such referral, the final decision on such matters shall be made by HMR, except as to Excepted Commercialization Matters, which shall be resolved as provided for in Section 5.1(b).
- (c) Except as provided for above in this Section 3.4, if the Steering Committee fails to reach unanimous agreement on a matter before it for decision within sixty (60) days following its receipt of the referral of the matter, such matter shall be referred to executive officers of the Parties pursuant to the dispute resolution procedures set forth in Section\* 12.2 of the License Agreement. The manner described in this Section 3.4 to resolve disputes regarding Excepted Development Matters and Excepted Commercialization Matters shall be the sole mechanism for resolving such matters under this Agreement. If either Amylin or HMR wishes to seek a non-binding opinion from a Third Party with respect to any issue before the Steering Committee for decision, it may do so at its own expense; provided, however, that if both Parties agree to seek such opinion, such expense shall be shared equally by the Parties.
- 3.5 ACCESS TO RECORDS. The Parties shall provide the Steering Committee and its authorized representatives with reasonable access during regular business hours to all records and documents in their possession relating to the Collaboration Compounds and the Collaboration Products which the Steering Committee may reasonably require in order to perform its obligations hereunder.
- 3.6 LIMITATIONS ON THE POWERS OF THE STEERING COMMITTEE. The Steering Committee shall have only such powers as are specifically delegated to it hereunder or as are specifically agreed to in writing by the Parties. Except as set forth in Section 3.3, the Steering Committee shall not be involved with the day-to-day management of the collaboration activities contemplated by this Agreement.
- 3.7 FORMATION OF THE JDC AND THE JCC AND APPOINTMENTS. The Parties shall form the JDC and the JCC within thirty (30) days after the Effective Date. For each of the JDC and the JCC, each Party shall appoint and replace its own representatives on such committees. Each such committee shall be comprised of equal numbers of members appointed by each Party (up to four (4) members for each Party per committee) of appropriately expert and experienced

individuals. Members of the Steering Committee shall not serve as members of the JDC or JCC, and the Parties shall use their best efforts to not appoint a person as a member of both the JDC and JCC. One of the members of the JDC appointed by Amylin will serve as the chairperson of the JDC. One of the members of the JCC appointed by HMR will serve as the chairperson of the JCC. Either Party may designate an alternate for a committee member to participate in the event one of that Party's regular committee members is unable to be present at a meeting.

- 3.8 MEETINGS OF THE JDC AND THE JCC. Meetings of the JDC or the JCC may be called by either Party on ten (10) working days prior written notice, unless such notice is waived by the Parties. Such committees may be convened, polled or consulted from time to time by means of telecommunication, video communication, or correspondence. Each of the JDC and the JCC will meet at least once every four (4) month period following the Effective Date, at sites to be designated by the chairpersons of such committees.
- 3.9 AGENDAS. Each Party will provide proposed agenda items to the committee chairpersons, together with appropriate information, at least five (5) working days in advance of each meeting of the Steering Committee, JDC or JCC. The committee chairpersons will then deliver an agenda for the meeting to each member of the committee at least three (3) working days in advance of the committee meeting.

#### 3.10 LIAISON OFFICERS.

- individual as Research and Development Liaison Officer, who will facilitate communication and coordination of activities relating to Research and Development between the Parties and provide support and guidance to the JDC and the Research and Development teams. Amylin will make available an office and secretarial services to the Research and Development Liaison Officer, and will provide reasonable access to Amylin technical staff, management, and documentation relevant to Collaboration Products. The Research and Development Liaison Officer is expected to attend project team meetings and JDC meetings. The Research and Development Liaison Officer also will have reasonable access to Steering Committee members from each Party.
- experienced individual as Commercialization Liaison Officer, who will facilitate communication and coordination of Commercialization activities between the Parties. HMR will make available to the Commercialization Liaison Officer an office and secretarial services and will provide reasonable access to marketing, sales, planning and other relevant HMR personnel assigned to work on Collaboration Products and to plans, market research, and other documentation relevant to Commercialization of Collaboration Products. The Commercialization Liaison Officer is expected to attend relevant product team meetings and JCC meetings. The Commercialization Liaison Officer also will have reasonable access to Steering Committee members from each Party.

- an employee of HMR and the Commercialization Liaison Officer will remain an employee of Amylin (the Research and Development Liaison Officer and the Commercialization Liaison Officer are referred to collectively herein as the "Liaison Officers"). Each Liaison Officer is expected to spend between "Liaison Officers" one-quarter and three-quarters of his or her working time at the premises of the Party who is not his or her employer in order to perform his or her liaison function effectively.
- (d) HMR and Amylin will propose, within thirty (30) days after formation of the JDC and JCC, respectively, candidates to serve as Liaison Officers to the chairpersons of the JDC and JCC, respectively, who shall approve the respective Liaison Officers within thirty (30) days following receipt of each such proposed candidate. Such Liaison Officers may be replaced from time to time by the Party employing them. Any such replacement must be approved by the chairperson of the JDC or JCC, as the case may be.

#### 3.11 ACCOUNTING.

- (a) For the purposes of determining all costs and expenses hereunder, any cost or expense allocated by either Party to a particular category for a particular Collaboration Product shall not also be allocated to another category for such Collaboration Product, and any cost or expense allocated to a particular Collaboration Product in a particular country shall not be allocated to another Collaboration Product of such Party or the same Collaboration Product in a different country.
- Party agrees to determine Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and all other costs and expenses hereunder with respect to the Products using its standard accounting procedures, consistent with United States Generally Accepted Accounting Principles, to the extent practical, as if such Products were solely owned products of the Party. The Parties also recognize that such procedures may owned products of the Party. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales, Royalty-Bearing Sales, Allowable Expenses, Research and Development Expenses, Pre-Marketing Expenses and such other costs and expenses. The Parties Expenses, Pre-Marketing Expenses and such other costs and expenses. The Parties adjustments shall be made to compensate the affected Party in order to preserve the same economics as reflected under this Agreement under such Party's accounting procedures in effect as of the date on which the activity in question (for example, Research, Development, marketing or manufacturing) first commences under this Agreement. Where the change is or would be economically material to expense category. For purposes of this Section 3.11, "economically material" expense category. For purposes of this Section 3.11, "economically material" shall mean, before the first commercial launch of a Collaboration Product, a change which affects Research Expenses, Research and Development Expenses and/or Pre-Marketing Expenses by five percent

(5%) or more, and after the first commercial launch of a Collaboration Product, a change which affects Operating Profits or Losses by five percent (5%) or more.

#### ARTICLE IV

#### JOINT RESEARCH AND DEVELOPMENT

# 4.1 RESPONSIBILITIES OF THE JDC.

- (a) Following the Effective Date, the JDC shall oversee the Research and Development of Collaboration Compounds in order to obtain Regulatory Approvals, as set forth in this Article IV. The JDC will also (i) oversee the preparation of Research and Development Plans and Research and Development Budgets and submit such plans and budgets to the Steering Committee for review and budget approval, (ii) evaluate and designate Collaboration Compounds for Research and Development and (iii) facilitate the flow of Information with respect to Research and Development being conducted for each Collaboration Product. In addition, in connection with an approved Commercialization Budget and/or an approved Launch Budget, the JDC will oversee Phase IIIB Clinical Trials, and shall provide such support with respect to Phase IV Clinical Trials as may be reasonably requested by the JCC.
- vote of the members of the JDC. If the JDC is unable to obtain a majority affirmative vote as to any matter involving Research or Development, except for (i) increasing the Research and Development Budget (other than as provided for in the Initial Research and Development Plan and Budget in Section 4.4(a)), (ii) altering the Research and Development Plan in a manner which would (1) change indications for which a Collaboration Product is being developed, (2) conduct Development for less than North America and the European Union or (3) change or add a route of delivery or line extension of a Collaboration Product in Development or (iii) terminating a Phase III Clinical Trial prior to completion in accordance with its protocol (collectively, the "Excepted Development Matters"), the decision of Amylin will be final and determinative so long as such decision does not contradict or modify the terms of this Agreement. Such Excepted Development Matters shall be referred to the Steering Committee for consideration pursuant to Section 3.4 of this Agreement.
- (c) The JDC will have the power to form subcommittees with appropriate representation from Amylin, HMR and appropriate Third Parties; provided, however, that any Third Party member of a subcommittee must be approved by HMR.
- (d) During clinical trials for any Collaboration Products, the JDC and JCC shall work together to assure a smooth transition from Development of such Collaboration Products to Commercialization of such Collaboration Products, including, without limitation,

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product claims, product positioning, pre-launch medical education and communications programs. In addition, the JDC shall keep the JCC informed of proposed changes in the dosage form of Collaboration Products and the countries in which Phase III Clinical Trials are being conducted.

- Research and Development Party with respect to all Collaboration Products and, as a result, shall be obligated and responsible for carrying out Research and Development pursuant to each Research and Development Plan. Amylin will commence reporting to the JDC within sixty (60) days following the Effective Date. Amylin will report to the JDC at such times and in such manner as is reasonably determined by the JDC from time to time. HMR agrees to carry out such Research and Development tasks as are reasonably requested by Amylin and accepted by HMR. In addition, consideration shall be given to HMR to participate in other Research and Development activities, as mutually agreed upon by the Parties. All HMR Research and Development Expenses will be included in Research and Development Expenses to the account of HMR.
- 4.3 RIGHT TO ENGAGE THIRD PARTIES. In the course of its business, Amylin regularly uses Third Parties to perform certain Research and Development activities. Amylin will continue to do so during the course of this Agreement, and expenses relating to such Third Party Development will be included in Amylin's Research and Development Expenses.
- 4.4 RESEARCH AND DEVELOPMENT PLAN AND RESEARCH AND DEVELOPMENT BUDGET.
- (a) The Research and Development of each Collaboration Product shall be governed by a Research and Development Plan and a Research and Development Budget, which shall provide for Development in at least all Core Dossier Countries and, together with updates, shall be prepared by Amylin, after taking into consideration HMR's comments, for budget approval by the Steering Committee. The Parties shall agree upon and approve an Initial Research and Development Plan and Budget within sixty (60) days after the Effective Date. If the Parties are unable to agree on the Initial Research and Development Plan and Budget within such sixty (60) day period, then the Initial Research and Development Plan and Budget shall be referred to the Steering Committee for resolution by the Steering Committee.
- proposed overall program of Research and Development Plan shall describe the proposed overall program of Research and Development for the subject Collaboration Product in each applicable country, including preclinical studies, toxicology, formulation, process development, clinical studies and regulatory plans and other elements of obtaining Regulatory Approval in each applicable country. HMR shall provide such guidance as Amylin reasonably requests regarding local Drug Approval Application submission requirements. The Research and Development Plan shall include a summary of estimated Research and Development Expenses of the program expected during the Research and Development process through obtaining Regulatory Approval

for each proposed indication and route of delivery, and shall also include a detailed Research and Development Budget for all Research and Development activities proposed for the following twelve (12) months.

- Development Budget shall be updated annually by Amylin, after taking into account HMR's comments, and shall be submitted by October 1 of each calendar year to the Steering Committee for review and for Research and Development Budget approval. The Steering Committee shall provide comments on each such Budget approval. The Steering Committee shall provide comments on each such updated Research and Development Plan and Research and Development Budget within thirty (30) days following its receipt of such plan and budget. Within ninety (90) days following its receipt of such plan and budget, the Steering Committee shall either approve the Research and Development Budget submitted by the JDC or approve a modified Research and Development Budget prepared by the Steering Committee consistent with the objectives for the Collaboration Products and the aims of the collaboration contemplated by this Agreement. If the Steering Committee fails to approve any budget increase in the Research and Development Committee fails to approve any budget increase in the Research and Development Research and Development Plan, the Research and Development Budget and the Research and Development Plan shall remain at its previously approved level or previous unmodified form.
- 4.5 DEVELOPMENT EFFORTS. Each Party agrees to exert the efforts necessary and reasonable to execute and substantially carry out the Research and Development Plan within the Research and Development Budget and to cooperate with the other Party in carrying out the Research and Development Plan.
- DRUG APPROVAL APPLICATIONS. Consistent with the Research and Development Plan, Amylin shall be responsible for preparing and filing all filings with the regulatory authorities with respect to HMR Compounds in each country in the Profit Sharing Territory ("Regulatory Filings"), including, but not limited to, Drug Approval Applications, and seeking Regulatory Approvals for Collaboration Products in the Profit Sharing Territory, including preparation of all reports necessary as part of a Drug Approval Application. All such Drug Approval Applications shall be filed jointly in the names of Amylin and HMR if Approval Applications shall be filed jointly in the names of Amylin and HMR if simultaneous filings of identical Drug Approval Applications, one in Amylin's name and one in HMR's name, shall be made ("Simultaneous Filings"). If neither of the preceding filing scenarios is permitted by a regulatory agency, the Drug Approval Application in such case shall be filed in the name of Amylin, and a Approval Application in such case shall be simultaneously provided to HMR together with written notice from the regulatory agency that neither joint filings nor Simultaneous Filings are permitted in such jurisdiction. Amylin shall be responsible for prosecuting all such Drug Approval Applications, including any such Drug Approval Applications filed in HMR's name. In the event a Drug Approval Application is filed in the name of a single Party, the other Party shall have the right of cross reference. The Parties shall consult and cooperate in the preparation of each Drug Approval Application and in obtaining Regulatory Approvals. Upon receipt of

each Regulatory Approval, Amylin shall promptly transfer ownership of the corresponding Drug Approval Application and Regulatory Approval to HMR, provided HMR is the marketing Party in the country wherein Regulatory Approval is obtained, and shall promptly notify the appropriate regulatory agency of such transfer of ownership. Transfer of sole ownership shall occur earlier in time if necessary for negotiating pricing approvals pursuant to Section 5.11. In the event HMR's right to market any Collaboration Products under this Agreement event HMR's right to market any Collaboration Products under this Agreement terminates for any reason, HMR shall promptly transfer any and all of its ownership rights in the corresponding Drug Approval Application and Regulatory ownership rights in the corresponding Drug Approval Applications being Approvals to Amylin. In connection with all Drug Approval Applications being Approvated by Amylin hereunder, each Party agrees to provide the other Party with a copy (which may be wholly or partly in electronic form) of all fillings to regulatory agencies it makes on its behalf or on the other Party's behalf hereunder.

# 4.7 COSTS OF DEVELOPMENT.

- (a) All Research and Development Expenses of Collaboration Products under this Agreement shall be shared equally by the Parties.
- (b) HMR shall advance to Amylin, on the next to last.

  business day of each calendar quarter ending subsequent to the Effective Date,
  HMR's share of the budgeted Research and Development Expenses for the following
  quarter, based on the most recently approved Research and Development Budget.
- Development Expenses incurred by it in accordance with procedures to be agreed upon between the Parties. Subsequent to the Effective Date, Amylin and HMR shall report quarterly to each other on their Research and Development Expenses, with such reports to be submitted within twenty (20) days after the end of each calendar quarter and within thirty (30) days after the end of each calendar. The Parties shall seek to resolve any questions related to such accounting reports within sixty (60) days following receipt of such reports. If the Parties are unable to resolve any disputes regarding such accounting reports within such sixty (60) day period, such dispute will be referred to the Steering Committee for resolution pursuant to Section 3.4.
- (d) Any differences between the actual expenses incurred in a particular quarter and the budgeted expenses for such quarter upon which HMR's advance payment was made to Amylin shall be applied as an adjustment to the following quarter's payment due from HMR as follows:
  - (i) in the event actual expenses exceed budgeted expenses for a particular quarter, the amount of the difference shall be added to the amount due under HMR's next quarterly advance payment of budgeted Research and Development Expenses; and

- (ii) in the event actual expenses are less the budgeted expenses for a particular quarter, the amount of the diffeshall be subtracted from the amount due under HMR's next quarterly advance payment of budgeted Research and Development Expenses.
- (e) Notwithstanding the provisions of Section 4.7 (d), Amylin shall be solely responsible for any Research and Development Expenses exceeding, during a calendar year, one hundred five percent (105%) of the most recently approved Research and Development Budget for such year, and such overage, if any, shall be paid by Amylin to HMR within ten (10) days after the amount of such overage is determined, unless the overage is (i) the result of actions of such overage is determined, unless the expense), (ii) is approved by the Steering Committee or (iii) is the result of the requirements of regulatory authorities (in which cases the Parties shall share the expense equally). If actual costs and expenses for a given calendar year are less than or equal to 5% below budgeted costs and expenses for such year, then such amount will be carried forward into the next calendar year's budget. If actual costs and expenses for such year, then the Parties will mutually determine the portion of such amount in year, then the Parties will mutually determine the portion of such amount in excess of 5%, if any, that will be carried forward into the next calendar year's budget.
- 4.8 ELECTION BY A PARTY TO TERMINATE ITS PARTICIPATION IN THE DEVELOPMENT OF A COLLABORATION COMPOUND OR COLLABORATION PRODUCT FOR SAFETY OR TOLERABILITY REASONS.
- (a) In the event material issues regarding the Safety or Tolerability of a Collaboration Compound or Collaboration Product arise during the Development thereof, each Party shall have the right to terminate its participation in worldwide Development of such Collaboration Compound or Collaboration Product as provided below in Section 4.8 (b). A Party's decision to terminate its participation in Development of a particular Collaboration Compound or Collaboration Product shall be in its own discretion.
- (b) In the event one Party's participation in Development of a Collaboration Compound or Collaboration Product is terminated pursuant to this Section 4.8, then (i) such termination shall be effective thirty (30) days following the date of receipt of written notice by the non-terminating Party of the terminating Party's decision to terminate its participation, (ii) the terminating Party shall not be responsible for any Research and Development Expenses related to such Collaboration Compound or Collaboration Product after the date the termination is effective, (iii) the non-terminating Party may thereafter proceed independently with research, development and/or commercialization of the

compound or product in question as an Independent Product, either alone or in conjunction with Third Parties and (iv) the terminating Party shall, to the extent not previously granted under this Agreement or the License Agreement, (1) grant exclusive licenses (even as to the granting Party) under Amylin Patents or HMR Patents, as applicable, Joint Patents and know-how Controlled by such Party to the non-terminating Party for continued research, development and/or commercialization of the compound or product in question, (2) shall transfer any related Drug Approval Applications or Regulatory Approvals (including transfer of all relevant data and information relevant to Regulatory Authorities) to the non-terminating party, and (3) otherwise cooperate to enable the non-terminating Party under this Section 4.8 to continue said research, development and/or commercialization. In the event a termination of participation in Development of a Collaboration Compound or Collaboration Product occurs under this Section 4.8, (i) ten (10) years from the first commercial sale of such Independent Product in such country and (ii) the expiration of the last to expire of any issued patents covering such Independent Product in any relevant country; provided, however, that such Collaboration Compound or Collaboration Product may not be so independently developed or commercialized for any indication for which a Collaboration Product or Royalty-Bearing Product is being (i) Developed, (ii) Commercialized, or (iii) Developed and/or Commercialized, in all cases in at least two Major Market Countries at the time the termination under this Section 4.8(b) became effective for any Collaboration Compound or Collaboration Product. Royalty payments, if any, due under this Section 4.8(b) shall be paid in accordance with the provisions of Section 6.6.

- (c) The rights set forth in this Section 4.8 to terminate participation in Development of a particular Collaboration Compound or Collaboration Product for Safety or Tolerability reasons shall be separate from, and in addition to, the right to terminate this Agreement pursuant to Article

## ARTICLE V

# COMMERCIALIZATION

# 5.1 RESPONSIBILITIES OF THE JCC.

(a) The purpose of the JCC shall be to (i) oversee the Commercialization of Collaboration Products in the Profit-Sharing Territory, including the planning, annual budgeting, commercial manufacturing, marketing, sales and distribution and sublicensing of Collaboration

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Products, (ii) monitor, review and comment on costs incurred by the Parties in the commercial manufacture, marketing, sale and distribution of Collaboration Products, (iii) review and comment on the Commercialization Plans and Launch Plans and the selection of trademarks for Collaboration Products, (iv) receive and provide to the Parties all sales, pricing, and financial reports pertaining to Pre-Marketing and Commercialization of Collaboration Products, (v) recommend to the JDC the principal indications and delivery routes for all Collaboration Products, (vi) review and comment on HMR's pricing recommendations prior to submission of such to the Steering Committee pursuant to Section 5.11, (vii) review and comment on HMR's manufacturing recommendations prior to submission of such to the Steering Committee pursuant to Section 8.1, and (viii) facilitate the flow of Information with respect to the Commercialization of each Collaboration Product. Subject to the provisions of Section 5.1(b) regarding Excepted Commercialization Matters, HMR shall make the final decision on all matters relating to the Commercialization of any Collaboration Product, including all day to day decisions.

- (b) Decisions of the JCC shall require a majority vote of all members of the JCC. If the JCC is unable to obtain a majority affirmative vote as to any matter involving Commercialization, the decision of HMR will be final and determinative, so long as such decision does not contradict or modify the terms of this Agreement, except with regard to (i) a decision to recall a Collaboration Product, which shall be decided pursuant to Section 5.12, (ii) a dispute related to pricing of a Collaboration Product, which shall be referred to the executive officers of the Parties pursuant to Section 5.11, (iii) a dispute related to manufacturing of a Collaboration Product, which shall be referred to the executive officers of the Parties pursuant to Article XII of the License Agreement, or (iv) a Third Party promotion support arrangement for a Collaboration Product which also involves the promotion support of a non-Collaboration Product(s), which must be approved by the Steering Committee pursuant to Section 5.3(a) (collectively, the "Excepted Commercialization Matters").
- (c) The JCC will have the power to form subcommittees with appropriate representation from Amylin, HMR and appropriate Third Parties; provided, however, that any Third Party members of such a subcommittee must be approved by Amylin.
- (d) During clinical trials for any Collaboration Products, the JCC shall coordinate with the JDC to assure a smooth transition from Development to Commercialization.
- (e) The JCC shall not be involved with the commercialization of (i) Independent Products or (ii) Royalty-Bearing Products in any Royalty-Bearing Countries.

# 5.2 HMR AS LEAD MARKETING PARTY.

(a) HMR will be the lead marketing party with respect to all Collaboration Products and, as a result, shall be obligated and responsible for carrying out Commercialization pursuant to each Commercialization Plan. HMR will assemble its product team and commence

reporting to the JCC within sixty (60) days following the Effective Date. Amylin agrees to carry out the Commercialization tasks referred to in Section 5.2(b) and such other Commercialization tasks as are reasonably requested by HMR and accepted by Amylin.

- (b) It is recognized that the Parties bring particular strengths to the ongoing Commercialization of Collaboration Products. HMR will assign to Amylin a role in Commercialization functions and activities, both during Development and following Collaboration Product launch, as follows:
  - (i) it is anticipated by the Parties that from the Effective Date throughout the marketing of Collaboration Products, Amylin will provide members for the HMR product teams, participating in the development of all strategies and performing activities relating to the following marketing functions as part of the Commercialization Plans and Launch Plans in the Core Dossier Countries:

Medical Symposia
 Scientific Exhibits
 Opinion Leader Program Development
 Medical Education Program Development;

- (ii) furthermore, in preparation for, but at least twelve (12) months prior to, product launch of the first Collaboration Product hereunder in the first Core Dossier Country, Amylin will provide a small (not to exceed one hundred (100) persons) dedicated field force of experienced, scientifically competent "Medical Liaison Officers"; and
- (iii) Amylin's activities will be performed in accordance with each approved Commercialization Plan and Commercialization Budget and each approved Launch Plan and Launch Budget. All other marketing activities that have not been assigned to Amylin will be the responsibility of HMR, unless determined otherwise by the JCC

# 5.3 RIGHT TO ENGAGE THIRD PARTIES.

(a) If HMR determines that it needs promotion support in the Profit Sharing Territory and Amylin does not provide it, or HMR determines Amylin is not reasonably capable of providing it, then HMR may contract for additional promotion support from a Third Party. In such event, the Parties will consult prior to the engagement of a Third Party. The costs of engaging such Third Party will be a Royalty Expense (as defined in Exhibit A). Any other use of a Third Party, such as the sublicensing of a Third Party with respect to co-marketing and/or co-promotion in the Profit Sharing Territory, must be approved by the Steering Committee as described in Section 3.4, except to the extent such arrangements either directly or indirectly also

involve the marketing, promotion, co-marketing and/or co-promotion of non-Collaboration Products. To the extent any non-cash consideration is conveyed to either Party as part of any arrangement under this Section 5.3, the other Party shall be made whole.

- (b) In the event that HMR decides not to market a Collaboration Product in a country, the Parties will consider whether it is desirable to license a Third Party to market in such country, and only if both Parties so agree, the Parties, through HMR with full participation by Amylin, shall attempt to license such rights to a Third Party. Royalties received under this provision, if any, shall be included in Net Sublicense Revenues.
- 5.4 COMMERCIALIZATION EFFORTS. Each Party agrees to exert the efforts necessary and reasonable to execute and substantially carry out the Commercialization Plans and Launch Plans within the Commercialization Budgets and Launch Budgets and to cooperate with each other in carrying out the Commercialization Plans. In addition, with regard to the determination of all pricing, sampling and discount strategies for Collaboration Products, HMR shall use a similar and no less rigorous approach as that used by it in determining such strategies for its own pharmaceutical products of comparable market potential.

# 5.5 COMMERCIALIZATION PLAN AND COMMERCIALIZATION BUDGET.

- HMR shall develop a commercialization plan (the "Commercialization Plan") for each Collaboration Product, which shall include but not be limited to (i) global demographics and market dynamics, Major Market Country market strategies, estimated country launch dates, a worldwide sales and expense forecast (including at least three (3) years of estimated sales and expenses, manufacturing plans and expected product profile based upon the Research and Development Plan, (ii) a market plan (including pricing strategies pertaining to discounts, samples and Nominal Price sales) for the United States, which will serve as a strategic reference for other market plans for countries such as Germany, the United Kingdom, France and Japan (it being understood that such market plans will evolve over time and shall be similar to existing market plans developed at such time by HMR for pharmaceutical products with comparable market potential), and (iii) a commercialization budget ("Commercialization Budget") for each Collaboration Product for all applicable countries so determined by HMR (but at a minimum, the countries covered by the then current Research and Development Plan), including the Third Parties to be utilized and the arrangements with them that have been or are proposed to be agreed upon. Each Commercialization Budget shall include a budget of the expenses expected to be incurred in connection with performing the Commercialization Plan, including Pre-Marketing Expenses and Allowable Expenses in each applicable country.
- (b) The first Commercialization Plan shall be in the form of an initial outline and the first Commercialization Budget shall be in the form of an estimated budget. The JCC shall submit such outline of the first Commercialization Plan and such estimated Commercialization Budget to the Steering Committee for review and approval no later than six

(6) months following the Effective Date. It is understood that such outline and estimate may contain open issues and identify areas wherein more information is needed to complete the outline and estimated budget and to prepare a more complete Commercialization Plan and Commercialization Budget. Thereafter, by October 1 of each subsequent year, HMR, after taking into consideration Amylin's comments, will prepare a Commercialization Plan for submission by the JCC to the Steering Committee for review and a Commercialization Budget for submission by the JCC to the Steering Committee for review and approval. Notwithstanding anything in this Agreement to the contrary, the Commercialization Budget shall be approved by the Steering Committee no later than October 31 of each year. For any subsequent Collaboration Products, HMR shall prepare and the JCC shall submit an outline of an initial Commercialization Plan for each such Collaboration Product to the Steering Committee for review and an estimated Commercialization Budget for review and approval no later than six (6) months after any Collaboration Compound is designated a Collaboration Product. Each such Commercialization Plan and Commercialization Budget shall be updated and refined on each subsequent October 1 as described above in connection with Collaboration Compounds. Any significant change in any Commercialization Plan or Commercialization Budget during the course of the year will be communicated promptly to the JCC. In addition, HMR shall provide an update of each Commercialization Plan and Commercialization Budget to the JCC in a manner consistent (with respect to timing and content) with such updates as are reported internally by HMR on its existing pharmaceutical products of comparable market potential.

#### 5.6 LAUNCH PLAN.

- (a) Each Commercialization Plan shall be updated, in advance of the launch of the applicable Collaboration Product in each country as the JCC determines is appropriate, to include a Launch Plan and Launch Budget for such launch and the twelve (12) month period following the launch date for such Collaboration Product. Each such Launch Plan and Launch Budget shall be developed by HMR, after taking into consideration Amylin's comments, and presented to the JCC for Launch Plan and Launch Budget review and approval and to the Steering Committee for Launch Budget approval, with HMR having the final decision at the JCC and Steering Committee as described in Section 3.4. The Steering Committee shall have sixty (60) days to review and approve such Launch Budget. If the Steering Committee is unable to approve the Launch Budget within such sixty (60) day period, the Launch Budget shall be submitted to the Parties' executives as provided for in Article XII of the License Agreement.
- (b) It is understood by the Parties that determining a date for Regulatory Approval and thus a launch date is difficult. The failure to accurately estimate the launch date shall not constitute a breach hereunder. As a result of this uncertainty, the JDC shall estimate for each country a realistic date for Regulatory Approval, and the JCC will use this estimated date to submit its Launch Plan and Launch Budget at least twelve (12) months prior to the estimated Regulatory Approval date, to the Steering Committee. By October 1 of each calendar year thereafter, if not yet executed, each Launch Plan and Launch Budget for each Collaboration

Product shall be updated by HMR and the updated Launch Budget shall be s by the JCC for approval by the Steering Committee.

- (c) Each Launch Plan shall include (i) updated marker sales forecasts in units and estimated revenues of Collaboration Product estimated resource requirements and (iii) such other matters deemed approby HMR.
- (d) Each Launch Budget shall include a breakdown of individual Allowable Expense items expected to be incurred in connection with performing the applicable Launch Plan. It is understood that there will not necessarily be a separate Launch Plan and Launch Budget for each country in which a Collaboration Product launch is planned, but that estimated launch dates, Launch Budgets and Launch Plans for each country in which a launch is planned may be incorporated into one or more comprehensive Launch Plans and Launch Budgets.
  - 5.7 ELECTION BY AMYLIN OF ROYALTY-BEARING COUNTRIES.
- (b) Subject to Sections 7.3, 11.2 and 11.3, the Commercialization of Royalty- Bearing Products shall be conducted independently by HMR.
- 5.8 ADVERTISING AND EDUCATION. HMR, after consultation with the JCC, will assign to the Parties, their Affiliates or any Third Party the preparation of advertising and education materials. Such materials shall be subject to prior review and comment by Amylin and HMR, which review and comment by Amylin and HMR shall be completed within thirty (30) days after receipt of such materials by Amylin and HMR. With respect to written and visual promotional or educational materials, to the extent such materials identify or otherwise make reference to either of the Parties, Amylin and HMR shall both be presented and described with equal prominence, as permitted by the applicable laws and regulations of each country in which such materials are to be presented. All product labeling, documentary information, promotional

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material and oral presentations (where practical) regarding the detailing and promoting of Collaboration Products shall display the names and logos of Amylin and HMR with equal prominence. All advertising and education and training materials for use in a country must also be approved in advance by the Party holding the relevant Drug Approval Application or responsible for the Regulatory Approval for such country, as necessary to ensure such Party's compliance with all applicable Regulatory Approvals. Such approval or disapproval shall be given by the Party within thirty (30) days after receipt of such advertising and education and training materials.

- Pre-Marketing Expenses; provided, however, that HMR will fund all Pre-Marketing Expenses for the first Collaboration Product. Amylin's 50% share of such Pre-Marketing Expenses for the first Collaboration Product shall be reimbursed by Amylin to HMR from its share of Operating Profits as provided in Section 6.2(b). In this regard, a written accounting of Pre-Marketing Expenses incurred by Amylin within a Commercialization Plan and Budget shall be submitted by Amylin to HMR within twenty (20) days of the end of each calendar quarter and within thirty (30) days of the end of each calendar year in which such expenses were incurred. HMR will repay Amylin within thirty (30) days of its receipt of such written accounting. Notwithstanding anything in this Agreement to the contrary, in the event that greater than 50% of the voting stock or substantially all of the assets of Amylin are acquired by (i) an entity with a market capitalization equal to or in excess of \$2.5 billion in publicly traded stock or (ii) a privately held entity with annual sales in excess of \$1 billion, then HMR's obligation to fund all Pre-Marketing expenses for the first Collaboration Product pursuant to this Section 5.9 shall terminate and be of no further effect.
- 5.10 TRAINING PROGRAM. HMR will develop adequate training programs for personnel involved in the Commercialization of Collaboration Products and/or Royalty-Bearing Products. Amylin shall play an appropriate role, as determined by the JCC, in the preparation of such training materials and conduct of training; provided, however, that Amylin shall not be involved in the preparation of training materials or the conduct of training with respect to Royalty-Bearing Products in a Royalty-Bearing Country or HMR's Independent Products. HMR shall submit to Amylin for its review all training materials, which review shall be completed within thirty (30) days of receipt of such materials by Amylin. The Parties agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy. Training shall be carried out at a time which is determined by HMR, and which is prior to but reasonably near the date on which Regulatory Approval is expected. The costs of transporting, housing and maintaining personnel to be trained, and the preparation of materials, shall be deemed to be Pre-Marketing Expenses or Marketing Expenses, as the case may be.
- 5.11 PRICING, PRICING APPROVALS AND PRODUCT DISTRIBUTION. If Amylin does not agree with the recommended price proposed by HMR with respect to a Collaboration Product, it may, within ninety (90) days following receipt of such recommended price from HMR, prepare

its own analysis of the market potential and recommended price for such Collaboration Product and present such analysis and recommendation to Steering Committee. If the Steering Committee is unable to agree on the for such Collaboration Product within sixty (60) days after receipt of and, if applicable, Amylin pricing recommendations, whichever is late analyses and recommendations of both Parties will be referred to a jo executive review panel composed of the Chief Executive Officer of Amylin — HMR's Chief Operating Officer. If this joint executive review panel is unable to agree on a price after reviewing the submissions from Amylin and HMR within thirty (30) days following receipt of such recommendations, then HMR shall set the applicable prices, which shall be somewhere between the prices proposed by each Party. The above described mechanism shall be the sole method for resolving disputes as to price(s) and shall not be subject to dispute resolution pursuant to Article XII of the License Agreement. HMR shall obtain for Collaboration Products such pricing approvals as may be required by, and arrange for distribution of each Collaboration Product in, each applicable country of the Profit Sharing Territory.

- 5.12 PRODUCT RECALLS. As an exception to the general authority of HMR under this Article V, if HMR commences an internal product quality investigation, it shall promptly notify and consult with Amylin regarding such investigation. Further, if either Party believes that a recall of a Collaboration Product is necessary, such Party shall notify and consult with the other Party within two (2) working days of its determination, and both Parties shall cooperate to allow such recall to occur under the direction of the Steering Committee. In the event of a dispute about whether to recall a Collaboration Product, such recall shall occur.
- 5.13 TAX CONSIDERATION. Either Party may take advantage of tax considerations which benefit it and not the other Party. In the event that a Party takes advantage of a tax consideration which benefits it and not the other Party takes advantage of a tax consideration which benefits it and not the other Party, no compensation to the other Party is required unless such affects the other Party's Operating Profits or Losses negatively, in which case compensation shall be provided to the other Party to make it whole. To the extent such negative impact on one Party's Operating Profits or Losses results from the manufacture of a Collaboration Product, such impact shall be addressed in the manner described in Section 8.1.
- 5.14 DISCOUNTED SALES. It is possible that Collaboration Products could be included as part of a multiple product offering to customers by HMR, and, at times, discounts may be offered independently. In the event that any Collaboration Products are offered along with other HMR products, the effect of the potential discounts may not impact the Average Net Selling Price below \*\*\*\* of the Ex-Manufacturer Selling Price in any given country. In the event that planned or executed discounting activities related to any Collaboration Product (pursuant to which such Collaboration Product is sold by HMR in combination with one or more non-Collaboration Products in any given country) as measured on a quarterly basis will reduce the Average Net Selling Price below \*\*\*\* of the Ex-Manufacturer Selling Price in any given country, HMR shall present an analysis of such discounting forecasts and activities to the JCC for review and comment. Such analysis will include all appropriate information for such Collaboration Product
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#### 6.2 PAYMENT.

- Subject to Section 6.2(b), within twenty (20) days of (a) the end of each of the first three calendar quarters and within thirty (30) days of the end of the fourth calendar quarter of each year following the launch of each Collaboration Product in a country, Amylin shall report to HMR and the JCC as outlined in Exhibit B, its revenues and individual Allowable Expense items (with appropriate supporting information) involved in the computation of Operating Profits or Losses and recognized during such quarter with respect to each such Collaboration Product. Within ten (10) days after receipt of such report, HMR shall provide for each Collaboration Product one worldwide consolidated Financial Statement and individual Financial Statements for each country in the Profit Sharing Territory to the JCC, and the JCC shall promptly direct the remittance between the Parties of an Equalization Payment with respect to each Collaboration Product. The reports and Equalization Payments for the fourth quarter of the fiscal year may include reconciliations and year-end adjustments with respect to previous quarters. The payment required by this Section 6.2(a), together with interest accrued from the end of each calendar quarter (to be paid at the commercial paper rate for high grade unsecured notes sold through dealers, as quoted in the Wall Street Journal on the last day of each such quarter), shall be made in any event within thirty (30) days of the due date of the receipt of reports described in the first sentence of this Section 6.2(a).
- 6.3 TERM. The Parties shall share Operating Profits or Losses hereunder with respect to each Collaboration Product in each Profit Sharing Territory until each such Collaboration Product is permanently withdrawn from and is no longer being sold anywhere in the relevant Profit-Sharing Territory.

# 6.4 ROYALTY-BEARING PRODUCTS.

(a) HMR shall pay to Amylin the applicable running royalty, as set forth in Section 5.7(a), on Royalty-Bearing Sales for Royalty-Bearing Products, if any.

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royalties to be paid to Amylin on Royalty-Bearing Sales for Royalty-Bearing Products shall be paid in accordance with the provisions of Section 6.6, on a country-by-country basis, from the date of the first commercial sale of each Royalty-Bearing Product in a particular country until the later of (i) ten (10) years from the first commercial sale in such country or (ii) the last to expire of any (1) Amylin Patents or (2) HMR Patents or Joint Patents, as applicable, which covers use or sale of the Royalty-Bearing Product in such country, subject to the following:

Notwithstanding anything in this Section 6.4 to the contrary, the aggregate reduction of royalties set forth in Subsections (i) and (ii) of this Section 6.4 (b) and in Section 9.4 of this Agreement shall not reduce the net royalty amount payable—under this Section 6.4 by more than

- (c) HMR may discontinue Commercialization of a Royalty-Bearing Product at any time in its sole discretion.
- sublicenses to others to make or sell Royalty-Bearing Products, or in the event either Party grants licences or sublicenses to others to make or sell royalty-Bearing Products, or in the event independent Products, such licenses or sublicenses shall include an obligation for the licensee or sublicensee to account for and report its Royalty-Bearing Sales of such Royalty-Bearing Products and/or Independent Products on the same basis as if such sales were Royalty-Bearing Sales by the Party, and such Party shall pay royalties to the other Party as if the Royalty-Bearing Sales of the sublicensee were Royalty-Bearing Sales of the Party granting the license or sublicense.

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- ROYALTY PAYMENTS AND REPORTS. A report summarizing the Royalty-Bearing Sales of any Royalty-Bearing Products and/or Independent Products during the relevant quarter shall be delivered to the receiving Party within twenty (20) days following the end of each calendar quarter and within thirty (30) days following the end of each calendar year for which royalties are due from the selling Party. Royalty payments under this Agreement shall be made to the receiving Party or its designee quarterly within thirty (30) days following the due date for the report as set forth in the first sentence of this Section 6.6.
- 6.7 TAXES. The Party receiving royalties shall pay any and all taxes levied on account of royalties it receives under this Agreement. If laws or regulations require that taxes be withheld, the Party paying royalties will (i) deduct those taxes from the remittable royalty, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of payment to the other Party within thirty (30) days following such payment.
- 6.8 BLOCKED CURRENCY. In each country where the local currency is blocked and cannot be removed from the country, at the election of the selling Party, royalties or the other Party's share of Operating Profits or Losses accrued in that country shall be paid to the appropriate Party in the country in local currency by deposit in a local bank designated by the receiving Party.
- 6.9 PAYMENTS TO OR REPORTS BY AFFILIATES. Any payment required under any provision of this Agreement to be made to either Party or any report required to be made by any Party shall be made to or by an Affiliate of that Party if designated by that Party as the appropriate recipient or reporting entity.
- 6.10 NO OVERLAPPING ROYALTIES. Notwithstanding any other provision of this Agreement to the contrary, in no event shall any royalty payment provided for under any Section of this Agreement be paid with respect to any sale of an Independent Product or Royalty-Bearing Product to the extent a royalty-payment has been paid pursuant to any other Section of this Agreement with respect to such sale; provided, however, that in the event of such overlapping royalty provisions, the highest royalty rate provided for such sale in this Agreement shall be the applicable royalty rate for such sale.

#### ARTICLE VII

#### LICENSES

- 7.1 LICENSES TO HMR TO CONDUCT RESEARCH AND DEVELOPMENT.
- (a) Subject to the terms of this Article VII, Amylin grants to HMR an exclusive (except as to Amylin) paid-up, worldwide license under the Amylin Patents, Amylin

Data and Amylin Know-how to conduct Research and Development with respect to Collaboration Products and Royalty-Bearing Products in accordance with the terms of this Agreement and an exclusive (even as to Amylin) paid-up, worldwide license to conduct Research and Development with respect to Independent Products in accordance with the terms of this Agreement.

- (b) A list of the Amylin Patents identified as of the Effective Date is attached hereto as Exhibit C. Amylin shall promptly notify HMR, and such Exhibit C shall be expanded from time to time, to reflect any changes to Amylin Patents, any Amylin Patents hereafter identified and/or to include any other Amylin Patents.
- 7.2 LICENSES TO HMR TO CONDUCT COMMERCIALIZATION. Subject to the terms of this Article VII, Amylin grants to HMR an exclusive (except as to Amylin) worldwide license under the Amylin Patents, Amylin Data and Amylin Know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Collaboration Products and Royalty-Bearing Products in accordance with the terms of this Agreement and an exclusive (even as to Amylin) worldwide license under the Amylin Patents, Amylin Data and Amylin know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Independent Products in accordance with the terms of this Agreement. Such licenses with respect to Royalty-Bearing Products and Independent Products shall be subject to royalty payments as provided in Sections 5.7 and 4.8, respectively.
- 7.3 LICENSE TO AMYLIN TO CONDUCT COMMERCIALIZATION. Subject to the terms of this Article VII, HMR grants to Amylin an exclusive (even as to HMR) worldwide license under the HMR Patents, HMR Data and HMR Know-how to conduct Commercialization (including the right to make, have made, use, import, sell, offer for sale and have sold) with respect to Independent Products in accordance with the terms of this Agreement. Such license shall be subject to royalty payments as provided in Section 4.8.
- 7.4 SUBLICENSING. During the term of this Agreement, neither Party may grant sublicenses of Joint Patents or Patents owned or Controlled by the other Party except with the express prior written approval of the other Party; provided, however, that (i) either Party may proceed with distribution and sale of a Collaboration Product through its usual and customary distributors performing their usual and customary distribution activities for such Party in accordance with this Agreement without the other Party's prior written approval of any necessary sublicenses in connection therewith, and (ii) in the case of Royalty-Bearing Products or Independent Products, the Party having a license with respect to such Products without approval of the other Party.

# 7.5 THIRD PARTY TECHNOLOGY.

- (a) The licenses granted under Sections 7.1, 7.2 and 7.3 may include sublicenses of Third Party technology. Any royalty amounts payable to Third Parties in connection with sales of Products shall be considered a Royalty Expense (as defined in Exhibit A) with respect to the sale of Collaboration Products and in any event shall be offset against any royalty amount owed with respect to the sale of Royalty-Bearing Products and Independent Products, as provided under Section 6.4(b)(ii).
- (b) The licenses granted under Sections 7.1, 7.2 and 7.3, to the extent they include sublicenses of Third Party technology, shall be subject to the terms and conditions of the license agreement pursuant to which the sublicense is granted.
- becomes aware of technology of a Third Party that would be valuable to the Development or Commercialization of Collaboration Products, the JDC will determine whether such technology should be brought into the collaboration contemplated by this Agreement and the cost of acquiring such technology shall be borne equally by the Parties. In the event that such acquired technology results in the payment of Third Party royalties, such royalties shall be a Royalty Expense with respect to the sale of Collaboration Products, and offset against any royalty owed with respect to the sale of Royalty-Bearing Products and Independent Products, as provided under Section 6.4(b)(ii).

# ARTICLE VIII

# MANUFACTURE AND SUPPLY

- 8-1 MANUFACTURE AND SUPPLY DURING DEVELOPMENT. Amylin will be responsible for manufacture of Collaboration Products for use during the Development of Collaboration Products. Payments to Third Party manufacturers for such manufacture of Collaboration Products and related costs will be included in Research and Development Expenses for purposes of Article IV. As used in this Article VIII, "manufacture" shall mean manufacture of Collaboration Products in bulk form or finished form.
- 8.2 MANUFACTURE AND SUPPLY DURING COMMERCIALIZATION. HMR shall be responsible for arranging for the commercial manufacture of Collaboration Products in such a manner as to achieve and maintain a substantially competitive Cost of Goods Sold and to assure quality control and quality assurance as stringent as such quality control and quality assurance standards used by HMR in the manufacture of its other pharmaceutical products of comparable market potential, continuity and security of supply, compliance with cGMP, compliance with all applicable regulatory requirements, and other terms and conditions of supply which best serve the interests of the collaboration contemplated by this Agreement. Such manufacturer(s) may

include either or both of the Parties as well as Third Parties. To enable the transfer of manufacturing to Amylin in situations under this Agreement where HMR is obligated to do so, with respect to all contracts entered into by HMR with a Third Party relating to the manufacture of Collaboration Products, HMR shall use commercially reasonable efforts to include a provision permitting the assignment of such contract to Amylin on the same terms for at least three (3) years. In selecting one or more manufacturers, the goals set forth in the first sentence of this paragraph shall take precedence over the consideration of whether one Party or the other then has unused or excess manufacturing capacity. Any selection of manufacturers for Commercialization shall be subject to the rights of any Third Parties existing at the time such determination is made.

(b) To the extent the Steering Committee decides that HMR or Amylin, as the case may be, should manufacture such Collaboration Product and the "make versus buy" analysis described in Section 8.2(a) shows one or more of the alternative manufacturers with quality control and quality assurance standards and Manufacturing Attributes reasonably acceptable to both Parties to be less expensive, the Steering Committee shall determine whether HMR or Amylin, as the case may be, should increase the Equalization Payment due to the other Party or decrease the Equalization Payment due from the other Party, as the case may be, each quarter by half the amount of such difference to make the other Party whole.

- (c) To the extent HMR or Amylin, as the case may be, manufactures such Collaboration Product pursuant to this Section 8.2, then at least once every three (3) years, the Party performing the manufacturing shall present to the JCC a review and analysis of the manufacturing cost elements identified in Section 8.2(a) to determine if the then current manufacturing arrangements are substantially competitive with other manufacturing alternatives at such time. Following such review and analysis, no change will be made to the Equalization Payment adjustment as described in Section 8.2(b).
- 8.3 QUALITY CONTROL, QUALITY ASSURANCE, ETC. During the term of this Agreement, HMR shall have day to day responsibility for commercial manufacturing and formulation issues related to product safety and regulatory compliance. Amylin shall provide technical support reasonably required by HMR or Third Parties for such manufacture of Collaboration Products.

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of providing on-going post-launch technical support shall be an The cos: Expense under Post-Launch Product R & D Expenses (as defined in Allowat . Regardless of the parties selected to manufacture the Collaboration Exhibit each of the Parties shall have rights of inspection and audit as Product. or reasonable to enable it to comply with its internal quality control necessa y assurance and reporting obligations, including those imposed by and qua authorities. In addition, before a final commitment is made to any regulat Parties or to any Third Party regarding manufacturing plant decisions, Party c ies shall have the right to perform plant quality assurance audits. both Pa

- PROVISIONS FOR THE MANUFACTURE OF COLLABORATION PRODUCTS. If a manufacturing and supplying the Collaboration Products pursuant to Party i .2, such Party shall be entitled to recover as an Allowable Expense Section y's Cost of Goods Sold for Collaboration Products so supplied, upon the such Pa uch Collaboration Products according to its standard accounting is consistently applied within and across its pharmaceutical operating proced: matching revenues with costs of products sold for pharmaceutical units : with a comparable market potential. In the event a Party would obtain a product it from such manufacture of Collaboration Products in a particular tax ber ion, such tax benefit shall be treated as described in Section 5.13. jurisd:
- TECHNOLOGY TRANSFER IN EVENT OF TERMINATION BY HMR. In the event n termination by HMR of this Agreement, HMR is manufacturing in whole that, ' t one or more Collaboration Products or Royalty-Bearing Products under or in cle VIII, then HMR shall continue to provide for such manufacture of this A. aboration Products and Royalty-Bearing Products to the extent provided such C notice of such termination, from the time notice of such termination is prior until such time as Amylin is able to secure an equivalent alternative provid ring source, in the event that Amylin is unable to secure such an manufa ve source during the notice period. To this end, as of the effective altern such termination, all Third Party manufacturing contracts that are date o e shall be assigned to Amylin, and the cost charged to Amylin by HMR assign. of the internal manufacturing activities to be continued by HMR pursuant for an Section 8.5 for the production of Collaboration Products and to thi Bearing Products shall be the same as HMR's cost during the time that Royalt ement was in effect; provided, however, that HMR may receive a profit the Ag internal manufacturing activities relating to such Products at a rate of for it \*\*\*\* upon Amylin's request, HMR shall provide such technical assistance and Furthe licenses on a royalty free basis as may reasonably be requested to know-h such technology needed by Amylin to commence or continue manufacture of transf ation Products and Royalty-Bearing Products. Collab
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Such technical assistance shall be provided at HMR's cost, which cost shall be reimbursed by Amylin within thirty (30) days after receipt of an invoice for such cost by Amylin.

#### ARTICLE IX

# ENFORCEMENT OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

# 9.1 GENERAL ENFORCEMENT RIGHTS.

With respect to infringement of any of the Amylin Patents or any of the Joint Patents by a Third Party through the manufacture, import, use, sale or offer for sale of a product competitive with a Collaboration Product being Developed or Commercialized under this Agreement, except as provided in Section 9.5(a) ("Competitive Product Infringement"), Amylin shall have the right to institute, prosecute and control any action or proceeding with respect to such infringement (with HMR having the right to participate in such action and be represented if it so desires by counsel of its own selection) and, if necessary, HMR agrees to be joined as a party plaintiff and to give Amylin reasonable assistance and any needed authority to control, file and prosecute such action. Amylin's and, if any, HMR's costs related to patent enforcement (including internal costs and expenses specifically attributable to said patent enforcement) and related recoveries with respect to Competitive Product Infringement shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. With respect to infringement of any of the HMR Patents by a Third Party through Competitive Product Infringement, HMR shall have the right to institute, prosecute and control any action or proceeding with respect to such infringement (with Amylin having the right to participate in such action and be represented if it so desires by counsel of its own selection) and, if necessary, Amylin agrees to be joined as a party plaintiff and to give HMR reasonable assistance and any needed authority to control, file and prosecute such action. The Parties shall consult with each other regarding the institution, prosecution and control of any action or proceeding with respect to any infringement of any of the HMR Patents, other than Competitive Product Infringement. In the absence of agreement with respect to such infringement, each Party may proceed in such manner as the law permits. HMR's and, if any, Amylin's costs related to patent enforcement (including internal costs and expenses coedifically attributable to acid attack. expenses specifically attributable to said patent enforcement) and related recoveries with respect to Competitive Product Infringement shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. In this regard, if it is believed in good faith that any Amylin Patents, HMR Patents, or Joint Patents are infringed by a Third Party through the manufacture, import, use, sale or offer for sale of a product competitive with a Collaboration Product the Party first having knowledge of such infringement shall promptly notify the other Party in writing thereof, which notice shall set forth the facts of such infringement in reasonable detail. If Amylin or HMR, as the case may be, fails to institute and prosecute an action or proceeding to abate the infringement within a period of ninety (90) days after receiving written notice or otherwise having knowledge of the infringement, then the other

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Party shall have the right, but not the obligation, to bring and prosecute any such action and the Party which failed to bring such action agrees to be joined as a party plaintiff and to give the Party bringing such action reasonable assistance and all authority to control, file and prosecute the suit as may be necessary; provided, however, that the Party which failed to bring such action shall have the right to participate in such action and to be represented in any such action by counsel of its choice. The Parties' costs of patent enforcement (including internal costs and expenses specifically attributable to said patent enforcement) and related recoveries with respect to actions brought under this paragraph shall be treated as Allowable Expenses and Net Sublicense Revenues, respectively. Any recovery of damages and costs in such action referred to in this Section 9.1(a) shall be apportioned between the Parties as follows: (i) the Party bringing suit shall first recover from any such award an amount equal to the cost and expense incurred by such Party and (ii) the remainder, if any, shall be divided equally by the Parties.

- (b) No settlement or consent judgment or other voluntary final disposition of suit under this Section 9.1 may be entered into without the joint consent of Amylin and HMR.
- DEFENSE AND SETTLEMENT OF THIRD PARTY CLAIMS AGAINST COLLABORATION PRODUCTS. If a Third Party asserts that a patent or other right owned by it is infringed by the manufacture, import, use, sale or offer for sale of any Collaboration Product, the Party first obtaining knowledge of such a claim shall immediately provide the other Party notice of such claim and the related facts in reasonable detail. In such event, the Steering Committee shall determine how best to control the defense of any such claim. In the event the Parties cannot agree on the defense of any such claim, such defense shall be controlled by HMR; provided, however that Amylin shall have the right to participate in such defense and to be represented in any such action by counsel of its selection at its sole discretion. The entity (whether Amylin and HMR, or HMR only) that controls the defense of a given claim with respect to a Collaboration Product, shall also have the right to control settlement of such claim; provided further, however, that no settlement shall be entered into without the written consent of the other Party. If there is no agreement between the Parties as to any proposed settlement, then the dispute shall be decided by the Steering Committee and if the Steering Committee is unable to decide the dispute, the matter will be resolved pursuant to the dispute resolution provisions of Article XII of the License Agreement. If the dispute is not resolved pursuant to Article XII of the License Agreement, then the case may not be settled.
- 9.3 ALLOCATION OF EXPENSES. The expenses of patent defense, settlement and judgments pursuant to Section 9.2 with respect to Collaboration Products shall be a shared expense of the Parties, except as otherwise expressly provided for in Section 9.2. Such costs which are incurred after the designation of a Collaboration Product for Development but prior to Regulatory Approval shall be borne in the same manner as if such costs were Development Expenses. Such costs which are incurred following launch of the subject Collaboration Product in a Major Market Country shall be an Allowable Expense, reimbursed to the Party incurring such expense.

- 9.4 SETTLEMENT OF THIRD PARTY CLAIMS FOR ROYALTY-BEARING PRODUCTS AND INDEPENDENT PRODUCTS; ROYALTY REDUCTION.
- (a) If a Third Party asserts that a patent or other right owned by it is infringed by any Royalty-Bearing Product, and as a result of settlement procedures or litigation under this Section 9.4, HMR is required to pay the Third Party a royalty or make any payment of any kind for the right to sell a Royalty-Bearing Product in a particular country, the royalty rate for such Royalty-Bearing Product shall be adjusted as recited in Section 6.4(b).
- (b) If a Third Party asserts that a patent or other right owned by it is infringed by any Independent Product, and as a result of settlement procedures or litigation under this Section 9.4), either Party is required to pay the Third Party a royalty or make any payment of any kind for the right to sell an Independent Product in a particular country, the royalty rate for such Independent Product shall be adjusted as recited in Section 6.4(b).
- 9.5 INFRINGEMENT BY THIRD PARTIES WITH RESPECT TO ROYALTY-BEARING PRODUCTS OR INDEPENDENT PRODUCTS.
- If any Amylin Patent is infringed by a Third Party in (a) any country in connection with the manufacture, import, use, sale or offer for sale of a product competitive with one or more Royalty-Bearing Products or Independent Products being marketed by HMR in such country, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail. Amylin shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement of the Amylin Patent, by counsel of its own choice, and HMR shall have the right to participate in such action and to be represented by counsel of its own choice. If Amylin fails to bring an action or proceeding within a period of ninety (90) days after having knowledge of that infringement, HMR shall have the right to bring and control any such action by counsel of its own choice, and Amylin shall have the right to participate in such action and to be represented by counsel of its own choice. be represented by counsel of its own choice. If one Party brings any such action or proceeding, the second Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and authority to control, file and prosecute the suit as necessary. The costs and expenses of the Party bringing suit under this Section 9.5(a) (including the internal costs and expenses specifically attributable to said suit) shall be reimbursed first out of any \*\*\*\*\*\*\* to HMR if Amylin institutes and controls such suit. However, if HMR institutes and controls such suit, any damage recovery shall be treated as Royalty-Bearing Sales and Amylin shall receive a portion of such damages equal to the applicable royalty rate (expressed as a percentage) payable to Amylin on said Royalty-Bearing Sales and all remaining damages shall be distributed to HMR.

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- If any HMR Patent or Joint Patent is infringed by a (b) Third Party in any country in connection with the manufacture, import, use, sale or offer for sale of a product competitive with one or more Royalty-Bearing Products being marketed by HMR, or with one or more Independent Products being marketed by Amylin in such country, the Party to this Agreement first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail. HMR shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement of the HMR Patent or Joint Patent, by counsel of its own choice, and Amylin shall have the right to be represented in that action by counsel of its own choice. If HMR fails to bring an action or proceeding within a period of ninety (90) days after having knowledge of that infringement, Amylin shall have the right to bring and control any such action by counsel of its own choice, and HMR shall have the right to participate in such action and be represented by counsel of its own choice. If one Party brings any such action or proceeding, the second Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and all authority to file and prosecute the suit as may be necessary. The costs and expenses of the Party bringing suit under this Section 9.5(b) (including the internal costs and expenses specifically attributable to said suit) shall be reimbursed first out of any damages or other monetary awards any damage recovery shall be treated as Royalty-Bearing Sales and HMR shall receive a portion of such damages equal to the applicable royalty rate (expressed as a percentage) payable to HMR on said Royalty-Bearing Sales and all remaining damages shall be distributed to Amylin.
- (c) No settlement or consent judgment or other voluntary final disposition of a suit under this Section 9.5 may be entered into without the joint consent-of Amylin and HMR.
- (d) Notwithstanding the provisions of Section 9.1 and this Section 9.5, neither Party shall file and prosecute an action for infringement of a Patent for which the other Party has the primary responsibility to file and prosecute such action, and pursuant to which that other Party having primary responsibility has commenced and is prosecuting at least one such action for infringement of said Patent, without the agreement of that other Party.
- 9.6 COLLABORATION PATENT EXPENSES. Prior to the first commercial sale of a Collaboration Product, Collaboration Patent Expenses shall be borne equally by the Parties. Within thirty (30) days following the end of each calendar quarter, each Party shall deliver a report outlining its Collaboration Patent Expenses for such quarter. Within forty-five (45) days following the end of each such quarter, the Party incurring less than one-half of the aggregate combined total of such reported Collaboration Patent Expense during the quarter shall reimburse the other Party an amount sufficient to equalize each Party's one-half share of such combined

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Collaboration Patent Expenses. Following the first commercial sale of a Collaboration Product, Collaboration Patent Expenses will be treated as an Allowable Expense.

9.7 ASSIGNMENT OF JOINT PATENTS. Neither Party may assign its rights under any Joint Patent except with the prior written consent of the other Party; provided, however, that either Party may assign such rights without consent to an Affiliate or other permitted assignee under this Agreement in connection with a merger or similar reorganization or the sale of all or substantially all of its assets, as provided in Section 15.1(b).

## 9.8 TRADEMARKS.

PRODUCT TRADEMARKS. The JCC shall oversee the selection, 9.8.1 prosecution of applications for, and maintenance of, trademarks in the applicable country for each Collaboration Product and shall designate which of the Parties shall be responsible for the related work. Under the supervision of the JCC, the Parties shall work together and seek to agree on the selection of trademarks for Collaboration Products for use in those countries where the subject trademarked product is to be marketed, whether as a Collaboration Product or as a Royalty-Bearing Product. In the event that the Parties cannot agree on a trademark for any Collaboration Product as a result of said joint selection efforts, HMR shall have the right to present three qualified trademarks that have been identified by the Parties to Amylin, and Amylin shall have the right to refuse any two such trademarks. The remaining trademark shall be the selected trademark for the subject Collaboration Product and shall be owned jointly by Amylin and HMR. To the extent expenses are incurred hereunder prior to the first commercial sale of the applicable Collaboration Product, such expense shall be treated as a Pre-Marketing Expense and thereafter, such expenses shall be treated as Allowable Expenses. Collaboration Products shall be sold under at least one trademark owned jointly by HMR and Amylin. All uses of a jointly owned trademark(s) to identify a Collaboration Product, whether sold as a Collaboration Product or as a Royalty-Bearing Product, shall comply with all applicable laws and regulations, and those laws and regulations particularly applying to the proper use and designation of trademarks in the countries of the Profit Sharing Territory or in Royalty-Bearing Countries, as applicable. Jointly owned trademark(s) shall be used only pursuant to the terms of this Agreement to identify Collaboration Products or Royalty-Bearing Products, and shall not be used by either Party to identify any other products. All jointly-owned trademarks shall be registered by HMR in the names of Amylin and HMR as joint owners in all countries where said marks will be used.

9.8.2 INFRINGEMENT OF TRADEMARKS. HMR shall take all reasonable and appropriate steps to protect, defend and maintain each jointly owned trademark for use by the Parties in connection with a Collaboration Product or Royalty-Bearing Product, and all registrations therefor, and each Party shall notify the other Party promptly upon learning of any actual, alleged or threatened infringement of a jointly-owned trademark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods or like offenses. Upon learning of such offenses HMR shall have the right but not the obligation to, in consultation with Amylin,

institute and control an appropriate action or proceeding to halt the offense. Amylin shall have the right to participate fully in all such actions or proceedings.

9.8.3 COSTS OF DEFENSE. All of the unrecovered costs, expenses and legal fees (including internal costs, expenses and legal fees) in bringing, maintaining and prosecuting any action to maintain, protect or defend a trademark (or registration therefor) covering (i) a Collaboration Product shall be an Allowable Expense in the applicable country or (ii) a Royalty-Bearing Product shall be a deduction from Royalty-Bearing Sales, and any recovery shall be Net Sublicense Revenue in that country.

# ARTICLE X

# REPRESENTATIONS AND WARRANTIES

Each of the Parties hereby represents and warrants to the other Party as follows:

- (a) This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a any agreement, it is bound, nor violate any law or regulation of any court, Party or by which it is bound, nor violate any law or regulation over it.
- (b) Such Party has not, and during the term of the Agreement will not, grant any right to any Third Party relating to its respective Patents and know-how in the Field which would conflict with the rights granted to the other Party hereunder.

# ARTICLE XI

# INFORMATION AND REPORTS

COMMERCIALIZATION. HMR and Amylin will disclose and make available to each other all preclinical, clinical, regulatory, commercial marketing, promotion, pricing, sales and other Information, including copies of all preclinical and clinical reports, known by HMR or Amylin directly concerning Collaboration Compounds or Collaboration Products at any time during the term of this Agreement. All significant Information will be disclosed to the other Party promptly after it is learned or its significance is appreciated. Each Party shall own and maintain its own database of clinical trial data accumulated from all clinical trials of Collaboration Products for which it was responsible and of adverse drug event information for all Collaboration Products. At the option of the requesting information for all Collaboration Products. At the option of the requesting information Party, such data shall be provided in a computer readable format by the providing Party, to the extent available, which shall also assist in the transfer and validation of such data to the receiving Party. Without limitation of the foregoing, each Party shall supply to

the other the Information required by the other Party and requested by it (either as a routine practice or as a specific request) for purposes of compliance with regulatory requirements.

- 11.2 COMPLAINTS. Each Party shall maintain a record of all complaints it receives with respect to any Collaboration Product or Royalty-Bearing Product in accordance with its own established record keeping procedures for pharmaceutical products of comparable market potential. Each Party shall notify the other of any such complaint received by it in sufficient detail and within five (5) business days after receipt, and in any event in sufficient time to allow the responsible Party to comply with any and all regulatory requirements imposed upon it in any country.
- of a Drug Approval Application may be required to submit information and file reports to various governmental agencies on (i) Collaboration Products and Royalty-Bearing Products under clinical investigation, (ii) Collaboration Products and Royalty-Bearing Products proposed for marketing or (iii) marketed Collaboration Products and Royalty-Bearing Products. Information must be Collaboration Products and Royalty-Bearing Products. Information must be submitted at the time of initial filing for investigational use in humans and at the time of a request for market approval of a new Collaboration Product and Royalty-Bearing Product. In addition, supplemental information must be provided on Collaboration Products and Royalty-Bearing Products at periodic intervals and adverse drug experiences must be reported at more frequent intervals depending on the severity of the experience. Consequently, each Party agrees to:
- (a) provide to the other Party for initial and/or periodic submission to government agencies significant information on the Collaboration Product and Royalty-Bearing Product from preclinical laboratory, animal toxicology and pharmacology studies, as well as adverse drug experience reports from clinical trials and commercial experiences with the Collaboration Product and Royalty-Bearing Product;
- (b) in connection with investigational Collaboration

  Products and Royalty-Bearing Products, report to the other Party within

  twenty-four (24) days of the initial receipt of a report of any unexpected or

  serious experience with the drug, if required for either Party to comply with

  regulatory requirements; and
- (c) in connection with marketed Collaboration Products and Royalty-Bearing Products, report to the other Party within five (5) working days of the initial receipt of a report of any adverse experience with the drug that is serious and unexpected or sooner if required for either Party to comply with regulatory requirements. "Serious" adverse experience means any experience that suggests a significant hazard, contraindication, side effect or precaution, or any experience that is fatal or life threatening, is permanently disabling, requires or prolongs inpatient hospitalization, or is a congenital anomaly, cancer or overdose. "Unexpected" adverse experience means an adverse experience not identified in nature, specificity, severity or

frequency in the current investigator brochure or the U.S. labeling for the drug. Each Party also agrees that if it contracts with a Third Party for research to be performed by such Third Party on a Product, that Party agrees to require such Third Party to report to the contracting Party the information set forth in subsections (a), (b), and (c) of this Section 11.3

complete and accurate records which are relevant to revenues, costs, expenses and payments under this Agreement, and such records shall be open during reasonable business hours for a period of five (5) years from creation of individual records for examination at the other Party's expense and not more often than once each year by a certified public accountant selected by the other Party for the sole purpose of verifying for the inspecting Party the correctness of calculations and classifications of such revenues, costs, expenses or payments made under this Agreement. In the absence of material discrepancies (in excess of 5%) in any request for reimbursement resulting from such audit, the accounting expense shall be paid by the Party requesting the audit. If material discrepancies do result, the audited Party shall bear the accounting expense. Any records or accounting information received from the other Party shall be confidential information.

# ARTICLE XII

# TERM AND TERMINATION

12.1 TERM. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the date on which the Parties are no longer developing, marketing or selling in any country (i) a Royalty-Bearing Product or an Independent Product for which, in either case, royalties are or may be owed by one Party to the other Party, or (ii) a Collaboration Product.

# 12.2 TERMINATION FOR MATERIAL BREACH.

- (a) Subject to the provisions of this Section 12.2, if either Party (the "Breaching Party?) shall have committed a Material Breach (as defined below) and such Material Breach shall remain uncured and shall be continuing for a period of ninety (90) days following receipt of written notice thereof by the other Party (the "Non-Breaching Party"), then, in addition to any and all other rights and remedies that may be available, the Non-Breaching Party and la have the right to terminate this Agreement effective upon the expiration of such ninety (90) day period. Any such written notice of alleged Material Breach by the Non-Breaching Party shall include a reasonably detailed description of all relevant facts and circumstances demonstrating, supporting and/or relating to each such alleged Material Breach by the Breaching Party.
- (b) If the Breaching Party, upon written notice delivered to the Non-Breaching Party prior to the expiration of such ninety (90) day period, shall assert in good faith that any

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such alleged Material Breach described in the Non-Breaching Party's notice, whether in payment of moneys or otherwise, was not a Material Breach, or was excused by reason of material failure of performance by the other Party or Third Parties or by reason of Force Majeure (as defined in Section 15.4), or shall otherwise in good faith dispute such alleged Material Breach, then the Parties shall continue to perform under this Agreement, subject to all of its terms and conditions, and the matter shall be resolved pursuant to the dispute resolution provisions of Article XII of the License Agreement. In such event, the Non-Breaching Party shall not be entitled to terminate this Agreement pursuant to this Section 12.2 unless and until (i) it shall be determined pursuant to the dispute resolution provisions of Article XII of the License Agreement that the Breaching Party has committed a Material Breach and (ii) such Material Breach has not been cured prior to such determination. To the extent that it is determined pursuant to a final and non-appealable decision under the dispute resolution provisions of Article XII of the License Agreement that the Breaching Party did commit a Material Breach and failed to cure the same within the period provided for in clause (ii) of this Section 12.2(b), then the Non-Breaching Party may immediately terminate this Agreement and, in addition to all damages determined pursuant to the dispute resolution provisions of Article XII of the License Agreement to be due and owing from the Breaching Party to the Non-Breaching Party under this Agreement, the Breaching Party shall be liable for the Non-Breaching Party's reasonable attorney's fees incurred in connection with resolving such matter.

- (c) If the Non-Breaching Party terminates this Agreement pursuant to the provisions of Sections 12.2(a) and (b), then the following provisions shall apply:
  - extent not already granted in this Agreement or the License Agreement, an exclusive (even as to the Breaching Party but subject to rights of Third Parties that are not Affiliates of the Breaching Party that pre-existed or accrued prior to such termination) worldwide right and license, with the right to grant sublicenses, to all HMR Patents or Amylin Patents, as applicable, of the Breaching Party and all of the Breaching Party's interest in jointly owned trademarks pursuant to Breaching Party's interest in jointly owned trademarks pursuant to Section 9.8.1, to make, have made, import, use, sell, offer for sale and have sold Collaboration Products, Royalty-Bearing Products and Independent Products, subject to the royalty obligations set forth below in Section 12.2(c)(ii), and shall have the exclusive right (but not the obligation) to enforce the Patents against Competitive Product Infringement and the exclusive right (but not the obligation) to enforce the trademark rights against infringers;

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(iii) the provisions of Sections 6.4(b) and 6.5 through 6.10 shall apply with respect to royalties payable under this Section 12.2.

- (d) In the event of termination of this Agreement pursuant to this Section 12.2, the Breaching Party shall use its best efforts to cause the transfer of all INDs, Drug Approval Applications and Regulatory Approvals related to Collaboration Compounds, Collaboration Products, Royalty-Bearing related to Independent Products to the Non-Breaching Party, and take such products and Independent Products to the Non-Breaching Party, as assignments and documents as other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the Non-Breaching Party.

Further, upon Amylin's request, HMR shall provide such technical assistance and know-how licenses on a royalty free basis as may reasonably be requested to transfer such technology as is needed by Amylin to commence or continue commercial manufacture of Collaboration Products and Royalty-Bearing Products. Such technical assistance shall be provided at HMR's direct cost, which cost such technical assistance shall be provided at HMR's direct cost, which cost shall be reimbursed within thirty (30) days upon receipt of an invoice from HMR shall be reimbursed within thirty (30) days upon receipt of an invoice from HMR shall or its designee. In the event that any technology needed by Amylin to commence or continue commercial manufacture of Collaboration Products and Royalty-Bearing Products is covered by one or more HMR Patents, Amylin shall receive a fully paid-up, royalty-free, non-exclusive worldwide license to practice any and all such HMR Patents for the purposes contemplated in this Section 12.2(e) together with the right to grant sublicenses.

(f) Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have

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hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation.

- shall mean the breach or failure to perform, in a material respect, a Party's material obligations under this Agreement. Without limiting the foregoing and by way of example only, the term "Material Breach" shall be deemed to include the failure of any Party in a material respect to meet such Party's payment or non-compete obligations. In no event shall a failure to gain Regulatory Approval for a Collaboration Product or to meet timelines or budgets specified in any Research and Development Plan, Research and Development Budget, Commercialization Plan, Commercialization Budget, Launch Plan or Launch Budget, in and of itself, be deemed to constitute a Material Breach, unless such failure is a result of acts and events or conduct that is otherwise a Material Breach.
- (h) The provisions of this Section 12.2 shall survive termination of this Agreement.
  - 12.3 TERMINATION WITHOUT A MATERIAL BREACH.
- (a) Each Party shall have a continuing right to terminate this Agreement for any reason, effective upon six (6) month advance written notice to the other Party, subject to this Section 12.3.
- (b) If either Party terminates pursuant to this Section 12.3, it shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement. In addition, as a result of such termination:
  - (i) all licenses and rights granted by the non-terminating Party to the terminating Party hereunder shall terminate;
    - Agreement or the License Agreement, the non-terminating Party shall receive an exclusive (even as to the terminating Party but subject to rights of Third Parties that are not Affiliates of the terminating Party that pre-existed or accrued prior to such termination) worldwide right and license, with the right to grant sublicenses, to all Patents of the terminating Party to import, use, sell, offer for sale and have sold Products for use in the Field, subject to the applicable royalty obligations set forth in Section 12.3(c) below, and shall have the right (but not the obligation) to enforce the Patents against Competitive (but not the obligation) applicable to the terminating Party's Patents in the event that the terminating Party does not or will not so enforce the Patents) and the exclusive right (but not the obligation) to enforce the trademark rights against infringers;

- (iii) all Confidential Information supplied by the non-terminating Party to the terminating Party shall be destroyed by the terminating Party; provided, however, the terminating Party may retain one copy of such information solely for legal archive purposes;
- (iv) if HMR is the terminating Party, HMR shall be obligated under Section 8.5 to the extent provided therein;
- (v) the terminating Party shall cooperate in the transfer of all INDs, Drug Approval Applications and Regulatory Approvals related to Collaboration Compounds and the Products, to the non-terminating Party, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the non-terminating Party;
- (vi) the terminating Party shall not exploit or commercialize Joint Patents or jointly-owned trademarks in competition with the non-terminating Party's commercialization of the HMR Compounds.
- (c) The terminating Party under this Section 12.3 shall be entitled to a royalty of 6% of worldwide Royalty-Bearing Sales of products incorporating HMR Compounds, which royalty shall be paid in accordance with the provisions of Sections 6.5 through 6.10 of this Agreement.
- 12.4 SURVIVING RIGHTS. The rights and obligations set forth in this Agreement shall extend beyond the term or termination of the Agreement only to the extent expressly provided for herein, or the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows:
- 12.4.1 In the event of expiration of this Agreement pursuant to Section 12.1, the following provisions shall survive: Article I (to the extent applicable to the interpretation of other surviving clauses), Sections 11.4, 12.4 and 12.5, and Articles XIII, XIV and XV.
- 12.4.2 In the event of termination of this Agreement pursuant to Section 12.2, the following provisions shall survive: Article I (to the extent applicable to the interpretation of other surviving clauses), Sections 4.8(b), 5.7(a), 6.4(b), 6.5 6.10, 7.4(a) and (b), 9.7, 11.2 11.4, 12.2, 4.8(b), 5.7(a), 6.4(b), 6.5 6.10, 7.4(a) and (b), 9.7, 11.2 11.4, 12.2, 4.8(b), 5.7(a), 13.1, 13.2 (solely with respect to acts or events occurring prior to such termination for which indemnity may be sought thereunder) and 13.3, and Articles XIV and XV.
- 12.4.3 In the event of termination of this Agreement pursuant to Section 12.3 the following provisions shall survive: Article I (to the extent applicable to the interpretation of

other surviving clauses), Sections 6.4(b), 6.5-6.10, 8.4, 9.7, 11.2 - 11.4, 12.3 - 12.5, 13.1, 13.2 (solely with respect to acts or events occurring prior to such termination for which indemnity may be sought thereunder) and 13.3, and Articles XIV and XV.

12.5 ACCRUED RIGHTS, SURVIVING OBLIGATIONS. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration, including damages arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of the Agreement.

# ARTICLE XIII

## INDEMNIFICATION

- 13.1 INDEMNIFICATION FOR ROYALTY-BEARING PRODUCTS. With respect to Royalty-Bearing Products (determined on a country-by-country basis):
- (a) HMR hereby agrees to save, defend and hold Amylin and its agents and employees harmless from and against any and all suits, claims, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, "Losses"), resulting directly from the manufacture, use, handling, storage, sale or other disposition of Royalty-Bearing Products by HMR, its agents or sublicensees except to the extent such Losses result from the negligence or willful misconduct of Amylin, its agents or sublicenses.
- (b) In the event that Amylin is seeking indemnification under Section 13.1(a), it shall inform HMR of a claim for Losses as soon as reasonably practicable after it receives notice of such claim, shall permit HMR to assume direction and control of the defense of such claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of HMR) in the defense of the claim.
- 13.2 INDEMNIFICATION FOR COLLABORATION PRODUCTS. With respect to Collaboration Products:
- other Party and its agents and employees harmless from and against any and all Losses resulting directly or indirectly from the manufacture, use, handling, storage, sale or other disposition of Collaboration Products by the indemnifying Party, its agents or sublicensees, but only to the extent such Losses result from the negligence or willful misconduct of the indemnifying Party or its employees and agents and do not also result from the negligence or willful misconduct of the Party seeking indemnification. Any other Losses from claims resulting directly or indirectly from the

manufacture, use, handling, storage, sale or other disposition of Collaboration Products shall be included as an Allowable Expense of either Party at the time such claim is finally determined, whether by judgment, award, decree or settlement.

- (b) In the event that either Party receives notice of a claim with respect to a Collaboration Product, such Party shall inform the other Party as soon as reasonably practicable. The Parties shall confer how to respond to the claim and how to handle the claim in an efficient manner.
- 13.3 INDEMNIFICATION FOR INDEPENDENT PRODUCTS. With respect to Independent Products:
- (a) Each Party hereby agrees to save, defend and hold the other Party and its agents and employees harmless from and against any and all Losses resulting directly or indirectly from the manufacture, use, handling, storage, sale or other disposition of Independent Products by the indemnifying Party, its agents or sublicensees, but only to the extent such Losses result from the negligence or willful misconduct of the indemnifying Party or its employees and agents and do not also result from the negligence or willful misconduct of the Party seeking indemnification.
- (b) In the event that either Party receives notice of a claim with respect to an Independent Product, such Party shall inform the other Party as soon as reasonably practicable. The Parties shall confer how to respond to the claim and how to handle the claim in an efficient manner.

# ARTICLE XIV

## DISPUTE RESOLUTION

The dispute resolution procedures of Article-XII of the License Agreement shall be applicable to any dispute, controversy or claim arising—out of or related to this Agreement, including, without limitation, the validity, construction, enforceability or performance hereof, and such procedures are incorporated herein by this reference.

# ARTICLE XV

# MISCELLANEOUS

# 15.1 ASSIGNMENT.

(a) Either Party may assign any of its rights or obligations under this Agreement in any country to any Affiliates; provided, however, that such assignment shall not

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relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement.

- Either Party may assign its rights or obligations under this Agreement or its ownership interest in Joint Patents to a non-Affiliate only as provided in Section 9.7, or in connection with a merger or similar reorganization or the sale of all or substantially all of its assets, or otherwise with the prior written consent of the other Party. This Agreement shall survive any such merger or reorganization of either Party with or into, or such sale of assets to, another party and no consent for such merger, reorganization or sale shall be required hereunder; provided, however, that in the event of such merger, reorganization or sale, no intellectual property rights of the acquiring corporation shall be included in the technology licensed hereunder.
- This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.
- RESEARCH AND DEVELOPMENT AND/OR COMMERCIALIZATION ENTITIES. Either Party may assign its rights and obligations under this Agreement to an entity or entities (e.g., partnership or corporation) that are specifically formed for financial purposes and that finance Research, Development or Commercialization performed by such Party pursuant to this Agreement; provided, however, that such assignment shall not relieve the assigning Party of responsibility for performance of its obligations under this Agreement.
- CONSENTS NOT UNREASONABLY WITHHELD. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.
- FORCE MAJEURE. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.
- INCORPORATION OF LICENSE AGREEMENT PROVISIONS; CONFLICTING PROVISIONS. Upon the Effective Date of this Agreement, the terms and conditions of the License Agreement are hereby incorporated by reference into this Agreement, except the provisions of the License Agreement that are superseded by the provisions of this Agreement, as set forth in Section 4.2 of

the License Agreement. Further, in the event that any term or provision of this Agreement is in conflict with a term or provision of the License Agreement, the term or provision of this Agreement shall prevail and shall be the operative term or provision.

- FURTHER ACTIONS. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- NO TRADEMARK RIGHTS. Except as otherwise provided herein or otherwise agreed to in writing by the Parties, no right, express or implied, is granted by this Agreement to use in any manner the name "Amylin," "HMR" or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.
- NOTICES. All notices hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, however, that notices of a change of address shall be effective only upon receipt thereof):

IF TO AMYLIN, ADDRESSED TO:

AMYLIN PHARMACEUTICALS, INC. 9373 Towne Centre Drive

San Diego, CA 92121

Attention: Office of the General Counsel

Telephone: (619) 552-2200 Telecopy: (619) 552-2212

IF TO HMR, ADDRESSED TO:

HOECHST MARION ROUSSEL, INC. Building B, Route 202-206

P.O. Box 6800

Bridgewater, New Jersey 08807-0800 Attention: Vice President, General Counsel,

Global Development Telephone: (908) 231-2000 Telecopy: (908) 231-2243

WAIVER. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights, or their failure to exercise any remedy, shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

- Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.
- 15.11 AMBIGUITIES. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 15.12 GOVERNING LAW. This Agreement shall be governed by and interpreted under the laws of the State of Delaware as applied to contracts entered into and performed entirely in Delaware by Delaware residents.
- 15.13 HEADINGS. The section and paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of said sections or paragraphs.
- 15.14 COUNTERPARTS. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- attached hereto and all documents delivered concurrently herewith, together with the License Agreement, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understanding between the Parties. There are no covenants, promises, agreements, warranties, between the Parties. There are no covenants, promises, agreements, warranties, the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

AMYLIN PHARMACEUTICALS, INC.

HOECHST MARION ROUSSEL, INC. J

By: /s/ Maurizio Denaro

By: /s/ Thomas Hofstaetter , -,

Name: Maurizio Denaro Title: Executive Vice President, Name: Thomas Hofstaetter Title: Senior Vice President, Business Development

Chief Technical Officer

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EXHIBIT A DETERMINATION OF CERTAIN ACCOUNTING TERMS

#### EXHIBIT A

#### DETERMINATION OF CERTAIN ACCOUNTING TERMS

As a supplement to the definitions provided in Article 1 of this Agreement, the following accounting terms shall be further specified as follows. As used herein, the term "operating unit" shall mean the smallest operating unit in which an operating profit and loss statement is prepared for management accounting purposes in the Party's normal accounting procedures, consistently applied within and across its operating units.

#### COST OF GOODS SOLD

Cost of Goods Sold shall be equal to the Standard Cost of each unit of Collaboration Product sold plus Other Costs Not In Standard incurred during the period, subject to limitation as provided in Item C below.

- A. "STANDARD COST" shall include the following:
- 1) Material Cost shall mean the prices paid for raw material components and purchased Finished Goods which are purchased from outside vendors as well as any freight and duty where applicable.

Standard Material Cost includes the quantity of the components included in the Bill of Material times the purchase price and the waste factor (i.e., scrap percentage) included in the Bill of Materials. It also includes the normal costed Quality Assurance sample quantity which is included in the Bill of Materials. Raw Material prices shall be adjusted on an annual basis by Purchasing.

- 2) Direct Labor Costs shall mean the standard labor hours required for an operation according to the Standard Operating Procedures for such Collaboration Product multiplied by the Direct Labor Rate for work centers within the relevant manufacturing operating unit.
- 3) Overhead Costs shall mean other costs associated with the operating unit(s) manufacturing a Collaboration Product, provided, however, that such Overhead Costs shall exclude costs associated with unused manufacturing capacity and any administrative costs other than indirect labor of the Manufacturing Department specifically attributable to the Collaboration Product in question. Overhead Costs shall include expenses associated with Quality Assurance, Manufacturing and Engineering associated with the operating unit(s) manufacturing a Collaboration Product and shall include Depreciation and Property Taxes associated with the plant(s) manufacturing a Collaboration Product. These costs shall be allocated to each product line in such operating unit(s) or plant(s), whichever is applicable, based on specific criteria consistent with the standard operating procedures for each product and work center overhead rates of the Party performing the work determined and allocated in a manner consistently applied within and across its operating units (except as specifically provided in Item C below).

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# 4) Manufacturing Variances shall include:

(a) Purchase Price Variance shall mean the difference between the actual price paid the vendor versus the standard cost of such material, times the quantity received.

(b) Spending Variance shall mean the difference between actual department spending and the budgeted spending included in Standard Cost for the relevant manufacturing operating unit.

(c) Absorption volume variances shall mean the difference between actual product hours earned (or units produced) and the hours budgeted for the period (or projected production units used) in the development of Standard Costs times the standard labor and overhead content of those units.

(d) Material usage shall mean the difference between the actual quantity of component raw materials or work-in-process used in the production of work-in-process or finished goods versus the standard quantity included in the Bill of Materials times the standard cost of the component or work-in-process item.

. (e) Rework shall mean the additional standard cost of components or work-in-process items used to turn rejected inventory into usable inventory. No labor or overhead rate is assigned to rework orders, only the additional value of the inventory which is issued to the other. Additionally, no production/absorption credit is generated for rework orders since the credit was already generated the first time the production occurred.

# B. "OTHER COSTS NOT IN STANDARD" shall include:

- Scrap Expense shall mean the total standard cost of inventory which is physically destroyed or transferred to Rejected Inventory awaiting disposition. Total Cost means total inventory value which includes material, labor and overhead.
- 2) Inventory revaluation shall mean under FIFO Inventory Valuation the difference between the prior year's ending inventory at the prior year's standard cost plus or minus the year-end full absorption adjustment (see below) versus the same inventory at the new year's standard cost.
- 3) Full Absorption Adjustment -- Under FIFO Inventory Valuation the monthly adjustment which is made to adjust inventories from standard to actual cost. This involves reserving a period of the Manufacturing Variances, beginning with the current month and going back according to the number of month's supply of inventory on hand at the end of each month or annually as the case may be.
- 4) Excess and Obsolete Inventory Adjustments -- The P&L impact of adjusting the reserves for excess and obsolete inventory up and down based upon a quarterly analysis or

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annually as the case may be.

- 5) Loss on Returns Expense -- These are expenses (similar to sales returns and allowances) which are incurred as a result of issuing reasonable sales credits to customers at standard cost. This is the offset to reversing the standard cost of sales when the sale is negated.
- 6) No Charge Shipments -- Those expenses associated with shipping replacement product to customers at no charge. This is the offset to relieving inventory at standard cost when the product is shipped.
- C. EXCLUDED COSTS. Notwithstanding the foregoing, Cost of Goods Sold shall exclude administrative costs other than indirect manufacturing labor specifically attributable to the Collaboration Product being manufactured and shall exclude allocation of unused capacity costs.

### MARKETING EXPENSES

Marketing Expenses shall be the sum of Selling Expenses, Marketing Management, Market and Consumer Research, Advertising, Trade Promotion, Consumer Promotion, and Education Expenses, each of which is specified below.

- A. "SELLING EXPENSES" shall include the following costs directly associated with the efforts of field sales representatives with respect to Collaboration Products: field sales force; field sales offices; home offices staffs directly involved in the management of and the performance of the selling functions; payments to Third Parties under co-promotion agreements approved by the Steering Committee. Reasonable field samples shall normally be charged to Trade Promotion, but if sales management has direct decision making authority for the distribution of field sales samples, it may be appropriate to charge these costs to Selling Expenses. The costs of detailing sales calls shall be allocated on a weighted average basis based on what detail position the involved Collaboration Product is assigned at an accounting charge rate consistently applied within and across its operating units and which is no less favorable to the collaboration than the internal charge rate used by HMR for its own internal cost accounting purposes for products other than Collaboration Products (excluding internal profit margins and markups).
- B. "MARKETING MANAGEMENT" shall include Product Management and Sales Promotion Management direct expenses. This shall include costs associated with developing overall sales and marketing strategies and planning for Collaboration Products. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement shall be included in this category.
- C. "MARKET AND CONSUMER RESEARCH" shall include direct expenses for Market and Consumer Research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of existing, new or proposed Collaboration Products such as market share services (e.g., IMS data), special research testing and focus groups.

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- D. "ADVERTISING" shall include all direct media costs associated with Collaboration Product advertising as follows: production expense/artwork including set up; design and art work for an advertisement; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.
- E. "TRADE PROMOTION" shall include reasonable allowances given to retailers, brokers, distributors, hospital buying groups, etc. for purchasing, promoting, and distribution of Collaboration Products. This shall include purchasing, advertising, new distribution, and display allowances as well as free goods, wholesale allowances and reasonable field sales samples. To the extent multiple products are involved and some of such products are not Collaboration Products then such allowances shall be allocated on a pro rata basis based upon net sales of each respective product by such operating unit during the most recent quarter.
- F. "CONSUMER PROMOTION" shall include the direct expenses associated with programs to promote Collaboration Products directly to the end user. This category shall include direct expenses associated with promoting products directly to the professional community such as professional samples, professional literature, promotional material costs, patient aids and detailing aids. To the extent multiple products are involved and some of such products are not Collaboration Products then such allowances shall be allocated on a pro rata basis based upon net sales of each respective product by such operating unit during the most recent quarter.
- G. "EDUCATION" shall include direct expenses associated with professional education with respect to Collaboration Products through any means not covered above, including articles appearing in journals, newspapers, magazines or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards and opinion leader development activities.
- H. "ROYALTY EXPENSES" shall mean royalties or other compensation payable to a Third Party under patents and/or technology rights of such Third Party to conduct Commercialization pursuant to the Collaboration Agreement.

# 3. DISTRIBUTION EXPENSES

Distribution Expenses shall be the sum of Stock and Shipping Expenses and Transportation Expenses, each as specified below.

- A. "STOCK AND SHIPPING" shall include the portion of distribution costs for the warehousing of Collaboration Product finished goods from the point of completion of production to the time the goods are turned over to a carrier for delivery as follows: order filling/assembly functions; reasonable order billing and customer service functions; reasonable portion of company owned/leased facilities relating to warehousing of finished products; storage of products at public warehouses.
- B. "TRANSPORTATION" shall include the portion of distribution costs relating to moving Collaboration Product goods from a warehouse to the customer as follows: outbound

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transportation costs; costs of moving goods from a manufacturing point to a warehouse at another location from which it is ultimately to be distributed to a customer.

4. POST-LAUNCH PRODUCT R&D EXPENSES

Post-Launch Product R&D Expenses shall include certain research and development costs incurred by a Party in relation to a Collaboration Product after the first commercial launch and shall exclude administrative expenses. Such post-launch research and development costs shall include:

- A. Phase IV Clinical Trials.
- B. Ongoing product support (as defined in Section 1.45 of the Collaboration Agreement).
- C. Ongoing medical affairs (as defined in Section 1.45 of the Collaboration Agreement).
  - D. Preclinical research.

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- E. Contract R&D costs performed by others for a particular project that have no alternative future uses in other R&D projects or otherwise.
- F. Fees and expenses of outside counsel in respect of regulatory affairs unrelated to obtaining Regulatory Approvals.
  - 5. CURRENCY GAINS OR LOSSES

Currency Gains or Losses shall include the following:

- from a change in exchange rates between the functional currency and the currency in which the transaction is denominated. The transaction gain or loss is determined by measuring the increase or decrease in the functional currency cash flow due to the changes in the exchange rate from the date of the transaction to the settlement date. The difference between the functional currency amount calculated using the current exchange rate at the transaction date and the amount calculated using the currency exchange rate at the settlement date is the transaction gain or loss. Transaction gains or losses on unsettled foreign currency transactions are also reported in this manner. When there is a balance sheet date between the transaction date and settlement date, the gain or loss on the unsettled balance shall be measured using the current exchange rate at the balance sheet date.
- B. HEDGED TRANSACTIONS. For purposes of this collaboration, neither Party shall buy or sell forward, directly or indirectly, foreign currencies in amounts greater than those which can reasonably be expected to be received or paid, as the case may be, over the relevant time period.

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If a Party enters into a hedged transaction, the gain or loss realized from the hedge must be included in the underlying transaction. If the currency transaction gain or loss has been included in Net Sales, Costs of Goods Sold, etc., it shall not be included in this category.

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EXHIBIT B

FINANCIAL STATEMENT FORMAT

# EXHIBIT B

# FINANCIAL STATEMENT FORMAT (CASE A - OPERATING PROFIT)

	HMR	Amylin	Total	% Net Sales
Gross Sales	****	***	****	****
Less:				
Discounts	****	****	****	****
Credits & Allowances	****	****	****	****
Taxes & Duties	****	****	****	***
Provisions for Uncollectible Accounts	****	****	****	****
Net Sales	****	****	****	****
Cost of Goods Sold:		****	****	
Standard Material Cost	***	****	****	****
Standard Direct Labor Costs	***	****	****	****
Standard Overhead Costs	****	****	****	****
Standard Manufacturing Variances	****	****	****	****
Scrap Expense	****	****	****	****
Inventory Revaluation	****	****	****	****
Full Absorption Adjustment	****	****	****	****
Excess & Obsolete Inventory Adjustments	****	****	****	****
Loss on Returns Expense	****	****	****	****
No Charge Shipments	****	****	****	****
Total Cost of Goods Sold	****			
Gross Profit	****	****	****	****
			_	<del>-</del>
Marketing Expenses:	****	****		****
Selling Expenses	****	****	****	****
Marketing Management	****	****		****
Market & Consumer Research	****	****	****	****
Advertising	****	****	****	****
Trade Promotion Consumer Promotion	****	****	****	****
Education	****	****	****	****
Royalty Expense	****	****	****	****
Total Marketing Expenses	****	****	****	****
Total marketing expenses				
Distribution Expenses:		****	****	
Stock & Shipping	****		****	****
Transportation	****	****	****	****
Total Distribution Expenses	****	****	***	***

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B (CONT.)

# FINANCIAL STATEMENT FORMAT (CASE A- OPERATING PROFIT)

	HMR	Amylin	Total	Net Sales
Post-Launch Product R&D Expenses:				
Phase IV Clinical Trials	****	****	****	****
Product Support	****	***	****	****
Medical Affairs	****	****	****	****
Preclinical Research	****	****	****	****
Other Contract R&D.	****	****	****	****
Total Post-Launch Product R&D Expenses	****	****	****	****
Patent Expenses	****	****	****	****
Currency Gains (Losses):				
Unhedged Transactions	****	****	****	****
Hedged Transactions	****	****	****	****
Total Currency Gains (Losses)	****	****	****	****
Net Sublicense Revenues	****	****	****	****
Operating Profits (Losses)	****	****	****	****
Equalization Receipt (Payment)	****	****	****	****
Balance After Equalization	****	****	****	****

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B

# FINANCIAL STATEMENT FORMAT (CASE B - OPERATING LOSSES)

•	HMR	Amylin	Total	* Net Sales
Gross Sales	****	****	****	
	****	****	****	
Less: Discounts	****	****	****	
Credits & Allowances	****	***	****	
Taxes & Duties	****	****	****	
Provisions for Uncollectible Accounts	****	****	****	•
Net Sales	****	****	****	****
Cost of Goods Sold:				
Standard Material Cost	****	****	****	****
Standard Direct Labor Costs	****	****	****	****
Standard Overhead Costs	****	****	****	****
Standard Manufacturing Variances	****	****	****	****
Scrap Expense	***	****	***	****
Inventory Revaluation	****	****	****	****
Full Absorption Adjustment	****	***	****	****
Excess & Obsolete Inventory Adjustments	****	****	****	****
Loss on Returns Expense	****	***	****	****
No Charge Shipments	***	****	****	****
Total Cost of Goods Sold	****	****	****	***
Gross Profit	****	****	***	****
Marketing Expenses:				•
Selling Expenses	***	****	****	****
Marketing Management	***	***	****	***
Market & Consumer Research	***	****	****	****
Advertising	***	****	****	****
Trade Promotion	. ****	****	_# * * *	****
Consumer Promotion	***	****	****	****
Education	****	****	****	****
Royalty Expense	***	****	****	****
Total Marketing Expenses	****	****	****	****
Distribution Expenses:		****	****	****
Stock & Shipping	****	****	****	****
Transportation	***	****	****	****
Total Distribution Expenses	****		***	***

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

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<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

# EXHIBIT B (CONT.) FINANCIAL STATEMENT FORMAT (CASE B- OPERATING LOSSES)

	HMR	Amylin	Total	Net Sales
Post-Launch Product R&D Expenses: Phase IV Clinical Trials	****		****	••••
Product Support	****	****	****	****
Medical Affairs	****	****	****	****
Preclinical Research	****	****	****	****
Other Contract R&D	****	***	****	****
Total Post-Launch Product R&D Expenses	****	****	****	****
Patent Expenses	****	****	****	****
Currency Gains (Losses): Unhedged Transactions	****	****	****	****
Hedged Transactions	****	****	****	****
Total Currency Gains (Losses)	****	****	****	****
Net Sublicense Revenues	****	***	****	***
Operating Profits (Losses)	***	****	****	****
Equalization Receipt (Payment)	***	****	****	****
Balance After Equalization	****	****	****	***

The numbers set forth above on this Exhibit B are provided only as examples of how to calculate financials under this Agreement and shall not be considered as projections or for any other purpose.

<sup>\*</sup> CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT C LIST OF AMYLIN PATENTS

NONE.

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Joseph A. Grundfest W. A. Franke Professor of Law and Business

Tel: 650.723.0458 Fax: 650.723.8229 E-mail: grundfest@stanford.edu

Crown Quadrangle 559 Nathan Abbott Way Stanford, CA 94305-8610

October 30, 2002

CC: ITA:RU (REG-106359-02) Room 5226 Internal Revenue Service POB 7604 Ben Franklin Station Washington, DC 20044 REGULATIONS UNIT CC:ITA:RU NOV 1 5 2002

**ROOM 5226** 

Giblen/Beck

Re: Proposed Treas. Reg. 1.482-7 (REG-106359-02)

This submission is in response to a request for comment regarding proposed regulations under Section 482 of the Internal Revenue Code relating to the treatment of equity-based compensation, such as stock options, under "qualified cost sharing arrangements" for intangible property (the "Proposed Regulations"). Prop. Treas. Reg. 1.482-7 (REG-106359-02).

This letter does not address the details of the Proposed Regulations. Nor does it address every policy concern implicated by the Proposed Regulations. Instead, this letter focuses on a small set of observations that are, I believe, fundamental to tax policy in general and that have profound implications for the Proposed Regulations in particular.<sup>1</sup>

The Department and the Service have long taken the position that the tax treatment of a transaction should be consistent with its underlying economic reality. See, e.g., Notice 2002-70 (Regarding Reinsurance Arrangements). The Department and the Service have recently, for example, attacked tax shelter transactions in which the valuation of an insurance policy is not based on its fair-market value as measured in an arm's-length transaction. See, e.g., Notice 2002-59.

The same principle should apply to the treatment of equity-based compensation in qualified cost sharing agreements. If independent third parties would, in an arm's-length transaction, change the equilibrium price of a cost sharing arrangement, whether for research and development or for any other purpose, because one of the parties has entered into an equity-based compensation arrangement with its employees, then the economic reality test would support application of a rule that attempts to "price" the impact of the equity-based compensation, at the margin, on the value of the contract at issue. However, if data and theory suggest that such equity-based compensation has no effect on the arm's-length value of such relationships then consistent application of the economic reality test suggests that equity-based compensation arrangements should not enter into the cost-sharing calculus for purposes of Section 482.

<sup>&</sup>lt;sup>1</sup> This letter is prepared at the request of Xilinx, Inc. I am also a member of the board of directors of Oracle, Corp. Both Xilinx and Oracle have interests that could be affected by the Proposed Regulations. The views expressed in this letter are, however, my own. They do not necessarily reflect the views of Xilinx, Oracle, or of my employer, Stanford Law School.

The data are overwhelming that the prices at which goods and services transact between independent third parties bear no relationship to the equity compensation structures used by vendors. See, e.g., William J. Baumol and Burton G. Malkiel, Status of Stock-Options in Shared-Cost Contracts (2002). Thus, the prices of cars sold by General Motors do not rise or fall with the number of options granted to employees. Nor does the price of software sold by Microsoft, the price of consulting arrangements offered by IBM, or the price of microprocessors marketed by Intel rise or fall with the size or structure of any of those companies' option grants to employees. And, as the world will soon observe, the price of Coca-Cola will neither rise nor fall because of the company's recent decision to recognize an expense for financial statement purposes in connection with the grant of employee stock options.

This finding is entirely unsurprising. Microeconomic theory teaches that, in equilibrium, prices are set at the point where marginal revenue equals marginal cost. See, e.g., Robert S. Pindyck and Daniel L. Rubinfeld, Microeconomics (5th ed. 2000) at 256 ("The rule that profit is maximized when marginal revenue is equal to marginal cost holds for all firms, whether competitive or not.") The cost of a firm's capital is a function of the riskiness of its individual projects, of overall equity market risk, and of the firm's capital structure. See, e.g., Pindyck and Rubinfeld, supra, at 548 ("The company cost of capital is a weighted average of the expected return on the company's stock (which depends on the beta of the stock) and the interest rate that it pays for debt."); Richard A. Brealey and Stewart C. Myers, <u>Principles of Corporate Finance</u> (5<sup>th</sup> ed. 1996) at 204-206. The cost of capital is most emphatically not a function of the number of shares that a firm has outstanding today, the number of shares that a firm had outstanding a year ago, or the number of shares it might have outstanding a year from now. Because the dominant effect of an anticipated equity-based compensation grant is to dilute the percentage of the enterprise's equity held by current equity-holders in the event optionable shares might in the future be issued if the options are "in the money" at the time of exercise, the option grant has no effect on the firm's aggregate cost of capital. Put another way, the decision to grant options to employees, when that decision is anticipated by the equity market, changes neither the firm's cost of equity nor its cost of debt. It also does not change its operating expenses.

To illustrate this point with a simple example, suppose that a corporation suddenly announces a two for one stock split. The price of each share would drop by half. The number of shares outstanding would, however, double and the firm's market capitalization and its cost of equity capital would not change by one iota. Nor would the price at which the firm enters into any contract with a third party change one whit as a consequence of the split. Suppose also that after the split, the company announced its intention to grant half of the newly split shares to the company's employees according to a plan that was fully disclosed to and anticipated by the market. The pre-existing shareholders would find that their percentage holding of the firm would have dropped, as anticipated, but the price at which the firm transacts with third parties would again remain unchanged and the firm's cost of capital would also remain unchanged.

The mathematics of the situation were explained, to a reasonable first order of approximation, by Yogi Berra. When visiting a pizzeria Yogi was asked if he wanted his pizza cut into four or eight slices. He replied, "Four. I don't think I can eat eight." Y. Berra, The Yogi Book (1998) at 80. There you have it. It makes no difference to the price of the pizza, or to the number of calories Yogi consumes, whether the pizza is sliced into quarters or eighths. Pizzerias do not advertise one price for a large pizza cut into four slices and a different price for the same large pizza cut into eight. Similarly, it makes no difference to the price at which a publicly traded company transacts it goods or services with third parties whether its total equity has a larger or smaller option overhang as a consequence of equity-based compensation arrangements with its employees.

The observation that option grants have no effect on a firm's "operating expense" as that term is generally understood, is also relevant for present purposes because the regulation at issue specifically states that:

"Operating expense includes all expenses not included in cost of goods sold except for interest expense, foreign income taxes..., domestic income taxes, and any other expenses not related to the operation of the relevant business activity. Operating expenses ordinarily include expenses associated with advertising, promotion, sales, marketing, warehousing and distribution, administration, and a reasonable allowance for depreciation and amortization."

Treas. Reg. §1.482-5(d)(3).

As clearly stated in the Declaration of Professor Roman L. Weil submitted in Xilinx, Inc. v. Commissioner, U.S. Tax Court, Docket No. 4142-01 (June 3, 2002), the Commissioner's definition of "stock-based compensation" does not constitute an "operating expense" under any accounting or other definition of that term of which Professor Weil is aware. Professor Weil is co-author of a leading text on accounting matters, see, Clyde P. Stickney and Romany L. Weil, Financial Accounting (7th ed. 1994), and I concur with his understanding. This understanding is, moreover, consistent with the observation that the arm's-length cost of the transactions here at issue would not be influenced by employee option grants, which also do not constitute "operating expenses."

None of this suggests that the options granted to a company's employees are without economic value. I am happy to recognize the obvious: Employee options do have economic value. That fact does not, however, change the preceding observation that the grant of options is irrelevant to the valuation of any transaction involving the issuer's goods or services. The reason in support of this conclusion is related to the source of the option's value. The economic value of the option arises because of the value of the equity-based dilution that shareholders are willing to absorb in order to provide an equity-based incentive to employees. If, in equilibrium, the grant of an option causes an employee to work harder or smarter to a degree that precisely offsets the value of the option granted, then the grant adds as much equity value to existing shareholders as it costs them in potential dilution. The value of the additional service thus offsets the value of the grant. Put another way, if the Service seeks to recognize the value of the option granted it must also recognize the value of the additional incentive generated by those options. It also follows that even though this incentive relationship has value, it does not change the relationship between marginal cost and marginal revenue as reflected in third party transactions for goods and services.

The fact that many accountants and policy makers urge that income statements recognize an expense upon the grant of an employee option also has no effect on this basic economic logic. Simply put, the income statement is chock full of entries that bear no rational relationship to true

<sup>&</sup>lt;sup>2</sup> No doubt, as is the case in every contingent relationship, employees will, in individual cases, find that they are sometimes overcompensated or undercompensated relative to the value of additional services generated as a consequence of the option grant. If employees are incented to provide services worth more than the value of the options, then the option grant actually reduces labor costs, *ex post*, relative to a comparably valued straight cash grant. If employees are incented to provide services worth less than the value of the options then the arrangement can, *ex post*, appear to increase labor costs relative to the value of a comparably valued straight cash grant. There is, however, no basis to assume, *a pirori*, that these relationships would be out of equilibrium. Accordingly, the rational assumption is to assume equilibrium pricing.

economic costs. For example, the depreciation rate applied to physical capital often bears no rational relationship to its true economic replacement cost. The income statement is also full of entries that bear no rational relationship to the marginal cost – marginal revenue equilibrium that determine pricing in arm's-length third party transactions. For example, the value of goodwill as reflected in a brand name often shows up nowhere in the income statement. Yet, a material portion of the value of a licensing transaction is often determined by the fair market value of the brand name that has no accounting value at all. Economics texts therefore warn that "economists often think of costs differently than financial accountants" and that accounting costs "can include items that an economists would not include and would not include items that economists usually do include." Pindyck and Rubinfeld, *supra*, at 204. Accordingly, even if it is correct as a matter of accounting principle to recognize an expense attributable to the grant of employee options, it is incorrect to conclude that these options influence the marginal cost – marginal revenue relationship that is, or should be, at the heart of these deliberations.

Therefore, if the objective of the Proposed Regulations is to establish a regime that measures the value of cost-sharing arrangements with reference to the economic reality of the underlying transaction, then options grants need not and should not enter the calculus even if one believes, as I do, that those options have real economic value.

Sincerely,

Joseph A. Grundfest

The William A. Franke
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cc: The Hon. Kenneth W. Dam Pamela F. Olson, Esq.

Docket Nos. 6253-12, 9963-12