IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT, DIVISION ONE

AMGEN, INC., Plaintiff and Respondent, **v.** **THE CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES, an agency of the State of California,** Appellant.	Case No. B296563

County Superior Court, Case No. 18-STCP-03147
The Honorable Mitchell L. Beckloff, Judge

APPELLANT'S OPENING BRIEF

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Case Name: *AMGEN, INC. v. THE CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES, an agency of the State of California*

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5/17/19
(Date)

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INTRODUCTION AND SUMMARY OF ARGUMENT

The trial court entered a preliminary injunction that bars defendant and appellant California Correctional Health Care Services ("CCHCS") from giving the news media, or anyone, a copy of a notice it received from plaintiff and respondent Amgen Inc., showing "potential" increases in the wholesale acquisition cost ("WAC") of certain Amgen drugs. Senate Bill 17 requires that drug manufactures provide advance notice of significant increases in the WAC of their prescription drugs to California purchasers, including health care service plans, insurance companies, pharmacy benefit managers, and state-agency purchasers. The Legislature adopted this requirement to increase transparency and shed light on prescription drug prices, which have skyrocketed in recent years and harmed millions of consumers. In all, some 174 private and public sector purchasers, including CCHCS, received a copy of Amgen's notice. Moreover, Senate Bill 17 does not require the purchasers who receive the notices to keep this information confidential. Nonetheless, the trial court held that Amgen was likely to prevail on its claim that its notice contains competitively sensitive "trade secret" information, and therefore is exempt from disclosure under the Public Records Act. The trial court also found that the balance of relative harms tips in Amgen's favor. The trial court abused its

discretion in granting the preliminary injunction and should be reversed.

For several reasons, Amgen has no likelihood of success on its claims. First, the Legislature has mandated that Amgen disclose this information to numerous state agencies and other public and private sector purchasers, none of which is obligated to keep the information confidential. This alone is fatal to Amgen's claim of confidentiality, even assuming arguendo that the information in its notice could otherwise be deemed a "trade secret."

Second, the Public Records Act exemption invoked by Amgen—for records subject to a claim of privilege under another statute, here Evidence Code section 1060—is not mandatory and allows disclosure in the interests of justice. Under controlling precedent, absent a clear showing that disclosure would harm the public interest—and Amgen made no such showing—there is no legal basis for interfering with CCHCS's decision not to assert the exemption.

Third, and in any event, under California law the information that Amgen seeks to protect is not a trade secret. The WAC is a generic list price and is public information; it is not the actual price paid by any purchaser for any drug. Actual drug prices are set by private contract and are generally kept

confidential. A planned change in the WAC is not a trade secret merely because it relates in some way to actual drug prices.

The balance of hardships also favors CCHCS, not Amgen. The fact that Amgen's competitors may learn about potential increases in the WAC of certain drugs is not a significant hardship, especially since Amgen is entitled to receive the same information about its competitors' own increases.

After granting the preliminary injunction, the trial court held further proceedings and sustained CCHCS's demurrer, with leave to amend, to Amgen's petition for a writ of mandate. On the last day for filing an amended complaint, Amgen filed a request for dismissal of the entire action without prejudice. Because the case presents an important issue, and one that is likely to recur, however, this Court should rule on the merits of this appeal and hold that the notices provided to purchasers under Senate Bill 17 are public information.

STATEMENT OF APPEALABILITY

The trial court granted Amgen's motion for preliminary injunction on March 11, 2019. (Appx. 2:383.)[1] The trial court's order is appealable under Code of Civil Procedure section 904.1, subdivision (a)(6). CCHCS timely filed its notice of appeal on March 19, 2019. (Appx. 2:396.)

[1] Citations to the Appendix are to volume and page number, e.g. Appx. 1:12.

STATEMENT OF THE CASE

I. Background

A. Senate Bill 17

Senate Bill 17 (hereafter "SB 17") was enacted in 2017 with overwhelming bipartisan support following years of staggering increases in the cost of prescription drugs, adversely affecting tens of millions of Californians. (Stats. 2017, ch. 603, §§ 1-9; see Appx. 1:148, 154-155 [detailing price spikes].) For example, the U.S. Government Accountability Office recently reported that 315 generic drugs had an extraordinary price increase of more than 100 percent from 2010 to 2015. (U.S. Government Accountability Office, *Generic Drugs Under Medicare* (Aug. 2016), GAO-16-176.)[2] SB 17 was designed to combat these egregious practices and "shin[e] a light on drugs that are having the greatest impact on our health care dollar" (Appx. 1:148, 171), by requiring pharmaceutical manufacturers to meet certain notice and reporting requirements for significant increases in the Wholesale Acquisition Cost (known in industry parlance as the "WAC") of their prescription drugs. (Health & Saf. Code, § 127677(a).)

[2] This report is available at https://www.gao.gov/products/GAO-16-706 (last accessed May 7, 2019).

The WAC is a generic list price, and is generally significantly higher than the actual amounts paid by particular purchasers for a drug. (Lieberman & Ginsberg, *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?* (June 2017) Brookings Institution 1-2, 8 (hereafter "Lieberman"); see Appx. 1:156.) It is the manufacturer's list price to wholesalers and direct purchasers, "not including prompt pay or other discounts, rebates or reductions in price" (see 42 U.S.C. § 1395w-3a(c)(6)(B)), and is publicly-available information. (See Lieberman, p. 1.) In contrast, the actual prices at which drugs are sold are determined through negotiations with individual purchasers, and are kept confidential. (*Id.*, pp. 1-2, 8; Appx. 1:147, 156.) SB 17 requires disclosure only of increases in the WAC, not actual prices or planned increases in actual prices.[3]

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[3] While the WAC is not the actual price of a drug, it is an important benchmark. In an effort "to address rising prescription drug list prices," the Department of Health and Human Services issued a new rule that requires television advertisements for certain prescription drugs to contain a statement "indicating the [WAC] for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." (84 Fed. Reg. 20,732-20,733 (May 10, 2019) (to be codified at 42 C.F.R. pt. 403).) The regulation explains, "[p]rice transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information," and that, although the WAC may not reflect what a patient actually pays, "the WAC is highly relevant to patients' [out of pocket] costs." (*Id.*

(continued…)

SB 17 requires manufacturers of certain prescription drugs to give purchasers 60 days' advance notice of a significant planned increase in the WAC. (Health & Saf. Code, § 127677(a).) Notice must be given if the planned increase, together with any "cumulative increases that occurred within the previous two calendar years," exceed 16 percent. (*Ibid*.)

The purchasers entitled to notice under SB 17 are a mix of private and public entities, including state-agency purchasers; licensed health care service plans; health insurers; and pharmacy benefit managers ("PBMs"). (Health & Saf. Code, § 127675, subd. (a); Bus. & Prof. Code, § 4430, subd. (j).) If a PBM receives notice of an increase in the WAC of a drug, it must in turn notify its large contracting purchasers of the increase. (Health & Saf. Code, § 127677, subd. (e).) At the time of the trial court's ruling, there were 174 registered purchasers receiving SB 17 notices from Amgen and other pharmaceutical makers. (Appx. 1:148, 191-207.) Purchasers include Kaiser, Anthem, Blue Shield, CVS Health, Stanford Health Care Advantage, and the County of Los Angeles.

(…continued)
at 20.734.) "[T]he WAC is an appropriate metric to use as a list price because it is commonly used, easily available and manufacturer developed." (*Id*. at 20,740.)

The notice must include the date of the increase, the current WAC of the drug, the dollar amount of the planned increase, and "a statement regarding whether a change or improvement in the drug necessitates the price increase," and if so, a description of the change or improvement. (Health & Saf. Code, § 127677, subds. (b)-(c).) Also, on a quarterly basis, manufacturers must report this information as well as other, more detailed information relating to each notice to the Office of Statewide Health Planning and Development ("OSHPD"), which is required to compile it and publish it on the agency's internet site. (*Id.*, § 127679, subds. (a), (c).)

SB 17 does not require purchasers who receive the notices to keep the information confidential. (See Health & Saf. Code, § 127677.) No provision of the statute imposes a non-disclosure obligation on registered purchasers. Indeed, the very purpose of the law "is to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing." (*Id.*, § 127676, subd. (b).) Moreover, the advance notice provisions of SB 17 give purchasers an opportunity "to adjust formularies, to negotiate price concession, and to seek other alternatives" before the WAC of a drug is set to increase dramatically. (Appx. 1:158.) Thus, purchasers can use the

advance notice information to, among other things, negotiate discounts or find cheaper alternatives from other manufacturers.

B. The California Public Records Act

Under the Public Records Act ("PRA") (Gov. Code, § 6250 et seq.), a state agency generally must make public records available to any person who requests them. (*Id.*, § 6253.) The PRA broadly defines "public records" as any "writing containing information relating to the conduct of the public's business prepared, owned, used, or retained by any state or local agency regardless of physical form or characteristics." (*Id.*, § 6252, subd. (e).)

The California Constitution requires the courts "to 'broadly construe[]' the PRA to the extent it furthers the people's right of access' and to 'narrowly construe[]' the PRA to the extent 'it limits the right of access.'" (*Sierra Club v. Superior Court* (2013) 57 Cal.4th 157, 166, quoting Cal. Const., art I, § 3, subd. (b)(2).)

The PRA contains numerous exemptions from disclosure for particular types of records, as well as a residual, "catch-all" exemption that may be invoked by an agency where the public interest in non-disclosure clearly outweighs the public interest in disclosure. (Gov. Code, §§ 6254-6255.) Absent a statute or constitutional provision that categorically bars disclosure, a public agency may, but is not required to, claim an exemption. (Gov. Code, § 6254; see *Marken v. Santa Monica-Malibu Unified*

School Dist. (2012) 202 Cal.App.4th 1250, 1262 (hereafter "*Marken*").)

Here, Amgen claims that its information is exempt from disclosure under Government Code section 6254, subdivision (k), which applies to "[r]ecords, the disclosure of which is exempted or prohibited pursuant to federal or state law, including, but not limited to, provisions of the Evidence Code relating to privilege."[4] The "state law" invoked by Amgen is Evidence Code 1060, which gives the owner of a trade secret a privilege to "prevent another from disclosing it, if the allowance of the privilege will not tend to conceal fraud or otherwise work injustice."

II. Events Leading to This Litigation and Procedural History

In November 2018, Amgen provided a notice of potential increases in the WAC of specified drugs to registered purchasers. (Appx. 1:82.)[5] CCHCS, which is a registered purchaser, received

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[4] In its Complaint, Amgen also alleged that its notice is exempt under Government Code section 6254.15. (See Appx. 1:13-15.) Amgen's motion for preliminary injunction does not mention that statute, the trial court did not rely on it in granting the preliminary injunction, and Amgen did not even attempt to defend those allegations in its opposition to CCHCS's demurrer. (Compare Appx. 2:243 with *id*. 2:403-421.)

[5] A copy of Amgen's notice was lodged with the trial court at the hearing. (See Appx. 2:389.) Once the trial court has entered the dismissal, which will dissolve the preliminary

(continued…)

a copy of it. (*Id*. 1:88.) On November 16, 2018, CCHCS received a PRA request from Reuters News for all such notices it had received from November 1, 2018 through November 16, 2018. (See *Id*. 1:88, 91-92.) Although some drug companies did not seek to prevent disclosure under the PRA, Amgen labeled its notice confidential, proprietary, and/or subject to a claim of trade secret. (See *Id*. 1:91.) CCHCS promptly informed Amgen that it intended to comply with the PRA request unless it was served with a court order by December 17, 2018. (*Ibid*.)

Amgen filed this action on December 11, 2018, seeking a writ of mandate preventing CCHCS from disclosing the Amgen notice to Reuters or others. (Appx. 1:8, 15.) Amgen also sought and obtained an unopposed temporary restraining order preventing CCHCS from disclosing "Amgen's Confidential Pricing Information". (*Id*. 1:53-54.) Amgen filed its motion for preliminary injunction on December 20, 2018. (*Id*. 1:55.) At the hearing on the motion on January 9, 2019, the trial court took the matter under submission and continued the TRO until a ruling on the motion. (*Id*. 1:227.)

On January 28, 2019, while the motion for preliminary injunction remained under submission, CCHCS filed a demurrer

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injunction, CCHCS will provide the document to this Court and request that the Court take judicial notice of it.

to the Complaint. (Appx. 2:228.) CCHCS demurred to the first cause of action, which seeks a writ of mandate, on the grounds that: (1) the PRA exemption for trade secrets does not apply because, in enacting SB 17, the Legislature determined that the information should be publicly disclosed, even if it is a trade secret; (2) alternatively, the PRA exemption for trade secrets is permissive, not mandatory, and CCHCS did not abuse its discretion or otherwise act contrary to law by declining to invoke the exemption; and (3) as a matter of law, Amgen's notice, which had been disclosed to nearly 200 private and public drug purchasers, and which provided minimal if any information about its actual prices, did not qualify for trade secret status. (*Id.* 2:241-250.) CCHCS also demurred to the second and third causes of action (for declaratory and injunctive relief, respectively) on the ground that the only available remedy in a reverse-PRA action[6] is a writ of mandate. (*Id.* 2:240-241.)

On February 1, 2019, the trial court issued its "Ruling on Submitted Matter," holding that Amgen had "met its burden for purposes of a preliminary injunction." (Appx. 2:330.) On March

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[6] The PRA specifically authorizes actions to compel the disclosure of public records. (Gov. Code, § 6258.) By contrast, an action to prevent an agency from disclosing public records, such as this case, may only be brought as a petition for writ of mandate under Code of Civil Procedure section 1085. (See *infra*, pp. 22-23.)

11, 2019, the trial court issued its formal order, which provides that CCHCS may not disclose Amgen's Notice or information contained in the notice "to any third parties pursuant to a Public Records Act Request or otherwise." (*Id.* 2:383.)[7] CCHCS filed this appeal on March 19, 2019. (*Id.* 2:396.)

On April 24, 2019, the trial court sustained CCHCS's demurrer to the first cause of action for a writ of mandate, with leave to amend; sustained the demurrer to the third cause of action for an injunction without leave to amend; and stayed the second cause of action for declaratory relief. (Appx. 2:440.) On May 14, the deadline for filing an amended complaint, Amgen filed a request for dismissal without prejudice of the entire action. (*Ibid.*; *id.* 2:441.)

III. Amgen's Alleged Trade Secret

Amgen's motion describes its alleged trade secret as "Confidential Pricing Information," which it defines as its "notice of potential price increases for certain [Amgen] drugs."

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[7] The initial Ruling on Submitted Matter stated, "Respondents shall not release the information contained in the Notice unless and until Petitioner effects a price increase to the WAC for the medications in the Notice." (Appx. 2:336.) Over CCHCS's objection, the final order prohibits release of the information contained in Amgen's notice even after Amgen has increased the WAC for the drugs listed in the notice. (See *id.* 2:341-342, 357, 383-84.)

(Appx. 1:62.) Although the actual WAC of a drug is public (*id.* 2:391; Lieberman at 1), Amgen claims that information concerning a yet-to-be-implemented increase in the WAC is confidential and competitively sensitive. (See *id.* 1:9, 63; RT, p. 12.)

The declaration of Rachelle Wan in support of Amgen's motion for preliminary injunction alluded cryptically to Amgen's "pricing strategy," and claimed, in conclusory fashion, that the alleged trade secret includes "valuable non-public information and insights into Amgen's pricing strategy, internal decision-making, internal forecasts, and a roadmap for Amgen's potential actions with respect to certain of its products." (Appx. 1:83.) However, SB 17 does not require Amgen to disclose any of this. It requires disclosure of only: the date of the planned increase; the current WAC for the drug; the new WAC; the amount of the increase; and whether the increase is necessitated by a change or improvement in the drug, and if so, what that change or improvement is. (Health & Saf. Code, § 127677, subd. (c).)

STANDARD OF REVIEW

Because the PRA only authorizes an action to compel disclosure of public records, (Gov. Code, §§ 6258-6259), a party seeking to prevent disclosure of public records must, as Amgen has done here, file a petition for writ of mandate under Code of Civil Procedure section 1085. (*Marken*, *supra*, 202 Cal.App.4th,

pp. 1265-1266 [discussing Gov. Code, § 6258 and observing that the PRA "expressly provides only for a cause of action to compel disclosure, not an action to prohibit disclosure"]; *National Conference of Black Mayors v. Chico Community Publishing, Inc.* (2018) 25 Cal.App.5th 570, 580; *Filarsky v. Sup. Ct.* (2002) 28 Cal.4th 419, 421; see Appx. 1:13-14.)

Thus, in order to prevail, Amgen must show that CCHCS has a "clear, present, and ministerial duty" to refrain from disclosing its "Confidential Pricing Information." (See *California High-Speed Rail Authority v. Superior Court* (2014) 228 Cal.App.4th 676, 707.) This is a deferential standard. "Mandamus will not lie to control an exercise of discretion, i.e., to compel an official to exercise discretion in a particular manner." (*Marken*, *supra*, 202 Cal.App.4th at p. 1265; see *San Gabriel Tribune v. Superior Court* (1983) 143 Cal.App.3d 762, 771 (hereafter "*San Gabriel Tribune*").) A writ will not issue unless the agency's decision is shown to be "arbitrary, capricious, or entirely lacking in evidentiary support." (*Bunnett v. Regents of University of California* (1995) 35 Cal.App.4th 843, 849.) "In determining whether an agency has abused its discretion, the court may not substitute its judgment for that of the agency, and if reasonable minds may disagree as to the wisdom of the agency's action, its determination must be upheld." (*Helena F. v.*

West Contra Costa Unified Sch. Dist. (1996) 49 Cal.App.4th 1793, 1799.)

In deciding whether to issue a preliminary injunction in a writ proceeding, a trial court weighs two interrelated factors, just as it would in an ordinary civil case: "'the likelihood the moving party ultimately will prevail on the merits, and the relative interim harm to the parties from the issuance or nonissuance of the injunction.'" (*Marken*, *supra*, 202 Cal.App.4th at p. 1260, quoting *Hunt v. Superior Court* (1999) 21 Cal.4th 984, 999.)

An appellate court reviews a trial court's order granting a preliminary injunction for abuse of discretion. (*Marken*, 202 Cal.App.4th at p. 1260.) "However, if the 'likelihood of prevailing on the merits' factor depends upon the construction of a statute or another question of law, rather than evidence to be introduced at trial, [the court of appeal's] review of that issue is independent or de novo." (*Id*. at p. 1261, citations omitted; see *Water Replenishment Dist. of Southern California v. City of Cerritos* (2013) 220 Cal.App.4th 1450, 1462.)

ARGUMENT

I. Notwithstanding Amgen's Dismissal of the Action, the Court Should Exercise Its Discretion to Review the Merits of this Appeal.

Although Amgen's dismissal of the Superior Court action terminates the dispute between the parties as to the single SB 17 notice at issue in the case, and voids the preliminary injunction

entered by the trial court, the Court should nonetheless exercise its discretion to decide this appeal, because it raises an issue of broad public interest and importance that is likely to recur and may evade review. (See *Conservatorship of Wendland* (2001) 26 Cal.4th 519, 524 fn. 1 [exercising discretion to decide extent of conservator's right to make end-of-life decisions notwithstanding conservatee's death, because the issues were important and would "tend to evade review because they typically concern persons whose health is seriously impaired"]; *Ramos v. Superior Court* (2007) 146 Cal.App.4th 719, 722 fn. 2 [dismissing writ petition as moot but exercising discretion to decide whether statute required felony complaint to be dismissed when preliminary hearing was not held within 60 days of arraignment]; *Apple Computer, Inc. v. Superior Court* (2005) 126 Cal.App.4th 1253, 1264 [deciding attorney disqualification issue notwithstanding attorney's withdrawal as counsel, because case presented "important issues that are capable of repetition yet tend to evade review"]; cf. *Harris v. Stampolis* (2016) 248 Cal.App.4th 484, 495-496 [stating that it would exercise jurisdiction to consider challenge to civil restraining order, even if order had not been renewed, because "it seems likely that the controversy will recur between the parties"])

The issue whether SB 17 notices must be publicly disclosed, so that proactive measures can be taken before a significant

increase in the WAC has been implemented, is an important one. The issue is also likely to recur. Indeed, although SB 17 only became effective on January 1, 2018, drug companies have already brought four reverse-PRA lawsuits (including this one) to prevent state-agency purchasers from providing copies of advance notice information to the news media and other public requestors. (See Appx. 1:103 [TRO obtained by GlaxoSmithKline on April 30, 2018; case voluntarily dismissed in May 2018]; *id*. 2:415-416, 420-424 [TRO obtained by GlaxoSmithKline and ViiV Healthcare on January 7, 2019; case stayed pending resolution of this case]; *id*. 1:89, 108-110 [TRO obtained by Ipsen Biopharmaceuticals, Inc.; case stayed pending resolution of this case].) CCHCS has been sued four times, California Public Employees' Retirement System (CalPERS) has been sued three times, Covered California has been sued once, and other state agency-purchasers have received communications from drug manufacturers demanding that their SB 17 notices not be publicly disclosed.. (Declaration of Gerri Milliken, ¶¶ 6-7, Exhibit 2 in Support of Appellant's Motion for Calendar Preference, filed April 12, 2017.)

Moreover, the issue is susceptible of evading judicial review. Notice of a planned increase in the WAC must be given only 60 days in advance, and the increase becomes public information once it has been implemented. Thus, if this appeal is dismissed, drug manufacturers can be expected to file more reverse-PRA

lawsuits, seek preliminary injunctive relief, and then voluntarily dismiss once the planned increase(s) have taken effect and been made public. This would allow the industry to secure confidentiality protections for information that simply is not entitled to protection as a matter of law, while avoiding any dispositive ruling on whether a state agency has discretion to provide this information to the public under the PRA or otherwise. (Cf. *People v. Marfield* (2007) 147 Cal.App.4th 1071, 1075 [noting that "trial courts consider the merits of timely filed petitions that are subsequently rendered moot as a result of delays inherent in the judicial process, which are beyond petitioner's control"].)

This danger is real. Already, two companies (GlaxoSmithKline and Amgen) have procured TROs or injunctions, only to dismiss their cases before a final judgment could be rendered, much less an appeal decided. GlaxoSmithKline brought a reverse-PRA action against CalPERS and CCHCS in April 2018 to prevent an SB 17 notice from being disclosed, only to dismiss the case after a temporary restraining order had issued. (See Appx. 1:63-64; 2:432). Similarly, after Amgen obtained the preliminary injunction at issue in this case, based on claims that it would suffer irreparable harm if the notice were disclosed under the PRA—even *after* the increases went into effect (see Appx. 2:364-365)—Amgen has now abruptly

dismissed its lawsuit.[8] There is nothing to stop Amgen from suing CCHCS again to prevent disclosure of a subsequent SB 17 notice.

Accordingly, notwithstanding Amgen's efforts to avoid an adverse ruling on the merits in this case, the Court should decide the appeal and settle the question of whether SB 17 notices are public information or not.

II. SB 17 Makes Clear that Advance Notices to Registered Purchasers Are Subject to Disclosure.

Amgen's allegation that its "Confidential Pricing Information" is exempt from disclosure under the PRA fails as a matter of law. SB 17 expressly requires that advance notices be provided to both public and private sector entities who purchase either directly from Amgen and other drug manufacturers or from PBMs, like CVS Caremark or Optum RX. (Health & Saf. Code, § 127677, subds. (d)-(e); see Appx. 1:191-207.) And nothing in SB 17 expressly or impliedly restricts the ability of any purchaser—public or private—to use or disclose the information

[8] The problem of the issue recurring and potentially evading judicial review is underscored by the fact that Amgen repeatedly argued to the trial court that TROs issued in other cases—which never resulted in a preliminary injunction, much less a final judgment —supported its motion for preliminary injunction in this case. (See Appx. 1:34; 1:63-64; 1:129-130.)

as they see fit. These basic features of the scheme are fatal to Amgen's claims for two overlapping reasons.

First, because registered purchasers are under no obligation to keep it secret, Amgen has no means of controlling the dissemination of its "Confidential Pricing Information." However, as discussed in more detail below, the ability to prevent disclosure to third-parties is the *sine qua non* of a trade secret. Without it, Amgen's trade secret claim fails as a matter of law. (See Section III.A. *infra*.)

Second, these features of the scheme demonstrate that the Legislature intended the information to be subject to disclosure, not just to registered purchasers, but to the public. All records in the possession of state agencies, including but not limited to state-agency purchasers of prescription drugs, are presumptively subject to public disclosure. (E.g., *Williams v. Superior Court* (1993) 5 Cal.4th 337, 447 [holding that "all public records are subject to disclosure unless the Legislature has expressly provided to the contrary"].) In the trial court, Amgen argued that the Legislature "could have drafted SB 17 to require public disclosure but chose not to do so." (Appx. 2:219.) But this is backwards. The Legislature did not need to affirmatively provide that the records at issue here shall be subject to disclosure under the PRA, because they are subject to disclosure *by default*.

Further, although SB 17 expressly requires that certain *other* information submitted to state agencies "shall be protected from public disclosure" (Health & Saf. Code, § 1367.243, subds. (a), (f); Ins. Code, § 10123.205, subds. (a), (f)), the Legislature made no such provision for the information at issue in this case. Thus, under the principle of e*xpressio unius est exclusio alterius*, (*Songsted v. Superior Court* (2001) 93 Cal.App.4th 1202, 1208; *Dean v. Superior Court* (1998) 62 Cal.App.4th 638, 641-42), the Legislature did not intend to bar disclosure under the PRA. If the Legislature so intended, it clearly knew how to do that, but did not.[9]

Although the plain language of the statute suffices, the legislative history of SB 17 confirms the conclusion that the Legislature deliberately decided not to shield advance notice information from disclosure under the PRA. Drug manufacturers opposed SB 17 specifically on the grounds that "the bill requires

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[9] See also Health & Saf. Code, § 127679, subds. (a) & (c). These provisions require drug manufacturers to provide detailed information to OSHPD for publication on its website, including, among other things, "specific financial and nonfinancial factors used to make the decision to increase the [WAC]," but provide that "[t]he manufacturer may limit the information . . . to that which is otherwise in the public domain or publicly available." (*Id*., subd. (b).) This is another instance in which the Legislature provided express protections for the confidentiality of other information, but *not* the information at issue in this case.

disclosure of commercially sensitive pricing information," and that "providing this information without confidentiality protections poses significant concerns." (Appx. 2:254, 286; see *id.* 1:160, 2:286.) Notwithstanding this opposition reflected in the Legislature's own reports, the Legislature elected to require disclosure to registered purchasers, without imposing any restrictions on the purchasers' use or disclosure of the information.

Beyond the plain language of the statute, a restriction on dissemination of this information by registered purchasers would defeat the Legislature's intent and weaken the efficacy of the law. Indeed, purchasers must be able to disclose it to third-parties in order for the statutory scheme to work as intended.

A key purpose of requiring advance notice of increases in the WAC is to give purchasers an opportunity to take proactive measures, including but not limited to using that information to negotiate better deals on competing drugs from other pharmaceutical companies. (Appx. 2:285; see *id.* 1:158.) Amgen's claims of secrecy are totally incompatible with this intended use of the information. In this regard, Amgen's claims also ignore that CCHCS and other state-agency purchasers receive SB 17 notices on the same footing as private purchasers, yet private purchasers have no statutory obligation to keep this information confidential. (See Health & Saf. Code, §§ 127675, subd. (a);

12677, subd. (a).) It would make no sense for the Legislature to prevent agencies like CCHCS from using the information in the same way and to the same extent that private purchasers may use it, including disclosing that information to Amgen's competitors in an effort to obtain an alternative drug at lower cost.

The California Supreme Court's decision in *State Farm Mutual Automobile Insurance Co. v. Garamendi* (2004) 32 Cal.4th 1029 (hereafter "*Garamendi*"), which involved an analogous situation, confirms the trial court's error. In that case, under a statute intended to rein in insurance rate increases, State Farm was required to, and did, file a "community service statement" with the Insurance Commissioner. (*Id.* at p. 1037.) It included with the statement a letter claiming that the information was a trade secret and "NOT TO BE DISSEMINATED . . . WITHOUT THE EXPRESS WRITTEN CONSENT" of State Farm. (*Ibid.*, emphasis in original.) After the Commissioner released the information to a private party requestor, State Farm sought an injunction requiring the return of its trade secret and barring the recipient from using it. The Supreme Court held that the Commissioner acted within his authority in promulgating a regulation that effectively stripped the information of trade secret protection by making it a public record. (*Id.* at p. 1047.)

Like the regulation in *Garamendi* requiring insurance companies to disclose certain information, SB 17—by requiring drug manufacturers to disclose information about planned increases in the WAC to purchasers, and imposing no restrictions on the purchasers' use or dissemination of that information—has stripped any claim of trade secret protection that might otherwise apply.

In sum, even assuming Amgen's "Confidential Pricing Information" might have qualified for trade secret protection before SB 17, it does not now as a matter of law.

III. The PRA Exemption on Which Amgen Relies Is Conditional, Not Absolute, and May Be Invoked Only on a Clear Showing that Nondisclosure Is in the Public's Interest.

Even if SB 17 did not mandate disclosure (and it does), Amgen still would have no likelihood of success on the merits. The trade secret privilege is a qualified privilege; it may only be used to bar disclosure under the PRA on a "clear showing that disclosure is against the public's interest." (*San Gabriel*, 143 Cal.App.3d at p. 777.) Amgen did not, and cannot, make such a showing. Indeed, the public interest strongly favors disclosure.

As noted above, Amgen claims its information is exempt from disclosure under Government Code section 6254, subdivision (k) (hereafter "Section 6254(k)"). Section 6254(k) is not an independent exemption; rather, it creates an exception to

the PRA's broad disclosure mandate for records that are protected by other state or federal laws. Some of those laws, including certain provisions of SB 17, categorically prohibit a public agency from disclosing the information in question. (E.g., Gov. Code, §§ 6254.15, 6254.7, subd. (f); Rev. & Tax Code, § 11655; Health & Saf. Code, 1337.243, subds. (a), (f); Ins. Code, 10123.205, subds. (a), (f).)

There is no categorical bar on disclosure in this case. Rather, Amgen relies on Evidence Code section 1060, which gives the holder of a trade secret a privilege to prevent others from disclosing it. (Appx. 1:67-68; 2:216, 221-222.). Of critical importance, section 1060 is a conditional privilege, not an absolute one; it may not be applied if non-disclosure would work an "injustice." (Evid. Code, § 1060.)[10] Moreover, the same division of this Court has specifically addressed the circumstances in which a public agency may claim the Section 6254(k) exemption for records that contain or reveal an alleged trade secret, and the bar is high. In *San Gabriel*, it held that "the [trade secret] privilege that section 6254(k) incorporates should

[10] Evidence Code section 1060 states that it applies specifically to a "trade secret" as defined in Civil Code section 3426, California's version of the Uniform Trade Secrets Act. However, by its express terms the California statute "does not affect the disclosure of a record by the state or a local agency under the [PRA]." (Civ. Code, § 3426.7, subd. (c).)

be applied conditionally *on a clear showing that the disclosure is against the public's interest*." (143 Cal.App.3d at p. 777, emphasis added; accord *Uribe v. Howie* (1971) 19 Cal.App.3d 194, 206-207, 213 fn. 2.)[11]

The court in *San Gabriel Tribune* further held that the effects of disclosure on an entity's private economic interests are not the appropriate focus; what ultimately matters is the public's interest. (143 Cal.App.3d at p. 777.) Thus, the court rejected the city's argument that disclosure of a private contractor's confidential business information would "both invade a private

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[11] The courts in both *San Gabriel* and *Uribe* also considered whether an alleged trade secret may be withheld under the "official information" privilege in Evidence Code section 1040 (for "information acquired in confidence by a public employee in the course of his or her duty and not open, or officially disclosed, to the public prior to the time the claim of privilege is made"). Like section 1060, section 1040 is a conditional privilege. It does not categorically bar disclosure of information given to a public agency, even on a confidential basis. Rather, it gives the agency "a privilege to refuse to disclose" it, but only if either (1) "[d]isclosure is forbidden by an act of the Congress of the United States or a statute of this state," or (2) "[d]isclosure of the information is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice." (Evid. Code, § 1040., subds. (b)(1)-(2).) The courts in both *San Gabriel* and *Uribe* suggest that, when a public agency considers whether a trade secret should be disclosed under the PRA, the analysis is the same under either section 1040 or section 1060.

company's privacy interests, as well as hav[e] a chilling effect on obtaining information in similar future transactions." (*Ibid*.) Such a "threat to future dealings" did not constitute "sufficient reason to withhold disclosure in the name of the public's interest," because it "*misstates what the public's interest is as serving the privacy interests of a private contractor, rather than in serving the public's interest in participating in local government*." (*Ibid*., italics added.)[12]

Judged against this standard, Amgen has no likelihood of success on the merits, because the public's interest strongly favors disclosure. The PRA declares that "access to information

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[12] Other court decisions are consistent. In *Marken*, this Court considered and rejected plaintiff's claim that disclosure of an investigative report and letter of reprimand would violate his constitutional right to privacy, and therefore disclosure was "otherwise prohibited by law." (202 Cal.App.4th at p. 1271.) The court held that even an "invasion of a privacy interest is not a violation of the state constitutional right to privacy if the invasion is justified by a competing interest," and that the public's interest in disclosure outweighed the plaintiff's privacy interest. (*Id.* at pp. 1274-1276, citation omitted.) There, as here, the public policy at issue was "[t]he 'strong public policy interest supporting transparency in government.'" (*Id*. at p. 1271, quoting *International Federation v. Superior Court* (2007) 42 Cal.4th 319, 331; accord *Bran v. City of Taft* (1984) 154 Cal.App.3d 332, 347 [holding that constitutional right of privacy must be balanced against the public's interest in the conduct of its business].) Here, too, no law prohibits disclosure of Amgen's "potential price increases."

concerning the people's business is a fundamental and necessary right of every person in this state." (Gov. Code, § 6250; see also Cal. Const., art. I, § 3(b)(1).) And, in enacting SB 17, the Legislature declared disclosure of large increases in the WAC to be in the public interest, i.e., "to provide accountability to the state for prescription drug pricing" (Health & Saf. Code, § 127674(b)); "shine[] a light on drugs that are having the greatest impact on our health care dollar" (Appx. 1:171); and give purchasers a means of negotiating better deals from competing suppliers. (*Id*. 1:158; see *supra*, p. 13, 16-17.)

Indeed, the public interest in allowing state-agency purchasers like CCHCS to disclose this information to Amgen's competitors in order to leverage lower prices is particularly strong. The Legislature adopted SB 17 not just to protect the state's consumers from skyrocketing drug prices, but also the public fisc. Because the source of CCHCS's funds to purchase drugs is the taxpayers, hamstringing CCHCS in its ability to use this information to obtain better prices would clearly harm the public interest.

Meanwhile, Amgen provided no evidence suggesting that disclosing its "Confidential Pricing Information" would damage the public interest. Amgen has only claimed that giving advance notice of increases in the WAC may create a rush to stockpile drugs, resulting in supply shortages. (Appx. 1:84.) But this is in

substance simply an argument against SB 17 itself, for it is purchasers—which are statutorily-entitled to advance notice—that could be expected stockpile drugs, creating (in Amgen's hypothesis) a supply shortage. And in enacting SB 17, the Legislature was well aware of these arguments, which are described SB 17's legislative history, for example:

> [Biotechnology Innovation Organization, a biotechnology trade association] is also concerned that the advance notice provisions in this bill would have serious unintended consequences for the drug supply chain because the substantial advance notice would provide enough time for wholesaler, hospitals, pharmacies, large provider networks, and buying groups to engage in stockpiling activity in advance of a price increase, which would disrupt the availability of medicines. . . .

(Appx. 1:160.) The Legislature implicitly rejected this "public interest" argument when it enacted SB 17 over the industry's objections.

Amgen has further contended that non-disclosure is in the public interest because it has alleged that *it* will otherwise suffer irreparable injury (Appx. 1:69; 2;222-223), but it has cited no relevant authority for this proposition and, more importantly, its argument conflicts with the analysis in *San Gabriel Tribune*, *Marken*, and other cases. What matters is the public's interest, not Amgen's financial interests. (*Los Angeles Unified Sch. Dist. v. Superior Court* (2014) 228 Cal.App.4th 222, 242 [holding that

"[w]hat is material is the public interest in disclosure, not the private interest of a requesting party"], citation omitted.)

For all these reasons, the trial court erred and should be reversed. Amgen made no showing that disclosure of its "Confidential Pricing Information" under the PRA would damage the public interest, let alone a "clear showing." Just the opposite, the record in this case makes clear that *non*-disclosure would seriously undermine the public interest.[13]

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[13] Courts have repeatedly held that the PRA exemptions set forth in Government Code section 6254 are "permissive," rather than mandatory. (*Marken*, 202 Cal.App.4th at p. 1266, fn. 12; see also *National Conference of Black Mayors v. Chico Community Publishing, Inc.*, *supra*, 25 Cal.App.5th at pp. 579-80; *CBS v. Block* (1986) 42 Cal.3d 646, 652; *Register Div. of Freedom Newspapers, Inc. v. County of Orange* (1984) 158 Cal.App.3d 893, 905.) This means that, absent a clear prohibition on disclosure, an agency may release a record to the public, even when an exemption from disclosure would otherwise apply. (*CBS v. Block*, *supra*, 42 Cal.3d at p. 656 [citing Gov. Code, § 6254].) The PRA "endows the agency with discretionary authority to override the statutory exceptions when a dominant public interest favors disclosure." (*Ibid.*)

In addressing this distinction between a permissive and a mandatory exemption under the PRA, the trial court held that "without the ability to bring a reverse-CPRA action, Petitioners' trade secret protection would be left to the discretion of Respondent." (*Id.* 2:391.) Similarly, it held that the Court of Appeal has "recognized the legitimacy of a reverse-CPRA action." (*Id.*) But this analysis misses the mark. CCHCS did not (and does not) contend it had *unfettered* discretion to disclose Amgen's

(continued…)

IV. As a Matter of Law, the Information in Amgen's Notice Is Not a Trade Secret.

For all of the reasons described above, regardless of whether the information at issue qualifies for some kind of trade secret protection, CCHCS's decision to disclose the information was proper. Nonetheless, as a matter of law, the information that must be disclosed under SB 17 is not a trade secret. (See *Uribe v. Howie*, *supra*, 19 Cal.App.3d at p. 207 [holding that the question of what constitutes a trade secret for purposes of possible exemption under the PRA is a question of law].)

A. The information in SB 17 Notices is not a trade secret because Amgen and other drug manufacturers cannot control its dissemination.

As discussed above in Section I, *supra*, "[t]he sine qua non of a trade secret . . . is the plaintiff's possession of information of a type that can, at the possessor's option, be known to others or

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(…continued)
information under Section 6254(k), that its decision is somehow immune from judicial review, or that Amgen had no right to bring an action to prevent disclosure. CCHCS contends there is no statutory or other prohibition on disclosing Amgen's information under the PRA. It further contends that deciding whether the public interest favors or opposes disclosure in this case required an exercise of discretion, and that there is no basis for finding that CCHCS abused its discretion in determining that the information should be provided to Reuters.

withheld from them . . . . Trade secret law, in short, protects only the right to control the dissemination of information." (*Altavion, Inc. v. Konica Minolta Systems Laboratory, Inc.* (2014) 226 Cal.App.4th 26, 53, emphasis in original, citation omitted.)

> Secrecy is an essential characteristic of information that is protectable as a trade secret. . . . It is well established that "[i]f an individual discloses his trade secret to other who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses his secret, his property right is extinguished.

(*Id.* at p 57.)

Here, Amgen and other drug manufacturers do not have the right or practical ability to control the dissemination of their information due to the simple fact that it must be disclosed to nearly 200 (at latest count) private and public purchasers, none of whom is under an obligation to keep it confidential. (Appx. 1:191-207; see *id.* 2:351.) *Whyte v. Schlage Lock Co.* (2002) 101 Cal.App.4th 1443, 1454-1455, is illustrative on this point. The court there held that information Schlage had disclosed to Home Depot was not a trade secret, because the record did not contain an agreement requiring Home Depot to keep the information confidential. (*Id.* at p. 1455.)[14] It also held that information

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[14] As the trial court recognized, the fact that Amgen labeled its notice "confidential" does not impose an obligation of secrecy on the recipients. (Appx. 2:394; see *Garamendi, supra*, 32

(continued…)

disclosed to customers, including price concessions, trade discounts, and rebate concessions, were not trade secrets. (*Ibid.*)

There is no way to reconcile Amgen's claims of secrecy with the dissemination of its "Confidential Pricing Information" to a long list of public and private purchasers who are entitled—indeed encouraged—to use the information to further their own economic interests. The purpose of the advance notice required by SB 17 is to "help purchasers understand and plan for specific price increases," (Appx. 2:285; see *id.* 1:158), including permitting the purchasers "to negotiate discounts and rebates" (Health & Saf. Code, § 127675, subd. (b)), or to "seek other alternatives, including obtaining alternative formulations for drugs for which there are therapeutic equivalents." (Appx. 1:158.) Thus,

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(…continued)
Cal.4th at p. 1037.) A unilateral announcement that something is confidential is not an agreement by the recipient to keep it confidential. Still, the trial court went on to hold that "there is no evidence [that registered] purchasers have not voluntarily complied with [Amgen's] request to maintain the confidentiality of the information." (Appx. 2:39.) This was error, because it reverses the burden. As the party seeking an injunction, Amgen had the burden of showing that purchasers have in fact "voluntarily complied," but it made no such showing. As it stands, the record is devoid of any information on this point, and there is no reason to think that further factual development will show that purchasers are voluntarily complying, let alone that Amgen can dictate their behavior.

purchasers may be expected to proactively use the information, including negotiating for alternative products offered by Amgen's competitors, and putting public pressure on Amgen to lower its prices—activities that are completely incompatible with keeping the information secret. (See *id*. 1:12-13.)

In short, the fact that Amgen has widely disclosed the information, however reluctantly, is fatal to its trade secret claim. Moreover, due to the trial court's preliminary injunction, of all of the purchasers that received Amgen's notice, *only CCHCS* is prohibited from disclosing it—a nonsensical result. [15]

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[15] Amgen also waived any claim to trade secret protection by publishing more information to purchasers than Senate Bill 17 requires. Instead of disclosing just the planned increase in the WAC for each drug, as required, its notice included a *range* of potential increases. (See Appx. 2:390.)

SB 17 does not require (or even permit) notice to purchasers of a *range* of possible increases; rather, a notice need only state the current WAC and "*the dollar amount of the future increase in the [WAC].*" § 127677, subd. (c)(1), emphasis added.) By voluntarily disclosing a "range of potential increases" without being statutorily required to do so, Amgen waived any possible trade secret protection that a "range" of possible increases would otherwise merit. Amgen's decision to disclose a range of potential increases also guts the trial court's conclusion that Amgen would not have disclosed the information at all but for SB 17, for contrary to the trial court's ruling, SB 17 did not "compel[] Petitioner to make the disclosure." (Appx. 2:391.)

B. A planned increase in the WAC is not entitled to trade secret protection.

As noted above, the WAC of prescription drugs is public information. It is a generic list price, and does not include "prompt pay or other discounts, rebates or reductions in price" that would affect the actual price paid by any particular purchaser. (42 U.S.C. § 1395w-3a(c)(6)(B); see *ante*, p. 5 & fn. 2.) As the Legislature understood, the WAC is not a price, but a benchmark.

> Price Benchmarks. Knowing how much a drug costs is difficult; there are many different prices for each drug and different ways of expressing those prices. In the US, the two most common ways of stating drug prices are the WAC and average wholesale price (AWP). *Neither one, though, is the actual price paid by a payer, nor are they what their names imply. Rather, they're standardized ways of expressing a price, thus allowing comparisons to be made from one drug to another. . . .*

(Appx. 1:156, emphasis added.) As such, it is not a trade secret.

The fact that information may *relate* in some way to actual prices does not a fortiori make it a trade secret. (See *Fortna v. Martin* (1958) 158 Cal.App.2d 634, 640 [holding that plaintiff's method of pricing and bidding was not a trade secret]; *Aetna Bldg. Maintenance Co. v. West* (1952) 39 Cal.2d 198, 206 [rejecting claim that plaintiff's procedure for estimating the price for new contracts was a trade secret]; *SI Handling Systems, Inc. v. Heisley* (3d Cir. 1985) 753 F.2d 1244, 1260 [holding that data

relating to materials, labor, overhead and profit market were trade secrets, "unlike the price" of a product].) Amgen cited no case holding that a planned change in a generic, publicly available list price is a trade secret, and the trial court identified none.

Further, a trade secret must be more than "simply information as to a single or ephemeral events in the conduct of a business. . . ." (*Uribe v. Howie*, *supra*, 19 Cal.App.3d at p. 207, citation omitted.) In *Uribe*, for example, the court rejected a claim that data about the composition of pesticides was a trade secret. The data at issue revealed "only a past decision, based on transitory conditions," and did not comprise a "process or device for continuous use in the operation of the business." (*Id*. at pp. 208-209.) Here, too, information on a single set of planned increases in generic list prices is not a trade secret.

In short, since the information does not qualify for trade secret protection under California law, no exemption—even the permissive exemption of section 6254(k), incorporating Evidence Code section 1060—can shield the information from disclosure under the PRA.

V. The Balance of Hardships Does Not Support the Injunction.

Amgen's claim of hardship, too, fails as a matter of law. A trade secret must be something that gives its holder "an opportunity to obtain an advantage over competitors who do not

know or use it." (*Uribe v. Howie*, *supra*, 19 Cal.App.3d at p. 207. Any unfair competitive advantage is lacking here, since Amgen's competitors also must comply with SB 17. (See *id*. at p. 210 [holding that the public interest required disclosure, even if the reports contained trade secrets, and noting that because the reports of all pesticide applicators would be made public, "one applicator will not be able to gain a competitive advantage over his fellows"].)

CONCLUSION

For the reasons stated above, the trial court abused its discretion in entering the preliminary injunction in this case. The Court should render a decision holding that SB 17 notices are subject to disclosure under the PRA.

Dated: May 17, 2019 Respectfully submitted,

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SA201910114

CERTIFICATE OF COMPLIANCE

I certify that the attached APPELLANT'S OPENING BRIEF uses a 13 point Century Schoolbook font and contains 8,422 words.

Dated: May 17, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the attached APPENDIX OPENING BRIEF uses a 13 point Century Schoolbook font and contains 8,489 words.

Dated: May 17, 2019

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DECLARATION OF SERVICE

Case Name: **Amgen, Inc. v. California Correctional Health Care Services**

No.: **B296563**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter. I am familiar with the business practice at the Office of the Attorney General for collecting and processing electronic and physical correspondence.

On May 17, 2019, I electronically served the attached **APPELLANT'S OPENING BRIEF** by transmitting a true copy via this Court's TrueFiling system. Because one or more of the participants in this case have not registered with the Court's TrueFiling system or are unable to receive electronic correspondence, on May 17, 2019, I placed a true copy thereof enclosed in a sealed envelope in the internal mail collection system at the Office of the Attorney General at 455 Golden Gate Avenue, Suite 11000, San Francisco, CA 94102-7004, addressed as follows:

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I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on May 17, 2019, at San Francisco, California.

Susan Chiang	/s/ Susan Chiang
Declarant	Signature

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