No. 2019-2156

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

GENENTECH, INC.,

Plaintiff-Appellant,

CITY OF HOPE,

Plaintiff,

v.

AMGEN INC.,

Defendant-Appellee.

On Appeal from the United States District Court
for the District of Delaware, No. 1:18-cv-00924-CFC, Judge Colm F. Connolly

NON-CONFIDENTIAL REPLY BRIEF FOR PLAINTIFF-APPELLANT GENENTECH, INC.

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CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Genentech, Inc. certifies the following:

1. The full name of every party or *amicus* represented by me is:

Genentech, Inc.

2. The names of the real party in interest represented by me are:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Genentech, Inc. is a wholly-owned subsidiary of Roche Holdings Inc. Roche Holdings Inc.'s ultimate parent, Roche Holdings Ltd, is a publicly held Swiss corporation traded on the Swiss Stock Exchange. Upon information and belief, more than 10% of Roche Holdings Ltd's voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

Genentech, Inc. v. Amgen Inc., No. 18-cv-924-CFC (D. Del.)

Dated: September 20, 2019

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CONFIDENTIAL MATERIAL OMITTED

The confidential information that has been deleted on pages iii, 12-13, 15-19, and 23 describes highly confidential, competitively sensitive information relating to the Herceptin biosimilars market including market entry, forecast planning, competitive intelligence, and the terms of third-party license agreements.

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INTRODUCTION

Amgen's opposition reinforces the legal errors underlying the district court's denial of a preliminary injunction. Amgen cites no authority holding that a patentee forfeits the right to a preliminary injunction by waiting to see whether the challenged conduct is likely to occur, particularly when the motion is filed before any such conduct has taken place. The statutory scheme does not impose such an obligation, and Amgen does not argue otherwise. Nor does Amgen dispute that, right up until the eve of Genentech's motion, Amgen and its witnesses repeatedly insisted that Amgen had not decided whether to launch Kanjinti at risk. Amgen barely acknowledges those statements, let alone explains how Genentech could be faulted for failing to act when Amgen itself represented that it had not yet decided whether to do so. There was thus no legal basis for the district court to find that the timing of Genentech's motion negated Genentech's showing of irreparable harm.

The district court also legally erred in concluding that Genentech could not establish irreparable harm based on its settlements with other biosimilar manufacturers. Genentech has granted licenses permitting the use of its dosing patents in the future, but nobody is licensed to use them now. The district court legally erred in concluding that those licenses for future conduct negate irreparable harm now. Indeed, Amgen does not address the cases cited in Genentech's brief holding that licenses for future entry do not show the absence of irreparable harm in

the present, nor does it cite any authority supporting the district court's contrary conclusion. And, when the shoe was on the other foot, Amgen conceded that an unlicensed biosimilar entry will give rise to irreparable harms.

The district court suggested in a footnote that the public interest weighed against an injunction, and Amgen points to Kanjinti's non-infringing uses as the source of that supposed interest. But Amgen does not dispute that the majority of Kanjinti's uses are infringing and that it could have avoided injunction proceedings altogether by launching with a "skinny" label reciting only non-infringing uses. Nor can Amgen establish harm to patients: Genentech's reference product Herceptin by definition meets the medical need, and Amgen has not raised any concerns about patient access to Herceptin.

The district court did not address Genentech's likelihood of success on the merits or the balance of hardships, both of which favor Genentech. Amgen does not dispute infringement. While it labels its invalidity theory "new," Amgen offers nothing consequential on invalidity beyond the arguments that already failed in IPRs under a lower burden of proof. Nor has Amgen rebutted Genentech's balance-of-hardships showing; on the contrary, Amgen's only alleged hardships stem from its own risk-taking.

Unless corrected, the district court's decision sets a dangerous precedent: It will force patentees to seek preliminary injunctions prematurely to avoid forfeiting

their rights. And it will make it difficult—if not impossible—to settle biosimilar litigation with licenses for future market entry without surrendering the patentee's right to exclude others now. The denial of a preliminary injunction should be reversed or, at a minimum, vacated and remanded for further consideration under the correct legal standard.

ARGUMENT

I. THE DISTRICT COURT'S DETERMINATION OF NO IRREPARABLE HARM RESTED ON LEGAL ERRORS.

A. The Court Applied An Incorrect Legal Standard To Conclude That Genentech's "Delay" Defeated Irreparable Harm.

1. The timing of Genentech's injunction motion alone cannot demonstrate the absence of irreparable harm.

Amgen casts the district court's delay analysis as a case-specific, factual determination. Br. 28-30. But the ***only*** facts upon which the district court relied in concluding that Genentech unduly delayed involved the period of time ***before*** Amgen had even announced its intention to infringe, let alone started to do so. For that reason, the district court legally erred in concluding that the timing of Genentech's motion was "sufficient by itself to deny the motion." Appx7.

A patentee may be found to have delayed unduly when it endured without complaint the sale of infringing products it then seeks to enjoin. *See, e.g.*, *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (delay after infringing sales "could suggest that the patentee is not irreparably harmed by the

infringement"); *Nutrition 21 v. United States*, 930 F.2d 867, 872 (Fed. Cir. 1991) (delay after sales commence "suggests that the *status quo* does not irreparably damage [patentee]"); *T.J. Smith & Nephew Ltd. v. Consolidated Med. Equip., Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1988) (delay after infringing sales is "incompatible with the emphasis on the right to exclude" underlying the patentee's theory of irreparable harm); *see also* Genentech Br. 26-29 (discussing cases). But the district court made no such finding here, nor could it: Genentech was not suffering—and did not know that it would suffer—the harms it sought to enjoin before July 2019.

Amgen's own authorities are in accord, and explain that relevant delay for purposes of irreparable harm does not begin to accrue "until the infringer actually started to (or was about to) commit that particular infringing act" that the patentee seeks to enjoin. *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, 2016 WL 4770244, at *9 (D. Del. Aug. 12, 2016). The district court's contention that Genentech waited "fourteen months after receiving the Notice of Commercial Marketing, three months after receiving a fairly specific launch date, and almost one month after Amgen had FDA approval to launch Kanjinti" therefore addresses the wrong question. Appx6. Nor is that a fair characterization of the record: it is undisputed that the "launch date" referred to above was the date by which Amgen had indicated it would be "ready" to launch ***if it decided to do so***, and that Amgen itself repeatedly insisted that no such decision had been made. Appx3770.

The cases that Amgen cites (Br. 24-26, 32-34) merely reinforce the district court's error. The only instances Amgen identified in which a court found delay relevant to irreparable harm involved a patentee that allowed infringing products to ***remain*** on the market. *See Apple, Inc. v. Samsung Elecs. Co.*, 2011 WL 7036077, at *22 (N.D. Cal. Dec. 2, 2011) (one-year delay after release of infringing products), *aff'd-in-part & vacated-in-part*, 678 F.3d 1314 (Fed. Cir. 2012); *Cordis Corp. v. Boston Scientific Corp.*, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003) (patentee failed to seek injunctive relief against related product with same patented features), *aff'd*, 99 F. App'x 928 (Fed. Cir. 2004).

The remaining cases cited in Amgen's brief refused to deny a preliminary injunction because of delay, even where the patentee waited months or even years after the infringing sales commenced before seeking preliminary injunctive relief. *See Integra LifeSciences*, 2016 WL 4770244, at *12 (two-month delay after the first infringing U.S. sale constituted "at most a slight delay" that "should not have a significant impact on an assessment of irreparable harm"); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (no delay where suit filed within two months of launch of infringing generic drug); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) (no delay where suit filed four months after infringing sales began); *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457

(Fed. Cir. 1988) (no error in concluding that multi-year delay in filing suit while litigating against another party did not demonstrate the absence of irreparable harm).

Amgen (Br. 34) attempts to analogize this case to *Cordis*. In *Cordis*, however, the patentee did not seek an injunction ***at all*** against a related infringing product that was incorporated into the accused product and formed the entire basis for the patentee's infringement action. *See Cordis*, 2003 WL 22843072, at *2 & n.3. It followed that the patentee was "willing to seek money damages," rather than a preliminary or permanent injunction, for the very infringement at issue in the case. *Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 934 (Fed. Cir. 2004) (nonprecedential). That conclusion was reinforced by the fact that other competitors were presently licensed to use the patented invention. *Id.* At most, the panel in *Cordis* affirmed that delay can be one of many factors to consider, and that a patentee may not be able to establish irreparable harm where it has suffered the defendant's infringement without complaint and is permitting the inventions to be used by others. Amgen cited no case holding that the absence of irreparable harm can be inferred from the timing of the patentee's motion ***alone***, much less where, as here, the patent owner was enjoying its present right to exclude infringing competition.

Contrary to Amgen's assertion (Br. 30-32 & n.2), the issue here is not whether a preliminary injunction motion is "categorically premature" before a biosimilar applicant launches or whether the "availability of preliminary injunctive relief [is]

triggered only by an applicant's decision to *immediately* begin selling its biosimilar." *Id.* A patentee might be able to seek a preliminary injunction at an earlier date when the circumstances warrant. The issue is whether Genentech was ***required*** to seek an injunction before the harm that it sought to enjoin had commenced and before ***any*** launch decision had been reported. The district court's affirmative answer was legal error.

2. Amgen ignores its repeated representations that it had not decided whether or when to launch Kanjinti at risk.

Amgen cannot dispute that Amgen and its witnesses repeatedly represented to the district court and Genentech that—even as of late June—Amgen still had not decided whether, much less when, to launch Kanjinti at risk. Indeed, Amgen's Rule 30(b)(6) witness testified on June 27, 2019—two weeks ***after*** Kanjinti was approved by the FDA—that "as of today, ***no decision has been made on launching*** either Mvasi or ***Kanjinti at all***."[1] Appx4838(353:12-19) (emphasis added). That same day, Amgen filed a brief in the district court reiterating that its decision as to whether to launch Kanjinti at risk is "something that has not occurred." Appx1299. Amgen made those representations weeks after its initial "go/no go" decision supposedly occurred, which refutes Amgen's suggestion now that the "*final* 'go/no go' decision

[1] Mvasi is Amgen's biosimilar product to Genentech's drug Avastin. Mvasi is not at issue in this case.

by Amgen management" in July 2019 was a mere formality. Amgen Br. 37-38 (citing Appx4074).

Amgen barely acknowledges those statements in its brief, nor does it defend the district court's failure to address them. Instead, it points to other witness testimony indicating that "Amgen was preparing to be ***ready*** to launch Kanjinti in July 2019." Amgen Br. 37-38 (quoting Appx6) (emphasis added). But Amgen's counsel made clear that being ***ready*** to launch is different from actually deciding to proceed with a launch. Appx1276(29:10-17) ("[T]hey're getting it all ready for an ultimate decision-maker to decide whether or not we take that product and we launch it before the expiration of the patent."). And its witnesses repeatedly disavowed that any such launch decision had been made. Genentech Br. 11-13.

Amgen attempts to downplay the significance of its counsel's statements at a June 18, 2019 discovery hearing—five days after Kanjinti was approved—that a privilege waiver dispute "may not be ripe" because Amgen had not yet decided whether to launch Kanjinti at risk. Amgen Br. 38 (quoting Appx1277(31:10-11)). But if a privilege-waiver dispute is not "ripe" because no launch decision had been made, a motion for a preliminary injunction stemming from that same launch decision would not be "ripe" for the same reasons.

Indeed, at that same June 18 hearing, Amgen's counsel argued that, although Amgen was preparing to launch at some point, there was still uncertainty

surrounding when that actual launch might occur—whether in "two months versus six months versus a year." Appx1277(30:3-8). Amgen suggests (Br. 38) that its counsel "reasonably did not give a definite launch date." But counsel did not simply forbear from giving a "definite launch date"; counsel stated that any launch could be ***as much as a year away***—well after the merits trial scheduled for December 2019. And Amgen's counsel recognized that "the circumstances from Genentech's standpoint and from the market standpoint may be very different in those different scenarios." Appx1277(30:6-8). Just so: Amgen represented that it might not launch until after trial, and in that situation there would be no reason to burden the court with an injunction request. However Amgen tries to rationalize and contextualize its representations now, Genentech should not be faulted for taking Amgen at its word.

In an effort to distract from its own representations, Amgen points to Genentech's statement during a May 16, 2019 hearing that "[w]e're not presently seeking injunctive relief." Appx1246(26:3-4). But Genentech was clear throughout this case that it would seek a preliminary injunction if Amgen decided to launch at risk. Appx5054(87:20-21) ("Your Honor, if there's a launch, we're going to request a preliminary injunction."). Genentech's statement that it was not "presently" seeking a preliminary injunction in May 2019—at a time when Amgen had

affirmatively disclaimed having made a launch decision—was not a disavowal of its right to seek an injunction if circumstances changed.

3. The timing of Genentech's motion is not contrary to the "spirit and purpose" of the BPCIA.

Lacking any authority to suggest that the timing of Genentech's motion negates irreparable harm, Amgen argues (Br. 32) that this case is somehow different because it arises under the BPCIA. To be sure, the BPCIA provides a framework that permits "litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes."[2] *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). But it does so by permitting a patentee to do what Genentech did in 2018: bring suit "even if the applicant has not yet committed an act that would traditionally constitute patent infringement" (*id.*); it does not require premature motions for preliminary relief. Even Amgen agrees that the BPCIA does not mandate that a reference-product sponsor must move for a preliminary injunction within a specified time. Br. 29; *see also* ECF 28 at 14 ("[T]here is no statutory mandate that Genentech seek a preliminary injunction at a particular time after the Notice of Commercial Marketing[.]"). The "spirit and

[2] For example, the BPCIA allows a biosimilar applicant to submit an application 4 years after the reference product's approval, giving the parties up to 8 years to resolve patent disputes before the biosimilar is licensed. 42 U.S.C. §§ 262(k)(7)(A), (B). Because Herceptin was first approved before the BPCIA was enacted, the period for resolving patent disputes before the biosimilar's approval is shorter here than what the BPCIA might otherwise provide.

purpose" of the BPCIA is permissive; it allows a patentee like Genentech to seek preliminary injunctive relief upon receipt of a notice of commercial marketing when the circumstances warrant. *See* 42 U.S.C. § 262(*l*)(8)(B). As Amgen concedes, however, that does not mean that a party must seek that relief even if there is no apparent need for it "or forever hold its peace." Br. 29.

Amgen asserts (Br. 29) that the district court did not adopt a "blanket rule" that a patentee must seek a preliminary injunction within 180 days of a notice of commercial marketing or risk forfeiting its right to injunctive relief. But neither the district court nor Amgen has identified an alternative date when the obligation to move immediately for a preliminary injunction supposedly accrued. And the facts of this case illustrate why a patentee should not need to seek injunctive relief immediately upon receipt of a notice of commercial marketing or risk a finding of no irreparable harm. Amgen's assertion (Br. 1) that its notice of commercial marketing meant it could begin commercial marketing "potentially within as little as six months" is simply not true. The FDA did not approve Amgen's initial application and instead provided a complete response letter, requiring Amgen to resubmit its entire application. *See* Genentech Br. 10-11. Amgen argues (Br. 36) that Genentech could have sought injunctive relief as soon as Amgen provided its notice of commercial marketing, but for many months after that Amgen did not even have an application on file that could have been approved by the FDA.

When Amgen finally resubmitted its application to the FDA on December 28, 2018, it had [redacted] the [redacted] covered by Genentech's dosing patents from its [redacted] due to [redacted] Appx1830; Appx1832. Had Amgen proceeded with its planned [redacted], Amgen's launch may have been [redacted]. It wasn't until March 25, 2019, after recognizing that Kanjinti would not be [redacted] without those [redacted], that Amgen [redacted] to a [redacted]. Appx4074. And, although Amgen suggests (Br. 36) that the [redacted] should have removed uncertainty about the scope of its launch, Amgen's own documents indicate that it was still thinking about pursuing a [redacted], even if that would result in a [redacted]. Appx4074 ("Getting approval with a [redacted], then evolving to a [redacted] remains to be viewed as a better scenario." (emphasis added)). Amgen never explains why Genentech should have assumed that Amgen would launch with a [redacted] when Amgen itself had not decided to do so.

Genentech moved for a preliminary injunction just one month after Amgen's product was approved with a full label. One month could hardly be considered "delay" in the best of circumstances. And here, even after FDA approval of the full

label, Amgen continued to represent that it had not decided whether or when to launch. *See supra* pp. 7-10; Genentech Br. 11-14.[3]

B. The Court Evaluated Genentech's Licensing History Under An Incorrect Legal Standard.

1. [redacted] licenses for future market entry do not, as a matter of law, show the absence of irreparable harm now.

This Court's precedents hold that a patentee's licensing history may be relevant to the extent it shows that it has parted with its exclusivity or monetized its inventions. *See* Genentech Br. 36-41. Genentech's licensing history here shows neither: it settled actual or threatened litigation by bargaining for exclusivity, not [redacted] (now or later). Amgen does not cite any authority holding that a [redacted] license providing for ***future*** entry negates irreparable harm from another party's infringement during the bargained-for period of exclusivity. Nor does Amgen explain how patentees could ever settle litigation if the mere existence of a license for future market entry surrendered the right to exclude all market participants at all times. Genentech Br. 44. Unless corrected, the district court's decision will stifle

[3] Amgen notes (Br. 37) that Genentech "understood it could seek injunctive relief" prior to FDA approval because it sought a schedule for such relief in another case involving a different biosimilar applicant. But in that case, the biosimilar applicant came forward and disclosed that it had made a launch decision several months before its intended launch date, allowing the parties to discuss an orderly schedule for preliminary-injunction proceedings. By contrast, Amgen insisted that it had made no launch decision until seven days before its intended launch, and even then did not volunteer that information, such that Genentech only learned of its plans through market intelligence. *See* Genentech Br. 11-14.

litigation settlements, especially in pharmaceutical cases where licenses for future entry dates are commonplace.

The only case Amgen cites (Br. 40)—*Cordance Corp. v. Amazon.com, Inc.*, 730 F. Supp. 2d 333, 341 (D. Del. 2010)—involved a patentee that had allowed its invention to be used by anyone freely for more than a decade. *Cordance* does not speak to the value of a patented technology before anyone is licensed to use it. Amgen previously characterized *Cordance* as "[t]he precedent most analogous to the facts of this case" (ECF 28 at 18); its inability to identify any authority finding an absence of present irreparable harm based on licenses for future market entry confirms just how unprecedented the district court's decision is.

When courts have addressed the relevance of licenses for future market entry, they have uniformly found that they do ***not*** show the absence of irreparable harm in the present. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061-1063 (Fed. Cir. 2010) (affirming injunction where defendant planned to launch its generic drug before the licensed launch date for another generic competitor); *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 843 (N.D. Ill. 2007) (licenses permitting future generic drug entry do not "automatically show that [the patentee] should not be able to reap the complete benefit of the power to exclude now"). To the extent that licensing activity has any relevance to irreparable harm, it is when the licensee already "changed the market by making available" a competing product. *Nichia*

Corp. v. Everlight Ams., Inc., 855 F.3d 1328, 1343 (Fed. Cir. 2017). The district court's determination that Genentech's licenses for future market entry could negate irreparable harm now was legal error.

2. None of Amgen's rationalizations for the district court's decision has any merit.

Amgen asserts (Br. 40) that the district court correctly found no irreparable harm because Genentech had already settled with "virtually every other potential trastuzumab competitor." But if anything, the fact that Genentech entered into multiple licenses—all of which guaranteed Genentech a period of exclusivity, and permitted only ***future*** access to Genentech's dosing patents—reinforces Genentech's unwillingness to part with its exclusivity ***now***. Amgen repeatedly observes (Br. 40, 43, 45) that Genentech provided licenses to other trastuzumab biosimilars "[redacted]." To be sure, [redacted] changed hands, but that does not mean that Genentech simply gave its rights away. What these licenses actually show is that Genentech so valued its exclusivity now that it was unwilling to accept [redacted] in exchange for its patent rights and therefore bargained to maintain that exclusivity instead.[4]

[4] Amgen has put Genentech's licenses at issue; its suggestion (Br. 44-45) that Genentech waived any argument regarding the [redacted] nature of those licenses is meritless. Genentech specifically disputed that its licenses demonstrated that its injuries could be fully quantified or compensated with money. Appx4730.

Contrary to Amgen's assertions (Br. 45), Genentech does not contend that "licenses granted in settlement can *never* be considered when weighing irreparable harm," only that the licenses that were granted here did not forfeit Genentech's right to maintain its ***present*** exclusivity.[5] Nor are money damages adequate simply because Genentech has licensed others to enter the market beginning in [redacted]. The length of time before others enter the market does not diminish the value of Genentech's exclusivity while it lasts or make it any easier to fully compensate Genentech for forcing it to surrender its right to exclude prematurely. All patents expire eventually, and exclusivity is not less valuable or more quantifiable for being at the end of its term. Nor will the irreparable injury from Amgen's infringement end when Genentech's licensees enter the market. If anything, the effects of Amgen's infringement will be even more difficult to untangle and fully compensate with additional biosimilars on the market. *See* Genentech Br. 42-43, 46-47. As for Genentech's "burden to prove monetary relief would be inadequate" (Amgen Br. 47), Genentech offered ample evidence, including declarations from fact and expert witnesses attesting to harm that Amgen itself has

[5] Contrary to Amgen's assertion (Br. 45), Genentech has not waived the argument that the fact that its licenses are litigation settlements is pertinent to the irreparable harm analysis. *See* Genentech Br. 40. Genentech emphasized that its licenses were "settlements of other lawsuits" (Appx4723) and that accepting such evidence as sufficient to defeat irreparable harm "would have a chilling effect on litigation settlements" (Appx4730).

forcefully argued in other contexts is irreparable. Genentech Br. 44-47 (citing Appx1396(¶58); Appx1399-1400(¶¶65-67); Appx1401-1402(¶¶70-72); Appx1411-1413(¶¶99-101); Appx1477(¶¶48-52); Appx1741; Appx1751-1752). The district court's bare assertion that any "potential damages for sales" prior to trial "should be quantifiable" is not supported by the record; indeed, it is mentioned only in a single sentence of unsupported attorney argument in Amgen's opposition brief. Appx3756.

Amgen argues (Br. 41) that Genentech's [redacted] internal "loss of exclusivity" date for Herceptin means that Genentech's dosing patents have no "real value." But the fact that Genentech was planning for potential competition upon the [redacted] of its [redacted] does not mean that Genentech will suffer no irreparable harm from Amgen's choice to infringe Genentech's dosing patents by including infringing indications in its product label—indications that Amgen thought important enough to warrant a [redacted] to a [redacted] notwithstanding [redacted]

Finally, Amgen contends (Br. 46-47) that there is no difference between Amgen and Genentech's licensees because Mylan and Pfizer market oncology products too. Of course, one crucial difference is that Amgen is on the market now, and those licensees are not. And it is not the mere fact that Amgen has other oncology products that makes it a particularly significant competitive threat; Amgen's long-standing relationships with clinics and payers and its reputation also

distinguish it from others.[6] Genentech Br. 21, 40-41. Amgen's own documents reinforce its unique market position: Amgen forecasts capturing a [redacted] of the biosimilar trastuzumab market than any other biosimilar product. Appx1741. The district court's reliance on the bare fact that Genentech had licensed others (Appx8-9), "without exploring any relevant differences from the current situation, hints at a categorical rule that [Genentech's] willingness to license its patents precludes the issuance of an injunction." *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1370 (Fed. Cir. 2013) ("*Apple III*").

3. The discovery dispute concerning the production of settlement licenses has no bearing on Genentech's irreparable harm.

Amgen repeatedly invokes (Br. 14-15, 20, 43-44) a discovery dispute over production of unredacted versions of Genentech's settlements, which provide [redacted] licenses for future market entry. Genentech and its licensees opposed Amgen's efforts to obtain all terms of their settlements at a time when Amgen was representing that it had made no decision to launch, and therefore no injunction demand appeared to be imminent. Amgen identifies no prejudice from these events: Following the May 16, 2019 hearing before the district court, Genentech produced redacted versions of the settlement agreements identifying which patents were

[6] Contrary to Amgen's waiver assertion (Br. 47), Genentech made the same argument based on the same record evidence before the district court. *Compare* Appx1357, *with* Genentech Br. 20, 40-41.

licensed and any "terms of the licensing and/or settlement agreements that have any relevance to the value placed upon any of the patents implicated therein, including but not limited to royalties, lump sum payments, or any other consideration identified in the agreement." Appx5064. Amgen thus knew from those redacted settlements that the licenses Genentech provided were [redacted]. Amgen knew which patents were covered by Genentech's licenses. Appx1258(76:20-77:5). And Amgen knew the identity of Genentech's licensees, who appeared in court to address Amgen's request for production of those licenses. Appx1241(9:1-17). Although the district court permitted Genentech to redact "the agreed-upon launch dates" (Appx5064), Amgen did not need the license agreements to know that those dates were in the future; it knew from the marketplace that none of Genentech's licensees had launched their products.

Amgen emphasizes the district court's statements at the May 16, 2019 hearing that it could consider the scope and timing of production of Genentech's settlement licenses to be relevant if Genentech subsequently moved for injunctive relief. Amgen Br. 14-15, 43-44 (quoting Appx1251(49:9-23)). But, contrary to Amgen's suggestion (Br. 44), the district court did not rely on any discovery dispute concerning the scope of production of Genentech's licenses as a basis for denying injunctive relief or draw any negative inferences about the content of Genentech's

licenses from it. Amgen therefore cannot rely on that prior discovery dispute to defend the district court's decision.

Furthermore, the isolated statement Amgen dwells upon does not reflect the full picture. At the time of the discovery hearing, Amgen was not FDA-approved and had not even decided whether to launch Kanjinti at risk, let alone when. *See supra* pp. 7-10; Genentech Br. 11-14. In that context, the district court recognized that it was prudent to defer deciding whether Genentech's licensees should have to disclose their launch dates until the issue of injunctive relief was ripe:

> I would rather not decide what I don't have to decide, particularly when it implicates very, very coveted, valuable, sensitive information.
>
> So the analysis, and I'm not saying I would agree, it has to be produced in an injunction context, but it's a different issue. Why not just wait and address that issue if it arises? It may not arise.

Appx1251(48:1-9); Appx1258(76:15-18) ("[I]f there's an injunction, I expect there will be a renewed motion on the part of the defendants to say, we need this information and we'll deal with it at that point.").

And in any case, the district court later clarified that the discovery dispute over the scope of production of Genentech's licenses might be relevant to whether to grant injunctive relief only if there was later a dispute over the production of the settlement agreements that delayed consideration of the injunction motion. Appx1254(60:7-15). That did not happen. Genentech disclosed, with permission from the licensee, the date of the first licensed entry in Genentech's preliminary

injunction motion. Appx1362. Shortly thereafter, Genentech obtained consent from its other licensees to provide Amgen with their licensed launch dates on an outside-counsel-only basis, which Genentech offered to provide Amgen on July 17, 2019—even before the district court decided Genentech's injunction motion.[7]

C. Genentech Established Irreparable Harm Attributable To Amgen's Infringement.

Amgen did not dispute before the district court that its infringement would cause Genentech irreparable lost market share and price erosion. *See* Appx3755-3758. Now, for the first time, Amgen asserts (Br. 48-49) that Genentech's evidence of lost market share and price erosion was not specific enough. But Genentech's evidence was neither "scant" nor "vague" (*id.*). Genentech laid out in detail, with supporting declarations from fact and expert witnesses, how the price erosion and lost market share from Amgen's launch will cause Genentech irreparable harm because the full extent of its injuries will be difficult to compensate. Genentech Br. 44-47 (citing Appx1396(¶58); Appx1399-1400(¶¶65-67); Appx1401-1402(¶¶70-72); Appx1411-1413(¶¶99-101); Appx1477(¶¶48-52); Appx1741; Appx1751-1752). These should not have been contested points; elsewhere, Amgen has recognized the obvious fact that biosimilar entry will result in those forms of harm.

[7] By July 26, 2019, Genentech produced to Amgen on an outside-counsel-only basis versions of its trastuzumab settlement agreements—including Samsung's—with all U.S. terms unredacted.

Id. at 45 (citing, *e.g.*, Appx1933-1934 (Amgen conceding that discounted biosimilar oncology products "will irreparably harm" the reference-product sponsor through price erosion)).

Here, Amgen labels Genentech's injuries as "financial harms remediable by damages." Br. 48. But elsewhere, Amgen has also recognized that these specific harms are irreparable. Genentech did not merely establish "potential lost sales." *Id.* (quoting *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006)). Genentech established that Amgen's infringement will cause price erosion and lost market share (Genentech Br. 44-47)—which Amgen understands are distinct injuries from mere lost sales alone because the extent of those injuries is not fully quantifiable. *See* Appx1922; Appx1932; Appx1939-1940; *Automated Merchandising Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009) (nonprecedential) (distinguishing "lost sales," which are compensable with money damages, from "lost market share" and "price erosion," which cannot be fully compensated and therefore constitute irreparable injuries).

Amgen argues (Br. 49) that Genentech's evidence was only "directed to price erosion and lost market share that might occur ***after trial***." That is simply not true. Genentech presented ample evidence to support its position that Genentech would suffer irreparable harm between July and December. Genentech Br. 44-47 (citing,

e.g., Appx1399-1400(¶¶65-67); Appx1401-1402(¶¶70-72); Appx1411-1413(¶¶99-101); Appx1477(¶¶48-52)).

Amgen says an internal Amgen presentation shows "that Herceptin's price will not begin to erode until *after* [redacted]" and that Genentech is not currently losing market share. Amgen Br. 49. Not so. Rather, the presentation shows that "Genentech will be harmed ***as soon as*** it faces competition from a biosimilar trastuzumab." Appx1395 (citing Appx1741) (emphasis added). Although Amgen forecasted that its discounts and market share would [redacted] over time,[8] Amgen cannot credibly claim that Genentech does not face lost market share and price erosion now.

Nor is there any basis for Amgen to assert that Genentech's losses due to Amgen's infringement will be less than [redacted] prior to trial. Br. 49. Ms. Oliger's testimony that Genentech's most recent forecasts showed losses from biosimilar competition in 2019 to be "considerably" less than [redacted] ***assumed*** that no trastuzumab biosimilar would enter the market prior to [redacted]. Appx4782-4783. It did not address the effect of Amgen launching in July, and is not evidence of Genentech's losses in a world where Amgen launched at risk. *Id.*

[8] *See* Appx1741 (Kanjinti discounts would [redacted] from [redacted]% in 2019 to [redacted]% in 2028 and its market share would grow to a [redacted]% in 2022).

Amgen also contends that Genentech's assertions of irreparable harm to other Genentech products, layoffs, and R&D spending should be discounted because Genentech does not have any internal forecasts predicting lost sales or price erosion for those products as a result of Herceptin biosimilar entry. Amgen Br. 50-51. But the fact that Genentech has no such forecasts does not mean those harms do not exist, and Genentech offered ample evidence to establish that it would suffer those injuries. Genentech Br. 48-50 (citing Appx1406-1409(¶¶85-89, 93); Appx1410-1411(¶96); Appx1413-1414(¶¶102-104); Appx1419-1420(¶¶117-119) Appx1467(¶11); Appx1469-1470(¶¶20, 23, 25); Appx1476(¶47); Appx1478(¶57). Instead, it means that those losses are particularly hard to quantify—and thus especially appropriate for injunctive relief.

Finally, Amgen argues that the Court should disregard harm to Genentech's reputation that would result from removing Amgen's product from the market because the "argument is effectively moot" now that Amgen has launched at risk. Br. 51. But Amgen only recently launched; Genentech may still be able to obtain tailored injunctive relief to prevent Amgen's market share from growing without disrupting patient care. *See infra* p. 26. That Amgen might someday become so entrenched that it cannot be removed from the market without even more harm to Genentech's reputation is no reason to allow that infringement to continue now.

II. THE DISTRICT COURT'S SUGGESTION THAT THE PUBLIC INTEREST WEIGHS AGAINST GENENTECH WAS AN ABUSE OF DISCRETION.

The district court relegated its analysis of the public interest to a footnote (Appx9-10 n.7), which Amgen defends primarily by arguing that Kanjinti's label includes non-infringing uses (Br. 53-54). But Amgen concedes (Br. 54) that the majority of uses (75%) are infringing. This Court has explained that access to non-infringing features may defeat a preliminary injunction where the enjoined product has "a far greater number" of non-infringing features compared to infringing features. *Apple III*, 735 F.3d at 1372. That is not the case here. Had the district court properly "consider[ed] the scope of [Genentech's] requested injunction relative to the scope of the patented [uses]," it would have realized that an injunction would not "depriv[e] the public of access to a large number of non-infringing [uses]." *Id.* at 1372-1373.

Nor can Amgen complain that Genentech's injunction is "overbroad" for seeking to prevent "Amgen from selling Kanjinti *altogether*." Br. 53. Genentech should not be left without recourse because Amgen chose to include infringing and non-infringing uses in the same product label. To the extent Amgen wishes to continue to market non-infringing uses of Kanjinti, it can attempt to carve-out the infringing uses from its product label, as the BPCIA allows. *See* 42 U.S.C. § 262(k)(2)(A)(i)(III); FDA, *Labeling for Biosimilar Products: Guidance for Industry* at 5 & n.12 (July 2018).

Amgen argues (Br. 53) that the district court justifiably denied an injunction because Genentech's composition-of-matter patents have expired. But one patent's expiration does not affect Genentech's right to exclude based on other patents still in force. The public interest undisputedly favors promoting continued innovation. There is no legal authority for limiting Genentech's right to exclude to a single invention.

Finally, contrary to Amgen's assertion (Br. 54), Genentech does not seek "to have Kanjinti taken *away* from patients in the midst of receiving potentially life-saving treatments." Rather, as previously explained (ECF 35 at 12), Genentech seeks a tailored injunction to avoid treatment interruptions for the few patients who may have already received Kanjinti due to Amgen's infringement, to minimize any possible effect of an injunction on the public.

III. GENENTECH SATISFIED THE REMAINING PRELIMINARY-INJUNCTION FACTORS.

A. Amgen's "New" Evidence Does Not Raise A Substantial Question Of Invalidity.

Although Amgen disparages Genentech's dosing patents as supposedly claiming a trivial difference over the prior art (Br. 56), the Patent Trial and Appeal Board did not think so: it upheld two of the patents at issue here after full IPR trials.[9]

[9] Genentech's '811 patent issued after the PTAB upheld the related '196 and '379 patents. The examiner specifically cited the IPR final written decisions in its reasons for allowance. Appx1231.

Amgen asserts (Br. 55, 58) that it has "new" evidence supporting a different result. But nothing Amgen offers is substantively new.

As an initial matter, the "new" evidence Amgen presents was not accompanied by any expert testimony before the district court. Genentech Br. 53-54. Amgen does not explain this conspicuous defect in its case. The say-so of Amgen's attorneys alone is insufficient to raise a substantial question as to the validity of the dosing patents. *See Allergan, Inc. v. Barr Labs., Inc.*, 501 F. App'x 965, 971 (Fed. Cir. 2013) (nonprecedential) ("Obviousness is one area in which expert testimony may be required.").

Most of Amgen's "new" evidence is testimony from the dosing patents' inventors and Genentech's consultant, Dr. Norton. Amgen Br. 58-61. But the inventors and others with access to Genentech's confidential information are not proxies for skilled artisans: these individuals have ***extraordinary*** insights that an ordinarily skilled artisan would not. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

Amgen's reliance upon pharmacokinetic modeling done by the named inventors and other researchers working with Genentech (Amgen Br. 58-59) is thus irrelevant to the obviousness inquiry because they had vastly more data about the pharmacokinetics of trastuzumab than was available in the prior art. Appx4847(20:11-17); Appx4848(30:1-9); Appx4849-4850(39:1-40:23);

Appx4851(61:4-11). The inventors' testimony about modeling done with the benefit of non-public data is not relevant to the modeling a skilled artisan could have done based on the limited information that was in the prior art. Appx4744(¶¶14); Appx4762-4766(¶¶61-70). Similarly, while Amgen highlights Dr. Norton's recollection that he modeled the tri-weekly dosing regimen on a scrap of paper (Br. 58), Dr. Norton's clinical trial did not implement tri-weekly dosing, but instead maintained the weekly dosing interval for trastuzumab and ***decreased*** the dosing interval for chemotherapy to match. Appx4861-4862(136:15-137:24).

Apart from that evidence, Amgen (Br. 61-62) cites just one additional prior-art reference: another Genentech patent naming Dr. Hellmann as its inventor. Appx4510-4535. Amgen argues that the Hellmann patent's description of "giving trastuzumab 'simultaneously' with chemotherapy" means that the disclosed combination of trastuzumab with the chemotherapy paclitaxel therefore discloses administration of trastuzumab every three weeks. Br. 61-62. But the example in the Hellmann patent refutes that interpretation. Patients in the clinical trial described in the patent were simultaneously treated with both trastuzumab and paclitaxel over the course of the treatment period, but the dosing interval was ***weekly*** for trastuzumab. Appx4531(30:63-67) ("patients received weekly administration" of trastuzumab). The Hellmann patent was not at issue in the IPRs for good reason; it simply does not disclose what Amgen imagines, as Genentech's expert confirmed. Appx4748(¶25).

Amgen has not provided any expert testimony to support its contrary misreading of Hellmann and therefore has not raised a substantial question as to anticipation by Hellmann.[10]

Finally, Amgen argues that it has new evidence regarding "shed antigen"—i.e., HER2 protein in the bloodstream which the PTAB recognized complicated designing dosing regimens for trastuzumab. Br. 60-61. Amgen argues that the record on this issue in this case is "the polar opposite" from the record in the IPRs (Br. 60), citing its own invalidity contentions in this case, in which it asserts that two prior art references (Pegram 1998 and Baselga 1996) teach that shed antigen is not a problem. Appx1808-1809. But that is the ***same*** prior art that was considered by the Board. Appx1787 (Amgen's invalidity contentions citing "Pegram 1998" and "Baselga 1996"); Appx3978 (Board citing same papers). That art is not new, and certainly is not the "polar opposite" from what the Board considered.

B. The Balance Of Hardships Favors Genentech, And Amgen's Alleged Hardships Are Not Legally Cognizable.

While Genentech will suffer irreparable injury absent an injunction against Amgen's continued infringement (*supra* pp. 21-24; Genentech Br. 44-51), any purported hardships to Amgen at this point are self-inflicted. Indeed, the only

[10] Amgen does not assert obviousness over Hellmann. Nor could it; Amgen asserts that Hellmann is prior art under 35 U.S.C. § 102(e) (2011), but such art cannot be used for obviousness for a patent owned by the same entity. *Id.* § 103(c) (2011).

hardships that Amgen discusses (Br. 62-63) stem from "its own calculated risk to launch its product pre-judgement," which cannot defeat an injunction. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006).[11]

Amgen asserts (Br. 63) that its infringement now is no different from "the impacts of the licensed sales" that will occur when Genentech's licensees enter in the future. But as previously discussed (*supra* pp. 13-18; Genentech Br. 40-41), Genentech's prior licenses specifically preserved Genentech's remaining exclusivity, permitting other licensed sales only in the ***future***. Amgen's infringement ***now*** is materially different. And future entrants will make it even more difficult to quantify and remedy the harm from Amgen's entry with money damages—harm that Amgen, as a formidable competitor, is particularly likely to inflict.

CONCLUSION

The district court's denial of a preliminary injunction should be reversed, or alternatively vacated and remanded for further proceedings.

[11] Amgen's alleged hardships to "patients, customers, and distributors" (Br. 62) are irrelevant to the balance-of-hardships factor, *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1330 (Fed. Cir. 2008), and can be addressed through an appropriately tailored injunction that avoids disruptions to patient care (*supra* p. 26).

Respectfully submitted,

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September 20, 2019

CERTIFICATE OF SERVICE

I hereby certify that, on this 20th day of September, 2019, I filed the foregoing Non-Confidential Reply Brief for Plaintiffs-Appellants Genentech Inc. with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Federal Circuit Rule 32(a).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b), the brief contains 6,998 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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