No. 2019-2156

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

GENENTECH, INC.,

Plaintiff-Appellant,

v.

AMGEN INC.,

Defendant-Appellee.

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

NON-CONFIDENTIAL BRIEF FOR DEFENDANT-APPELLEE AMGEN INC.

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Genentech, Inc. **v.** Amgen Inc.

Case No. 2019-2156

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ■ (appellee) ☐ (amicus) ☐ (name of party)

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Amgen Inc.	None.	None.

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:

COOLEY LLP: Michelle Rhyu, Susan Krumplitsch, Daniel Knauss, Orion Armon, Eamonn Gardner, Benjamin Lin, Philip Mao, Alexandra Leeper, Priya Arora, Lauren Krickl, Xiaoxiao Xue, Alissa Wood, Cameron Vanderwall

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

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. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

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

9/4/2019
Date

/s/ Jeffrey A. Lamken
Signature of counsel

Please Note: All questions must be answered

Jeffrey A. Lamken
Printed name of counsel

cc: All counsel by ECF

Reset Fields

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CONFIDENTIAL MATERIAL OMITTED

Material has been redacted in the Non-Confidential Brief for Defendant-Appellee Amgen Inc. The redacted material contains confidential commercial information pursuant to the First Amended Stipulated Protective Order entered by the district court on June 12, 2019. Redacted material on pages 1-3, 5, 11, 15, 17, 36-37, 39-47, 49, and 63 contains references to competitively sensitive information regarding patent licenses, and business plans, forecasts, and strategies.

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INTRODUCTION

The district court properly exercised its discretion in denying Genentech's last-minute motion to preliminarily enjoin sales of Amgen's cancer drug Kanjinti. The court did so on three independently sufficient grounds. Genentech failed to meet its burden to prove irreparable harm, having unduly delayed in seeking relief—despite provisions of the Biologics Price Competition and Innovation Act (BPCIA) that encourage early resolution of patent disputes. Genentech's "pattern" of granting its competitors [redacted] licenses—allowing them to enter the market in just [redacted] time—likewise belied its claim of irreparable harm. And the public interest weighed against an injunction, the court found, because two of Kanjinti's four FDA-approved uses concededly do not infringe Genentech's patents. While the district court did not address the balance of hardships or likelihood of success (given the "hurried" nature of Genentech's motion), those factors weigh in Amgen's favor as well. This Court should affirm the denial of a preliminary injunction.

* * *

Consistent with the BPCIA's notice requirements, Amgen notified Genentech in May 2018 that it intended to commercially market Kanjinti, a biosimilar of Genentech's cancer drug Herceptin (trastuzumab), potentially within as little as six months. Genentech promptly sued for infringement of patents

related to "dosing" of trastuzumab. But it did not seek a preliminary injunction. Genentech soon learned through discovery that Amgen planned to begin selling Kanjinti in July 2019. Contrary to the BPCIA's purpose of resolving patent disputes *before* commercial marketing commences, Genentech did not seek a preliminary injunction then either. Instead, Genentech waited until Amgen was already launching Kanjinti—with contracts signed and medicine ready to ship—to file an "emergency" preliminary injunction motion on July 10, 2019. The district court properly rejected that belated demand.

As the district court found, Genentech had ample notice of Amgen's plans to market Kanjinti. But "Genentech did not file its motion for a preliminary injunction until . . . 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." Appx6. The court reasonably found that this lengthy and unexplained delay was undue—especially in the context of the BPCIA—and negated Genentech's assertion of irreparable harm.

The court found that Genentech's "pattern" of licensing the asserted patents independently defeated its claim of irreparable harm. Appx7. Genentech's decision to license biosimilar competition by multiple competitors as soon as [redacted]—just [redacted] later—reasonably indicated that legal relief would be adequate, as "any potential damages for [Kanjinti] sales in the next four

months should be quantifiable." Appx9. Genentech protests that, because those licenses were granted [redacted], its dosing patents must be invaluable—it [redacted] Br. 35. But Genentech did not raise that argument below, and the district court would not have been obligated to accept it regardless. Genentech *withheld* from the district court (and Amgen) virtually all of the licenses' material terms—despite the court's express warning about the consequences of doing so. It was reasonable to infer that the heavily redacted licenses Genentech produced were inconsistent with its assertion that [redacted] of lost market exclusivity would cause incalculable harm.

The district court further found that the public interest weighed against an injunction. Genentech requested an injunction that would prohibit *all* sales of Kanjinti—even though two of Kanjinti's four FDA-approved uses indisputably do not infringe Genentech's dosing patents, and Genentech's composition-of-matter patents had already expired. The fact that an injunction would "'depriv[e] the public of access'" to non-infringing but potentially life-saving treatments, the court reasonably concluded, "weighs against granting an injunction." Appx10 n.7.

Genentech does not seriously contend that any of the district court's factual findings were clearly erroneous, or that the court could not reasonably deny a preliminary injunction in light of those facts. Genentech instead attempts to conjure legal error, accusing the district court of imposing various "blanket

rule[s]," "categorical rule[s]," and legal "require[ments]." Br. 31-32, 33, 34. But those supposed rules and requirements are imagined. They appear nowhere in the district court's opinion. Instead, the court reasonably concluded, based on the specific facts of this case, that Genentech's last-minute demand for a preliminary injunction came too late (particularly given the BPCIA's design); that monetary relief would adequately remedy any harm occurring in the next four months; and that cancer patients should not be denied access to concededly non-infringing treatments. It was not an abuse of discretion to deny a preliminary injunction on those grounds.

While the district court did not need to address the remaining preliminary injunction factors—likelihood of success and balance of hardships—those factors also strongly militate against relief. Genentech is not likely to succeed on the merits because its patents are invalid. The claims asserted here are limited to dosing methods that merely call for tripling the previously established weekly dose for trastuzumab and then administering it once every three weeks. Those claims are obvious in light of prior art and testimony never considered in proceedings before the Patent Office or anywhere else.

A preliminary injunction would also impose undue hardship on Amgen and its customers. Kanjinti's launch was already interrupted once, when the district court imposed a standstill immediately after Genentech filed its "emergency"

preliminary injunction motion on July 10. When the court lifted the standstill order and denied Genentech's motion on July 18, Amgen launched Kanjinti. Since then, healthcare providers have prescribed Kanjinti and begun treatment regimens for cancer patients. A second interruption would seriously damage Amgen's reputation with customers, destroy its efforts to compete, and interfere with physicians' treatment of patients who have begun Kanjinti therapy. In contrast, Genentech's predicted harms are no different in kind, and certainly lesser in scope, than the impact commercial sales by Genentech's four licensees will have when they begin in [redacted].

A jury trial on Genentech's infringement claims is currently scheduled for December 9, 2019. If Genentech succeeds on the merits, it will have the opportunity to make its case for a permanent injunction. Genentech's request that this Court order a preliminary injunction removing Kanjinti from the market in the meantime should be denied.

ISSUE PRESENTED

Whether the district court permissibly exercised its discretion in denying Genentech's motion for a preliminary injunction for three independent reasons.

STATEMENT OF THE CASE

I. STATUTORY BACKGROUND

This case arises under the Biologics Price Competition and Innovation Act (BPCIA). Biologics are "a type of drug derived from natural, biological sources

such as animals or microorganisms," as opposed to "traditional drugs, which are typically synthesized from chemicals." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669-70 (2017). The BPCIA creates an abbreviated pathway for regulatory approval of "biosimilars"—products that are "highly similar" to already-approved biologic drugs. 42 U.S.C. § 262(i)(2). It also creates a streamlined process for resolving patent disputes over biosimilars.

A. The Biologics Price Competition and Innovation Act Creates a Pathway to Market for Biosimilar Drugs

Enacted in 2010, the BPCIA created an abbreviated pathway for FDA approval where a biologic is shown to be "biosimilar" to a previously approved biologic. *See* 42 U.S.C. § 262(k). Under the statute's framework, "the manufacturer of a biosimilar (applicant) . . . may piggyback on the showing made by the manufacturer (sponsor) of a previously licensed biologic (reference product)." *Sandoz*, 137 S. Ct. at 1670. The applicant must submit data "show[ing] that its product is 'highly similar' to the reference product and that there are no 'clinically meaningful differences' between the two in terms of 'safety, purity, and potency.'" *Id.* (quoting § 262(i)(2)(1)(A), (B)); *see* § 262(k)(2)(A)(i). If the applicant satisfies the statute's requirements, the Food and Drug Administration will approve and license the biosimilar. § 262(k)(3), (5)(B).

An applicant, however, "may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar

until 12 years after the reference product is first licensed." *Sandoz*, 137 S. Ct. at 1670; *see* § 262(k)(7)(A), (B). The original biologic manufacturer thus "enjoys a 12-year period when its biologic may be marketed without competition from biosimilars." *Sandoz*, 137 S. Ct. at 1670.

B. The BPCIA Provides for Early Adjudication of Patent Disputes

To speed market entry of biosimilars, the "BPCIA facilitates litigation during the period *preceding* FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz*, 137 S. Ct. at 1670 (emphasis added). To that end, the statute "sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Id.*

The process begins once an applicant submits a biosimilar application to the FDA. The applicant may invoke the BPCIA's procedures and protections by providing a copy of the application to the "sponsor," *i.e.*, the manufacturer of the previously licensed biologic (the "reference product"). *Sandoz*, 137 S. Ct. at 1670, 1675; 42 U.S.C. § 262(*l*)(2)(A). The sponsor and applicant work to identify patents the biosimilar might infringe, § 262(*l*)(3)(A)-(B), then proceed to immediate litigation on designated patents, § 262(*l*)(4)-(6). The BPCIA accelerates that litigation by "provid[ing] that the mere submission of a biosimilar application constitutes an act of infringement," allowing the sponsor to sue (and seek

injunctive relief) even though the product may not yet have been made, used, sold, or imported in the United States. *Sandoz*, 137 S. Ct. at 1670; *see* 35 U.S.C. § 271(e)(2)(C), (4)(B).

Another key event in the BPCIA process occurs when the applicant provides the sponsor with a notice of commercial marketing. 42 U.S.C. § 262(*l*)(8)(A). That notice informs the sponsor that the applicant may begin selling its biosimilar as soon as 180 days thereafter. § 262(*l*)(8)(A). The notice may be given before the FDA approves the biosimilar application. *Sandoz*, 137 S. Ct. at 1677. Once the notice is given, all relevant patents, including any not previously designated for immediate litigation pursuant to § 262(*l*)(4)-(6), may be litigated and asserted as a basis for preliminary injunctive relief. *See* § 262(*l*)(8)(B).

II. FACTUAL AND PROCEDURAL BACKGROUND

This case involves Kanjinti, Amgen's biosimilar of the breast cancer drug trastuzumab—and Genentech's efforts to prevent Kanjinti's commercial launch.

A. Trastuzumab and Genentech's Dosing Patents

Genentech markets trastuzumab under the brand name Herceptin. Trastuzumab is a monoclonal antibody product developed in the 1980s and approved by the FDA in 1998. Genentech Br. 6. Genentech's 12-year period of exclusivity under the BPCIA thus expired nearly a decade ago. *See* § 262(k)(7)(A). Genentech's last patent claiming the trastuzumab antibody expired on June 18,

2019. Appx9 n.7. Genentech's preliminary injunction request in this case is, as a result, based on three "dosing patents" (the '196, '379, and '811 patents) claiming particular trastuzumab treatment methods. *See* Appx3.

1. *The Dosing Patents and the Prior Art*

Herceptin's original label in September 1998 recited an initial trastuzumab dose of 4 mg/kg (milligrams per kilogram of patient weight), followed by weekly 2 mg/kg doses. Appx4719. That is known as a "4/2—weekly" regimen. Genentech's dosing patents claim methods of administering trastuzumab, including at "a larger initial dose of 8 mg/kg trastuzumab followed by subsequent doses of 6 mg/kg every three weeks." Genentech Br. 7; *see* Appx4; Appx1494 (¶26); Appx49 ('196 patent claims 11 & 22); Appx87-88 ('379 patent claims 11 & 21); Appx139 ('811 patent claims 6 & 7). This is known as an "8/6—three weekly" dosing regimen.

Genentech admits that the sole benefit of the dosing patents is to make trastuzumab therapy "more convenient" by reducing dosing frequency. Appx1348. The only difference between the dosing patents and Herceptin's original regimen is to increase the initial dose and then give three times the maintenance dose at intervals three times further apart. Appx4; Appx1494 (¶26).

By the dosing patents' priority date in August 1999, oncologists appreciated the need to dose trastuzumab less frequently. Appx3840 (96:1-15). Herceptin

patients complained to doctors about "having to come in weekly" for Herceptin administration. Appx3961-3962 (Baughman Dep. 229:22-230:13). Moreover, Herceptin was often prescribed in tandem with chemotherapies that used 3-weekly dosing regimens. Appx4718; Appx3990-3991; Appx1867-1868. One reference, Hellmann 1998, explained that combining trastuzumab with those chemotherapies was "favor[ed]" because it "markedly increases the clinical benefit" of chemotherapy. Appx4532 (32:40-50). Matching trastuzumab dosing to chemotherapy's 3-weekly dosing schedule would improve patients' quality of life and make care easier for providers. Appx3990-3991; Appx1867-1868.

Detailed pharmacokinetic, efficacy, and safety data from several clinical trials were available by August 1999 to help optimize a higher dosage. The original Herceptin label summarizes much of those data. Appx4718-4719. Another reference disclosed the safety of an 8 mg/kg dose and teaches separation of the first and second trastuzumab doses by three weeks. Appx3807-3809 (Watanabe 1998). Still other publications taught half-life, target serum concentration, and further pharmacokinetic parameters detailing trastuzumab's behavior. *See* Appx3811-3818 (Baselga 1996); Appx3820-3832 (Pegram 1998). Reams of data thus were available to reduce uncertainty associated with optimizing longer dosing intervals.

2. *The Inter Partes Review Proceedings*

The Patent Trial and Appeal Board reviewed the ’196 and ’379 patents at issue here in inter partes review proceedings brought by entities that are not parties to this case. The Board concluded that the prior art disclosed all elements of the challenged claims, save shifting the prior-art doses to higher amounts on longer schedules. Appx3986; Appx1863. It further found there was a clear motivation to optimize the trastuzumab dosing regimen as claimed in the dosing patents (*i.e.*, using a “8/6—three weekly” regimen). Appx3987-3993; Appx1864-1870. The dosing patents survived only because the Board found the challengers had not, on the record they presented, demonstrated that skilled artisans would have reasonably expected the claimed dosing regimens to be efficacious. Appx3993-4005; Appx1870-1882.

3. *Genentech’s Pattern of Licensing the Dosing Patents*

Genentech has granted [redacted] licenses for the dosing patents (and about [redacted] other patents) to Mylan, Pfizer, and Celltrion. Appx4536-4716. Those companies represent virtually all of Genentech’s trastuzumab biosimilar competition, apart from Amgen. Appx1476 (¶45).

The first of Genentech’s licensed competitors will enter the market on [redacted], when Mylan will begin selling its trastuzumab biosimilar. Appx8; Appx1476 (¶45). The label on Mylan’s product includes the same

indications that Genentech alleges Amgen will infringe by selling Kanjinti. Appx4170. The other companies' biosimilars will presumably launch soon thereafter with similar labels.

B. The District Court Litigation

1. *Amgen Files Its Biosimilar Application—and Genentech Sues*

Amgen submitted its biosimilar application for Kanjinti to the FDA in July 2017. Appx3054. After the FDA accepted the application, Amgen provided a copy to Genentech in October 2017. Appx4314. On May 15, 2018, Amgen provided its 180-day notice of commercial marketing to Genentech. Appx2; *see* 42 U.S.C. § 262(*l*)(8)(A).

Genentech sued Amgen in June 2018, alleging infringement of 37 patents. Appx147; Appx4314. Genentech has since dismissed most of those patents from the suit. Appx148. Litigation in the district court is continuing, with trial scheduled for December 9, 2019. Appx1022. Of the remaining asserted patents, the only ones on which Genentech sought a preliminary injunction—and the only ones at issue in this appeal—are the three dosing patents discussed above.

2. *Genentech Learns of Amgen's Plans To Launch Kanjinti*

As the district court found, Genentech long has known of Amgen's plans to commercially launch Kanjinti. First, "Genentech has known of Amgen's intent to market Kanjinti since Amgen served its 180-day Notice of Commercial Marketing on May 15, 2018." Appx5.

Second, the district court found that "Genentech received information through discovery that made clear Amgen's plan to launch its marketing of Kanjinti in July 2019." Appx5-6. "Specifically, in February 2019, Amgen produced to Genentech documents showing that it filed a 'resubmission' to the FDA in December 2018." Appx6. "Given the known six-month regulatory timeline for the FDA to consider the resubmission," the district court found, "Genentech would have understood at the time" that Amgen would receive a response—and potentially approval—from the FDA "by the end of June 2019." Appx6.

Third, "[i]n April 2019," the court found, "Amgen produced documents with its launch plan redactions removed, thus enabling Genentech to see that Amgen planned to launch [Kanjinti] in July 2019." Appx6. Other produced documents explained the timing of Amgen's decisionmaking for the anticipated July 2019 launch. Appx4074 ("There will be a go/no go established in May regarding the launch decision. An additional go/no go will be established just prior to product shipment."). And "[f]rom late April through mid-June, five Amgen witnesses testified during depositions that Amgen was preparing to be ready to launch Kanjinti in July 2019," pending a final decision from management. Appx6. One witness specifically identified "July 13th or 14th" as the target launch date. Appx4106 (Skeeters Dep. 18:5-10).

3. *Genentech Blocks Disclosure of Its License Agreements by Denying That It Is Seeking a Preliminary Injunction*

Genentech did not file a preliminary injunction motion upon receiving Amgen's statutory notice of commercial marketing, or upon receiving details of Amgen's plan for a July 2019 launch. Instead, Genentech told the district court that it was *not* seeking preliminary injunctive relief.

To defend against any request for injunctive relief, Amgen sought discovery about Genentech's license agreements. At a discovery hearing on May 16, 2019—weeks after Genentech received documents and testimony reflecting Amgen's anticipated July 2019 launch—Amgen again sought those documents. Appx1245 (24:11-25:9). Genentech successfully blocked that request by "represent[ing] to the [c]ourt . . . that it was not seeking a preliminary injunction." Appx7 n.6. The court asked Genentech: "[A]re you seeking injunctive relief?" Genentech responded: "We have a request for a permanent injunction at the trial. *We're not presently seeking injunctive relief.*" Appx1246 (26:1-4) (emphasis added). While accepting Genentech's representation, the district court cautioned that Genentech risked jeopardizing any future request for a preliminary injunction:

> Doesn't the risk of that all fall on the plaintiff? . . . Maybe I will say, well, look, you know what. You had your day. You agreed we should put this issue of settlement agreement disclosure, you should put that off until an injunction arose, and so you don't get a TRO, you don't get an injunction proposed preliminarily until it's adjudicated. That would fall on [Genentech], wouldn't it?

Appx1251 (49:9-23).

Despite the court's warnings, Genentech maintained that it was not seeking preliminary injunctive relief. Appx1252 (53:10-19). The court thus denied Amgen's motions to compel, allowing Genentech to redact everything in the licenses except financial terms. Appx1258 (76:1-77:5). Those terms showed that Mylan, Celltrion, and Pfizer received [redacted] licenses to more than [redacted] patents, including the three dosing patents at issue here. Appx4537-4544; Appx4633-4646; Appx4700-4716. Genentech also granted a license to Samsung Bioepis, but did not produce that license in any form.

4. *Amgen Receives FDA Approval for Kanjinti and Begins Commercial Marketing Activities*

The FDA approved Kanjinti on June 13, 2019, with a label listing the same four indications as Herceptin's label. Appx6; Appx2884-2886; Appx3054-3059. The district court held another discovery hearing five days later on June 18, but Genentech again did not raise the issue of a preliminary injunction. Appx1269-1297.

On July 8, 2019, Amgen management made the final go/no-go decision to launch Kanjinti on July 15. Appx3770 (¶5). The Kanjinti team initiated commercial marketing activities on July 8, in anticipation of the July 15 launch. Appx3771 (¶6). As part of those activities, Amgen sent contracts to payers,

providers, and group purchasing organizations, and finalized arrangements for shipping Kanjinti to distributors. *Id.*

C. Genentech's "Emergency" Motion for a Preliminary Injunction

On July 10, 2019, Genentech filed an "emergency" motion for a preliminary injunction, asking the district court to bar Amgen "from commercially launching, marketing or selling" Kanjinti through trial, judgment, and appeal. Appx1332. As the district court observed, the "emergency" nature of the motion was the result of Genentech's failure to bring the preliminary injunction motion earlier—leading to a "'race to court for immediate relief,'" Appx7. The district court nonetheless issued an oral "standstill" order that forestalled Kanjinti's launch until the court could decide the motion. Appx2-3. Amgen complied with that order, halting its commercial launch activities. Appx3771 (¶6).

After full briefing, the district court denied Genentech's preliminary injunction motion and lifted the standstill on July 18. Appx1-10. The court denied Genentech's motion on three independent grounds.

First, the court found Genentech had not met its burden of showing irreparable harm. To the contrary, Genentech's delay in requesting a preliminary injunction was "undue" and negated any assertion of irreparable harm. Appx7. As recounted above (at 12-13), the court made detailed findings that Genentech knew of Amgen's launch plans as early as May 2018, and received confirmation of those

plans on numerous occasions thereafter. Yet "Genentech did not file its motion for a preliminary injunction until . . . 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." Appx6. That delay, the court found, was "contrary to the spirit and purpose of the BPCIA," which provides parties and courts with a 180-day window for resolving patent disputes precisely to avoid the sort of "'hurried motion practice'" that "Genentech has engineered in this case." Appx7 (quoting *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063, 1065 (Fed. Cir. 2016)).

Second, the district court made a separate "finding of no irreparable harm" based on "the fact that Genentech has engaged in a pattern and practice of licensing" the dosing patents at issue here. Appx7. Specifically, "Genentech granted [redacted] licenses for the Dosing Patents to Mylan, Celltrion, and Pfizer that allow a [trastuzumab] biosimilar to enter the market in [redacted], which is [redacted] from now." Appx8. From that, the court found that "Genentech has been able to place a value on the patents and has approved competitors entering the market in [redacted]." Appx8-9. "Under these facts," the court concluded, "any potential damages for sales in the next four months should be quantifiable." Appx9. Because legal relief—damages—for that short time

period would be an "adequate remedy," equitable relief in the form of an injunction was unwarranted. Appx8.

Third, the court found that, on the facts of this case, the public interest in access to cancer treatments "weigh[ed] in favor of denying the motion for a preliminary injunction." Appx9-10 n.7. Because "only two of the four indications on the Kanjinti label allegedly infringe," the court reasoned, an injunction would "'depriv[e] the public of access to a large number of non-infringing features'" of "drugs that prolong and save lives." *Id.* That too "weigh[ed] against granting an injunction." *Id.*

D. Denial of an Injunction Pending Appeal

With the standstill lifted, Amgen resumed its launch of Kanjinti. ECF #27-3 (Jacobson Decl. ¶¶5-8). Kanjinti entered the market on July 18, 2019, and oncologists soon began using it to treat cancer patients. *Id.*

After the district court ruled, Genentech sought injunctive relief pending appeal. Appx4885-4904. The district court denied that request. Appx4964-4965 (51:4-52:20). Genentech then moved this Court for an injunction pending appeal. ECF #8. This Court likewise denied Genentech's request. Applying the same preliminary injunction factors as the district court, this Court concluded that "Genentech has not established that an injunction pending appeal is warranted here under these factors." ECF #38 at 2.

SUMMARY OF ARGUMENT

I. The district court reasonably found that Genentech's delay in seeking injunctive relief was undue and negated its claim of irreparable harm. Genentech did not seek a preliminary injunction until fourteen months after receiving Amgen's statutory notice of its intent to commercially market Kanjinti, three months after learning that Amgen specifically planned to launch in July 2019, and a month after the FDA's approval of Kanjinti removed the last obstacle to market entry. Instead, Genentech waited until Amgen was already in the process of launching Kanjinti before seeking relief—despite having represented to the district court and Amgen, in the months preceding its motion, that it was *not* seeking preliminary injunctive relief. The district court reasonably found that Genentech's delay was particularly undue given the BPCIA provisions encouraging parties and courts to resolve preliminary injunction motions *before* commercial marketing.

Genentech's attempts to invent a theory of legal error fail. The district court did not apply a "blanket rule" that a preliminary injunction is forbidden outside the BPCIA's 180-day window. It merely found that Genentech's unjustified failure to act within that time frame, or any reasonable time frame, weighed against relief in this case. Genentech's own proposed rule that a district court is categorically barred from considering a patent owner's pre-commercial-marketing delay defies the statute and case law. And Genentech's attempts to justify its persistent delays

on the facts of this case do not come close to showing that the district court abused its discretion.

II. The district court reasonably found that Genentech's pattern of licensing its dosing patents to competitors independently defeated its claim of irreparable harm. That extensive licensing pattern indicated that any harm would be quantifiable, and thus legal relief (damages) would be an adequate remedy if Genentech ultimately prevailed in its infringement suit. The weight to accord the prior licenses was squarely within the district court's discretion. While Genentech faults the district court for not examining putative differences between the licenses and the current situation, Genentech ignores that it *withheld* virtually all material terms of those licenses from the district court (and from Amgen). It was reasonable to infer that the withheld terms were inconsistent with Genentech's insistence that the dosing patents could not be valued. Substantial record evidence, moreover, confirmed that Genentech recognized the low value of the dosing patents.

Genentech's predictions of lost sales do not compel a different conclusion. The only harms Genentech claims are financial impacts Genentech itself has quantified, making equitable relief unwarranted.

III. The district court reasonably found that the public interest in access to life-saving cancer treatment weighed against the injunction Genentech sought here.

That was particularly true given that two of Kanjinti's four FDA-approved indications concededly do not infringe Genentech's dosing patents.

IV. The remaining preliminary injunction factors favor Amgen as well. Genentech has not shown it is likely to succeed on the merits in light of Amgen's invalidity defenses. Genentech hides behind Patent Trial and Appeal Board statements, made in proceedings to which Amgen was not a party, finding an absence of proof that skilled artisans would have had a reasonable expectation of success as to the claimed methods' efficacy. But Amgen has adduced new evidence—unavailable to the Board—that fills the purported gap. Amgen has also advanced an anticipation theory based on prior art that the Board did not consider and Genentech does not address.

Finally, the balance of hardships tilts strongly in Amgen's favor. Amgen gave Genentech ample notice of its Kanjinti launch plans, fully complying with its BPCIA obligations. Amgen launched the drug consistent with those long-disclosed plans, and Kanjinti is now in the hands of doctors and patients. Removing Kanjinti from the market at this point would cause substantial injury to Amgen, its customers, and patients.

ARGUMENT

"'A decision to grant or deny a preliminary injunction is within the sound discretion of the district court.'" *Procter & Gamble Co. v. Kraft Foods Glob.,*

Inc., 549 F.3d 842, 847 (Fed. Cir. 2008). The district court reasonably exercised its discretion to deny Genentech's last-minute demand for a preliminary injunction.

To obtain such extraordinary relief, Genentech was required to show (1) that it was likely to succeed on the merits; (2) that it would suffer irreparable harm if the injunction were not granted; (3) that the balance of hardships between the parties favors relief; and (4) that an injunction is in the public interest. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010). Here, the district court found that Genentech's undue and repeated delay in seeking preliminary relief, as well as its pattern of licensing the asserted patents to competitors, vitiated Genentech's claim of irreparable harm. The court also found that the public interest in ensuring access to life-saving cancer drugs defeated relief, given that Genentech concedes that two of Kanjinti's four approved indications do not infringe its dosing patents.

Each of those three findings is individually sufficient to defeat Genentech's request for a preliminary injunction. Genentech does not come close to showing that *any* of them rests on clearly erroneous factual findings, legal errors, or a clear lapse in judgment. Nor can Genentech establish that the other factors it would have to satisfy to obtain a preliminary injunction—likelihood of success and balance of hardships—weigh in its favor. The district court's decision should be affirmed.

Standard of Review. A decision to grant or deny a preliminary injunction is reviewed for abuse of discretion. *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1203 (Fed. Cir. 2017); *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017). "Abuse of discretion is a highly deferential standard of appellate review." *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302, 1306 (Fed. Cir. 2017). And the movant carries a heavier burden to obtain a reversal when a preliminary injunction is *denied* than when one is *granted*. *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992). "The movant must show not only that one or more of the factors relied on by the district court was clearly erroneous, but also that a denial of the preliminary relief sought would amount to an abuse of the court's discretion upon reversal of an erroneous finding." *Id.* Moreover, "[i]f a preliminary injunction is denied, the absence of an adequate showing with regard to *any one* of the four factors may be sufficient, given the weight or lack of it discretionarily assigned the other factors by the trial court, to justify the denial." *Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 932 (Fed. Cir. 2004) (citation omitted) (emphasis added).

I. THE DISTRICT COURT PROPERLY FOUND THAT GENENTECH FAILED TO PROVE IRREPARABLE HARM

A. The District Court Properly Found That Genentech's Delay Was Undue and Negated Irreparability

A party cannot obtain a preliminary injunction without showing it would suffer irreparable harm absent an injunction. *AstraZeneca*, 633 F.3d at 1049. Here, the district court reasonably found that Genentech failed to carry its burden of proving irreparable harm because its "undue delay in seeking a preliminary injunction 'negate[d] the idea of irreparability.'" Appx5 (quoting *Pfizer, Inc. v. Teva Pharms., USA, Inc*., 429 F.3d 1364, 1382 (Fed. Cir. 2005)).

As this Court has explained, "delay in . . . seeking a preliminary injunction [is a] factor[ ] that could suggest that the patentee is not irreparably harmed by the infringement." *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012). And the Court has expressly recognized that "a showing of delay may be so significant, *in the district court's discretion*, as to preclude a determination of irreparable harm." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) (emphasis added).

That was the case here. Exercising its sound discretion, the district court reasonably found that Genentech's delay in seeking a preliminary injunction undermined its claim that Kanjinti's market entry would cause irreparable harm. As the court found, "Genentech has known of Amgen's intent to market Kanjinti

since Amgen served its 180-day Notice of Commercial Marketing on May 15, 2018." Appx5. But Genentech did not seek a preliminary injunction then. Discovery then specifically disclosed "that Amgen planned to launch in July 2019." Appx6. But Genentech did not seek a preliminary injunction then. And the FDA's approval of Kanjinti on June 13, 2019, removed the last obstacle to the drug's market entry. *Id.* But Genentech did not seek a preliminary injunction then, either.

Indeed, Genentech exploited the fact that it was not pursuing preliminary injunctive relief for its own advantage. When Amgen sought full disclosure of Genentech's license agreements to defend against claims for injunctive relief, Genentech successfully blocked that request by "represent[ing] to the [c]ourt . . . that it was *not* seeking a preliminary injunction." Appx7 n.6 (emphasis added); *see* pp. 14-15, *supra*. The district court specifically warned that withholding the documents would prejudice any later request for preliminary relief. Appx1251 (49:9-23). But Genentech did not relent. *See* pp. 14-15, *supra*.

Despite ample knowledge of Amgen's plans, Genentech waited until Amgen was already in the process of launching Kanjinti before seeking a preliminary injunction on July 10, 2019. As the district court found, that request came "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." Appx6.

Genentech does not—and cannot—contend that any of those factual findings were clearly erroneous. Given those undisputed facts, it was well within the district court's broad discretion to find Genentech "had not proceeded as quickly as it could have in seeking preliminary injunctive relief," *Apple*, 678 F.3d at 1325, and to deny relief as a result.

B. The District Court Properly Found That Genentech's Delay Was Contrary to the Spirit and Purpose of the BPCIA

The district court's conclusion was reinforced by "the spirit and purpose of the BPCIA." Appx7. As the Supreme Court has explained, the BPCIA is designed to "facilitat[e] litigation *during the period preceding FDA approval* so that the parties *do not have to wait until commercial marketing* to resolve their patent disputes." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017) (emphasis added). Under that "carefully calibrated scheme," *id.*, a biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product," 42 U.S.C. § 262(*l*)(8)(A). That six-month window, this Court has explained, is designed to allow parties and courts to resolve preliminary injunction motions "'without the reliability-reducing rush'" and "'hurried motion practice'" that last-minute

"'requests for relief against immediate market entry'" can create. Appx7 (quoting *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063, 1065 (Fed. Cir. 2016)).

Here, the district court found, Genentech "engineered" "exactly the circumstances" that the BPCIA's "180-day period is designed to prevent." Appx7. Amgen served its notice of commercial marketing on Genentech on May 15, 2018. Appx2. But Genentech did not seek a preliminary injunction during the ensuing six months—or even the six months after that. Instead, it waited *fourteen months* before filing an "emergency" preliminary injunction motion on July 10, 2019. By that time, the FDA had already approved Kanjinti and Amgen had begun commercial marketing activities in preparation for a July 15 launch, just five days later. *See* pp. 15-16, *supra*. Amgen was forced to interrupt those activities to accommodate a standstill order, to engage in the "hurried" motion practice Genentech had engineered, and to afford the district court time to decide Genentech's eleventh-hour request on an expedited basis. Appx9.

The court properly found that Genentech's behavior was "contrary to the spirit and purpose of the BPCIA." Appx7. The court did not abuse its discretion in finding that Genentech's decision to disregard the statute's "carefully calibrated scheme" and "wait until commercial marketing" to seek a preliminary injunction, *Sandoz*, 137 S. Ct. at 1670, weighed against granting equitable relief, Appx7.

C. Genentech's Contrary Arguments Lack Merit

Genentech does not challenge any of the district court's factual findings as clearly erroneous. Instead, Genentech asserts that "the district court adopted an erroneous legal standard." Br. 24 (capitalization altered). But Genentech faults the district court for applying a "blanket rule" the district court never adopted, *id.* at 33, and for failing to adopt a blanket rule, of Genentech's own devise, that lacks support in the BPCIA or precedent. Genentech's remaining "legal" objections are unfounded pleas for this Court to reweigh the evidence and second-guess matters firmly committed to the district court's discretion.

1. *The District Court Did Not Adopt the "Blanket Rule" Genentech Imagines*

Genentech directs its fire against a supposed "blanket rule" interpreting the BPCIA to "*requir[e]* a reference-product sponsor . . . to seek a preliminary injunction *immediately* upon receipt of a notice of commercial marketing." Br. 31, 33 (emphasis added). The district court did not adopt any such categorical rule. (Genentech practically concedes as much, arguing only that the district court "seemed to suggest" such a rule. Br. 31.) Nothing in the district court's opinion suggests that a preliminary injunction motion is forbidden more than 180 days after a notice of commercial marketing. The court merely observed that, on the facts of this case, Genentech's *repeated* and *unjustified* delay in seeking relief was inconsistent with "the spirit and purpose of the BCPIA," which is designed to

avoid the sort of "'hurried motion practice'" that Genentech's last-minute motion precipitated here. Appx7 (quoting *Apotex*, 827 F.3d at 1065). It was not error for the district court to consider that purpose. A preliminary injunction is equitable relief. It is well established that "a court of equity" properly "seek[s] to administer the law according to its spirit." *In re Kane*, 127 F. 552, 553 (7th Cir. 1904).

Urging that the district court misapprehended the BPCIA's purpose, Genentech criticizes the court for relying on *this Court's* discussion of the Act's purpose in *Apotex*. Br. 34. According to Genentech, *Apotex*'s view of statutory purpose is no longer valid after the Supreme Court's decision in *Sandoz*. *Id.* But *Sandoz* took the same view of the Act's purpose. The BPCIA, the Supreme Court explained, is designed to "facilitat[e] litigation *during the period preceding FDA approval* so that the parties *do not have to wait until commercial marketing* to resolve their patent disputes." 137 S. Ct. at 1670 (emphasis added). The district court reasonably found that Genentech's unjustified decision "to wait until commercial marketing" was underway, *id.*, was inconsistent with that purpose.

Amgen did not advocate—and would not support—a "blanket rule" that a biologic patent owner must seek a preliminary injunction within 180 days of a notice of commercial marketing or forever hold its peace. And the district court did not adopt such a rule. It merely found, on the facts of this case, that Genentech's persistent and unexplained failure to seek relief during the 180-day

window—or for months thereafter—defied the BPCIA's purpose and weighed against injunctive relief. That determination was not an abuse of discretion.

2. *The District Court Was Not Forbidden from Considering Genentech's Pre-Commercial-Marketing Delay*

Genentech faults the district court for not adopting a blanket rule of Genentech's creation. In Genentech's view, a district court considering preliminary injunctive relief under the BPCIA is *categorically barred* from considering delay that precedes a biosimilar's entry into the marketplace. *See* Br. 25-31. Until the biosimilar actually launches, Genentech maintains, any motion for a preliminary injunction is "premature" because the patent owner "ha[s] not yet suffered any harm." *Id.* at 25, 30. That absolutist position lacks support.

The BPCIA rejects the notion that preliminary injunctive relief must wait until commercial marketing. As the Supreme Court has explained, the statute "facilitates litigation during the period preceding FDA approval so that the parties *do not have to wait until commercial marketing to resolve their patent disputes*." *Sandoz*, 137 S. Ct. at 1670 (emphasis added). To that end, the Act declares that "the mere submission of a biosimilar application constitutes an act of infringement" that allows the patent owner to sue and seek "injunctive relief." *Id.*; 35 U.S.C. § 271(e)(4)(B); *see* § 271(e)(2)(C). The statute also specifically authorizes patent owners to "seek a preliminary injunction prohibiting . . . the commercial manufacture or sale" of a biosimilar "[a]fter receiving the notice [of commercial

marketing] and *before such date of the first commercial marketing*." 42 U.S.C. § 262(*l*)(8)(B) (emphasis added).[1] Those provisions make clear that such a request is not categorically premature. To the contrary, a patent owner is expressly authorized—indeed encouraged—to seek preliminary relief before commercial marketing, so as to ensure orderly process. Nothing forbids district courts from considering a patent owner's pre-marketing delay in seeking relief—especially when that delay leads to the rushed proceedings and disruption of marketing activities the BPCIA was meant to avoid.

Genentech's contrary position would make a hash of the BPCIA. Under the statute, the 180-day notice of commercial marketing is the *only* notice a biosimilar applicant must give regarding its intent to launch. *See Sandoz*, 137 S. Ct. at 1677 (discussing § 262(*l*)(8)(A)'s "single timing requirement"). If the availability of preliminary injunctive relief were triggered only by an applicant's decision to *immediately* begin selling its biosimilar, as Genentech urges, *every* preliminary injunction motion (and related appeals) would require emergency proceedings that are disruptive for courts and parties alike. That approach would flout Congress's

[1] By its terms, § 262(*l*)(8)(B) addresses preliminary injunctions as to patents the parties have not previously designated for immediate adjudication. *See* § 262(*l*)(8)(B)(ii); § 262(*l*)(4)-(6); pp. 7-8, *supra*. *A fortiori*, a patent owner can seek preliminary relief regarding patents (like the dosing patents here) that have been chosen for immediate adjudication.

intent in designing the BPCIA to promote early, orderly adjudication of patent disputes. *Sandoz*, 137 S. Ct. at 1670.[2]

Nor does "precedent" foreclose the district court's consideration of pre-marketing delay. Genentech Br. 29. Genentech identifies no case—much less binding precedent—that adopts the prohibition it urges. None of Genentech's cases involved the BPCIA's "carefully calibrated scheme" for resolving patent disputes without "wait[ing] until commercial marketing." *Sandoz*, 137 S. Ct. at 1670. To the extent Genentech's non-BPCIA cases might be relevant, they undermine its position.

Time and again this Court has observed that delay is an appropriate consideration when deciding a motion for preliminary injunction. *See, e.g.*, *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("evidence

[2] Genentech thus errs in suggesting that any motion filed before commercial marketing cannot establish sufficiently threatened or "imminent" injury. Br. 33. That consideration is context-specific. By authorizing injunctive relief before commercial marketing, the BPCIA makes clear that sufficiently threatened harm can be shown *before* commercial marketing occurs. Genentech itself alleged, in its June 2018 complaint, that harm from Amgen's "sale" of Kanjinti was "imminent" because Amgen had given notice "pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it may commence commercial marketing." D. Ct. Dkt. #2 (¶¶149, 160). Having alleged "imminent" harm then, Genentech cannot reverse positions now. Under Third Circuit law, moreover, imminence looks to whether "the harm will occur before a trial on the merits can be had," and can be satisfied even if the predicted harm will not occur "for at least a year." *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000). Genentech's appeal is premised on its assertion that, absent relief, it will suffer harm before the December 2019 trial.

that a patent owner unduly delays in bringing suit against an alleged infringer negates the idea of irreparability"). Genentech's cases also highlight that the weight afforded to evidence of delay is a fact-intensive determination committed to the district court's discretion. *See Integra Lifesciences Corp. v. HyperBranch Med. Tech., Inc.*, 2016 WL 4770244, at *8 (D. Del. Aug. 12, 2016) (delay must be considered "in the context of the totality of the circumstances").

The closest Genentech comes to supporting authority is *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970 (Fed. Cir. 1996). *Polymer* found no undue delay where a patent owner sued four months after infringing activity began. *See* Br. 27. In that case, however, there was no evidence the plaintiff "knew or should have known about [the defendant's] plans" to produce the accused product, and the plaintiff could not bring suit before production actually began. *Polymer*, 103 F.3d at 976. Here, by contrast, the district court found that "Genentech ha[d] known of Amgen's intent to market Kanjinti" *fourteen months* before seeking a preliminary injunction. Appx5. Genentech was able to—and did—bring suit as soon as Amgen filed its biosimilar application, but it failed to timely seek preliminary relief. In *Polymer*, moreover, "the district court did not rely upon evidence of delay"; the defendant-appellee merely offered it as an alternative ground for affirmance. 103 F.3d at 976. The case thus did not involve the highly deferential abuse-of-discretion review applicable here. Tellingly, Genentech has not found a

single case where this Court has overturned a district court's denial of a preliminary injunction based on the patent owner's undue delay in seeking relief.

By contrast, this Court has *affirmed* a district court's reliance on undue delay in very similar circumstances. In *Cordis Corp. v. Boston Scientific Corp.*, No. CIV.A. 03-027-SLR, 2003 WL 22843072 (D. Del. Nov. 21, 2003), *aff'd*, 99 F. App'x 928 (Fed. Cir. 2004), the district court denied a preliminary injunction motion filed *before* FDA approval and market entry of the accused product. 99 F. App'x at 932. The court found no irreparable harm in part because the patent owner delayed seeking a preliminary injunction for sixteen months after learning about the defendant's infringing development of the accused product. *Id*. The patent owner protested that it sought a preliminary injunction as soon as it became likely the FDA would approve the product (precipitating its launch), but the district court found that explanation unpersuasive. *Id*. at 934. This Court affirmed, explaining that "[d]elay is a factor in evaluating irreparable harm." *Id.* at 933-34. *Cordis* confirms that a district court may properly consider a patent owner's pre-marketing delay in deciding a preliminary injunction motion. The BPCIA does not render that consideration impermissible.

3. *Genentech's Remaining Objections Lack Merit*

Genentech's remaining arguments reduce to a disagreement with the district court's finding that Genentech's delay was unjustified on "[t]he facts of this case."

Br. 32; *see id.* at 30. But Genentech does not challenge any of the district court's factual findings as clearly erroneous. And whether a given delay is "so significant . . . as to preclude a determination of irreparable harm" is firmly committed to "the district court's discretion." *Hybritech*, 849 F.2d at 1457. Genentech cannot show the district court abused its discretion here.

Genentech primarily argues that its delay was reasonable because it sought a preliminary injunction on July 10, 2019, "two days after Amgen made its decision to launch and five days before Amgen's intended launch date." Br. 25. The district court, however, found that "Genentech ha[d] known of Amgen's intent to market Kanjinti since . . . May 15, 2018." Appx5. But Genentech did not seek a preliminary injunction then. Nor did it do so upon learning in February 2019 of the FDA's anticipated approval date; upon receiving documents in April 2019 showing that "Amgen planned to launch [Kanjinti] in July 2019"; upon hearing from five witnesses between April and June 2019 about the July launch date; or upon the FDA's approval of Kanjinti in June 2019. Appx5-6; p. 13, *supra*. The court reasonably concluded that those repeated delays were just too much, particularly given the 180-day period the BPCIA specifically provides to facilitate prompt resolution of patent disputes.

Genentech says it was justified in not taking advantage of the BPCIA's 180-day window because Kanjinti's label was amended prior to FDA approval. Br. 32.

The district court reasonably concluded otherwise. Amgen's biosimilar application—which Genentech received under 42 U.S.C. § 262(*l*)(2)(A)—sought a full label with *all* the indications listed on Genentech's Herceptin label. Appx4314-4315; *see* § 262(k)(2)(A)(i)(III) (biosimilar's label may include any use previously approved for reference product). Amgen continued to seek the full label throughout the *entire* 180-day period, from May to November 2018, following its notice of commercial marketing. Appx4314. Nothing hindered Genentech from seeking a preliminary injunction during that time—or for months thereafter.

Amgen's brief pursuit of a [redacted] did not justify Genentech's extreme delay either. Amgen asked the FDA to [redacted] the [redacted] on its [redacted] on December 28, 2018, Appx1830; Appx1832, but [redacted] to the [redacted] on March 25, 2019, Appx1837; Appx4074—less than three months later. During the other eleven months of Genentech's fourteen-month delay—including the four months after Amgen [redacted] to the [redacted]—there were no pending changes that might have "moot[ed] any need for [injunctive] relief." Genentech Br. 33.

Insofar as Genentech alleges uncertainty about the scope of Kanjinti's [redacted] *after* Amgen [redacted] to the [redacted], Br. 32 (citing Appx4074), Genentech is mistaken. The document Genentech cites shows the opposite. It laid out Amgen's complete launch playbook and explained that Amgen's strategy was "to proceed

with the [redacted]." Appx4074 ("***Decision***: We believe we are in the strongest position *to proceed with the* [redacted]. ***Next Steps***: There will be a go/no go established in May regarding the launch decision. An additional go/no go will be established just prior to product shipment." (Second emphasis added)). Moreover, as the district court noted, in other trastuzumab biosimilar litigation, Genentech sought a schedule for a preliminary injunction *before the biosimilar received FDA approval*. Appx7 n.6. Genentech thus fully understood it could seek injunctive relief even if the final [redacted] was unresolved.

Genentech attempts to blame Amgen for its delay, claiming that Amgen witnesses testified that Amgen had not decided whether to launch. Br. 11-14, 25. But the district court found those witnesses' testimony showed "Amgen was preparing to be ready to launch Kanjinti in July 2019." Appx6. That finding was amply supported by the record. *See* Appx4081 (Yant Dep. 66:15-19) ("July 2019" is "the only date that I'm aware of"); Appx4090 (Jacobson Dep. 40:20-23) ("Our plan is to launch sometime in July"); Appx4098 (Hall Dep. 79:9-24) ("The operations team is targeting being called launch ready in July"); Appx4106 (Skeeters Dep. 18:5-21) ("I believe we're targeting July 13th or 14th"); Appx4114 (Benson Dep. 33:16-18) ("the updated discussion was to be prepared to launch in mid-July"). To the extent that any statements indicated Amgen "had not decided whether to launch," Genentech Br. 25, they merely reflected the (previously

disclosed) fact that a *final* "go/no go" decision by Amgen management would occur "just prior to product shipment," Appx4074.

Genentech attacks Amgen's lawyers, asserting that "Amgen's counsel . . . represented to Genentech and the district court that no [launch] decision had been made" and that, "in view of these uncertainties, Amgen argued that disputes relating to a potential launch 'may not be ripe.'" Br. 13; *see id.* at 25. The only thing Amgen's counsel said "may not be ripe" was a dispute about the scope of *a privilege waiver* based on the production of opinions of counsel. Appx1277 (30:14-31:11). That was because reliance on those opinions by the "ultimate decision-maker[s]" would not occur until Amgen's "upper management" made the final go/no-go decision just before launch. Appx1276 (29:15-19). Counsel reasonably did not give a definite launch date in open court, instead referring generally to "launch[ing] in two months versus six months versus a year." Appx1277 (30:4-5); *see* Appx1276 (26:22-27:7) (courtroom not sealed). Counsel made clear, however, that Amgen employees were "getting it all ready" for the anticipated launch. Appx1276 (29:10-15). Amgen simply did not argue that *a preliminary injunction motion* would be unripe prior to launch. The district court properly declined to credit Genentech's assertions otherwise.

II. THE DISTRICT COURT PROPERLY FOUND THAT GENENTECH'S PATTERN OF GRANTING LICENSES TO THE ASSERTED PATENTS SHOWED LEGAL REMEDIES WOULD BE ADEQUATE

The district court found Genentech's undue delay "sufficient by itself" to defeat irreparable harm. Appx7. But the court also found a lack of irreparable harm for a second, independent reason: Genentech had engaged in a "pattern" of licensing its dosing patents, with competitors entering the marketplace as soon as [redacted]. Appx7-9. Given that, the district court reasonably found Genentech had not proven that damages would be inadequate to compensate for any harm it might suffer for the [redacted] between Amgen's launch in July and entry of other competition in [redacted]. Appx9.

A. The District Court Properly Found That Genentech's Pattern of Granting Licenses to the Asserted Patents Was Inconsistent with Its Claim of Irreparable Harm

As the district court recognized, "[a]n injunction is a form of equitable relief and, therefore, available only when there is no adequate remedy at law." Appx8; *see eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). To prove irreparable harm, a patent owner seeking a preliminary injunction must "*clearly establis[h]* that monetary damages could not suffice." *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (emphasis added). The district court properly found that Genentech did not carry that burden here, in light of its extensive licensing of the dosing patents.

Genentech did not just engage in *some* licensing. The district court found that "Genentech has engaged in a *pattern and practice* of licensing the Dosing Patents." Appx7 (emphasis added). Specifically, "Genentech granted [redacted] licenses for the Dosing Patents to Mylan, Celltrion, and Pfizer"—virtually every other potential trastuzumab competitor. Appx8. And those licenses "allow a biosimilar to enter the market in [redacted], which is [redacted] from now." Appx8. Based on that licensing pattern, the district court concluded that "Genentech has been able to place a value on the patents and has approved competitors entering the market in [redacted]." Appx8-9. "Under these facts," the court determined, "any potential damages for sales in the next four months should be quantifiable." Appx9.

That conclusion was entirely reasonable. The last of Genentech's dosing patents does not expire until February 2022. Appx50. Yet Genentech chose to surrender its right to exclusivity in [redacted]—[redacted] before the patent term expires—and it did so[redacted]. Those unchallenged facts signaled that Genentech had assessed its patents' worth and assigned them a low (perhaps nonexistent) value. *Cf. Cordance Corp. v. Amazon.com, Inc.*, 730 F. Supp. 2d 333, 341 (D. Del. 2010) (finding that patent owner's "decision to grant a free license to anyone willing to use its technology" counseled against "grant[ing] injunctive relief in defense of [the patent owner's] exclusive right to use such technology").

Although Genentech withheld most of the license agreements' terms, *see* pp. 43-44, *infra*, the disclosed terms and other evidence amply supported the district court's finding. The redacted copies Genentech produced showed that the licenses cover not just the three dosing patents, but also about [redacted] other patents. Appx4537-4544; Appx4633-4646; Appx4700-4716. Giving away [redacted] of patents to one's competitors hardly suggests that *three* of those patents hold incalculable value. *See Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1343 (Fed. Cir. 2017) (affirming finding of no irreparable harm where patent owner had granted licenses to "'significant competitors' who posed 'major threats' to [its] flagship products").

Other evidence similarly indicates Genentech did not think its exclusive rights under the dosing patents had any real value. Genentech's internal [redacted] date for Herceptin was [redacted]—the date Genentech's [redacted] patent expired. Appx3792-3793 (Abreu Dep. 194:25-195:25). When making [redacted] for Herceptin, Genentech "*always* used [redacted] or [redacted]" as the [redacted] date, *id.* (emphasis added)—even though the last of the dosing patents would not expire until years later. That, too, suggests Genentech assigned those patents minimal value that could be compensated through monetary relief.

Regardless, the district court appropriately recognized that only [redacted] were at issue. Appx9. The first of Genentech's licensed competitors will

enter the market in [redacted], while trial in this case is scheduled for December 2019. "[G]iven the short period time" at stake, the district court reasonably concluded that damages from any harm Genentech might suffer would be relatively "easy to calculate." Appx9 (citing *King Pharm., Inc. v. Sandoz, Inc.*, 2010 WL 1957640, at *6 (D.N.J. May 17, 2010)).

B. Genentech's Contrary Arguments Lack Merit

1. *The District Court Did Not Adopt a "Categorical Rule" That Licenses Make It "Impossible" To Establish Irreparable Harm*

Genentech's primary submission is that the district court adopted a "categorical rule" that licensing patents "makes it impossible to establish irreparable harm and obtain injunctive relief." Br. 35; *see id.* at 37 (supposed rule "that licenses for future entry foreclose finding irreparable harm"). Amgen did not ask for, and the district court did not adopt, any such categorical rule. While "'a plaintiff's willingness to license its patent'" is relevant, *eBay*, 547 U.S. at 393, the district court nowhere suggested that it, standing alone, forecloses a finding of irreparable harm.

Instead, the district court followed the settled principle that "evidence of licensing activities . . . can carry weight in the irreparable-harm inquiry." *Nichia*, 855 F.3d at 1343. It considered the particular facts of Genentech's licensing activities: a "pattern" of licensing the dosing patents to every other FDA-approved trastuzumab competitor, allowing market entry in just a few months, and doing so

[redacted]. Appx7-9. It then reasonably concluded that those unique facts weighed against a finding of irreparable harm in this case. Appx8-9.

2. *The District Court Did Not Abuse Its Discretion in Considering Genentech's Heavily Redacted License Agreements*

Genentech argues that the district court failed to "'explor[e] any relevant differences'" between the license agreements and the current situation. Br. 35. While Genentech presents that as a claim of "legal error," *id.* at 36, Genentech really argues that the district court gave insufficient weight to various features of the licenses. Genentech thus faces a stout uphill climb. The "weight accorded to the prior licenses" in the irreparable harm analysis is a matter that "falls squarely within the discretion of the [district] court." *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008). Genentech shows no abuse of discretion.

The fundamental problem is that Genentech *prevented* a full examination of any differences between this case and earlier licenses, by *withholding* the details of its licenses from Amgen and the district court. Earlier in the case, Amgen moved to compel production of the Mylan, Celltrion, and Pfizer license agreements. But Genentech produced only heavily redacted copies that excluded all material terms except the royalty rate. Appx1258 (75:14-77:5); Appx4537-4716. The district court permitted Genentech to do so only because Genentech represented that it *was not seeking* preliminary injunctive relief. Appx1246 (26:1-4). When Amgen explained that it would need to know more about the licenses to defend against any

future request for injunctive relief, Appx1251 (47:17-49:8), the district court made clear to Genentech that the risk of withholding the full licenses "would fall on them," *id.* (49:9-23). By "put[ting] this issue of settlement agreement disclosure . . . off until an injunction arose," Genentech risked having the injunction decided against it. *Id.* Yet Genentech maintained its position and withheld the license details. *See* pp. 14-15, *supra*.

Once Genentech reversed course and sought a preliminary injunction, it was entirely reasonable for the district court to infer that the withheld license terms were inconsistent with maintaining the right to exclude, or with a finding that harm (during a short, [redacted] period) would not be remediable by damages. The district court was not obligated to blindly accept Genentech's self-serving assertion that a [redacted] license term must mean the licensed patents are invaluable.

Even setting aside Genentech's nondisclosure, its arguments fail. Genentech now beats the drum that it [redacted] Br. 39. But Genentech did not raise that argument below until *after* the district court had denied Genentech's motion for a preliminary injunction (the ruling now under review). Genentech first raised the argument when seeking a Rule 62(d) injunction pending appeal. Appx4897-4898. Genentech has thus forfeited the argument. *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012) ("The general rule is that this court does not consider arguments not raised below.");

Bluebonnet Sav. Bank, F.S.B. v. United States, 466 F.3d 1349, 1361 (Fed. Cir. 2006) (argument first made in motion for reconsideration is waived). "The district court did not abuse its discretion by failing to consider an argument that was never presented to it." *Smith v. Marsh*, 194 F.3d 1045, 1052 n.5 (9th Cir. 1999).

Regardless, the argument lacks merit. The district court understood that Genentech's licenses provided for market entry only in the future. Appx8. But it recognized that the future was fast approaching, with the first licensed competitor entering the market just [redacted] later. Appx8-9. The district court reasonably concluded that extraordinary equitable relief was not warranted for that brief time—particularly in light of the [redacted] of patent life Genentech had [redacted] *away* [redacted]. Genentech never explained why it granted [redacted] licenses allowing imminent and early market entry. It can hardly complain about the reasonable inferences the district court drew from those licenses in the absence of any such explanation.

Genentech also argues on appeal that the district court should have given its license agreements less (or no) weight because "Genentech entered into those agreements to settle patent disputes." Br. 40. Genentech never made that argument to the district court either. It too is forfeited. *Celsis In Vitro*, 664 F.3d at 931. The argument fails regardless. To the extent Genentech argues that licenses granted in settlement can *never* be considered when weighing irreparable harm,

that position lacks support in law or logic. *See AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1336 (Fed. Cir. 2015) ("[T]here is no per se rule barring reference to [license agreements] simply because they arise from litigation"); *Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 462 n.769 (W.D. Pa. 2000) (considering license entered "in settlement of litigation" in irreparable harm context). To the extent Genentech argues that *these* license agreements merited no weight, it has not shown an abuse of discretion. Genentech's willingness to offer [redacted] licenses to its major competitors fairly suggests that Genentech was able to place a value (albeit a low one) on the asserted patents, and that competitors' market entry would not cause it irreparable harm. Appx8-9. If other license terms could suggest otherwise, Genentech elected to withhold that information.

Finally, Genentech asserts that "Amgen is in a unique position" because it has "multiple long-selling oncology products," "an established track record as a successful biologic manufacturer, and a reputation that will establish its credibility with oncology group purchasing organizations as a reliable, high-quality supplier." Br. 40. Flattery will get Genentech nowhere. Before the district court, Genentech's argument regarding Amgen's "unique" threat focused on Amgen's "multiple" oncology products. Appx1357. But Genentech conspicuously failed to explain how *its licensees* fare by comparison. Appx1357. Those licensees are no

slouches: Pfizer and Mylan, for example, both claim "multiple" oncology products. Pfizer reports "an industry-leading portfolio of *eighteen* approved innovative cancer medicines."[3] Mylan boasts *twenty* oncology treatments.[4] As for the other factors Genentech invokes, Br. 40-41, none were discussed in Genentech's preliminary injunction briefing. The district court did not err by not commenting on arguments Genentech failed to brief.

Genentech forgets that *it* bore the burden to prove monetary relief would be inadequate. It failed to carry that burden, and in fact actively frustrated the inquiry it now says was required. Genentech insisted on keeping the district court (and Amgen) in the dark about the details of its license agreements. Even in its preliminary injunction briefing, Genentech offered no explanation why it decided to grant [redacted] licenses to its competitors and allow market entry beginning in [redacted]. Nor did Genentech provide the district court any comparative analysis between its licensees and Amgen. Genentech's *post hoc* criticisms of the district court's opinion should be rejected.

[3] *Pfizer Oncology Press Kit*, Pfizer, https://www.pfizer.com/news/press-kits/oncology (last visited Aug. 31, 2019) (emphasis added).

[4] *Mylan's Commitment to Oncology*, Mylan, https://www.mylan.com/en/oncology (last visited Aug. 31, 2019) (emphasis added).

C. Genentech's Purported Evidence of Irreparable Harm Fails

Genentech argues that—if one ignores its repeated, unexplained delays and profligate licensing to competitors—there is irreparable harm to be found. Br. 44-51. Some of Genentech's scattershot arguments rest on alleged financial harms remediable by damages. Others rest on speculation and conjecture. The district court did not clearly err in declining to accept them.

1. *Lost Market Share and Price Erosion*

The only alleged harms for which Genentech offers any evidence are lost market share and price erosion. Br. 45-47. Even where it is clear "that generic competition will impact [a patent owner's] sales of" a brand-name drug, this Court has rejected the notion that "potential lost sales alone demonstrate manifest irreparable harm." *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (internal quotation marks omitted). "[A]cceptance of that position," the Court has explained, would improperly "require a finding of irreparable harm to *every* manufacturer/patentee, regardless of circumstances." *Id.* (emphasis added; internal quotation marks omitted).

Instead, a patent owner seeking injunctive relief has the burden to "clearly establis[h] that monetary damages *could not suffice*" for such financial harms. *Abbott*, 452 F.3d at 1348 (emphasis added). The district court properly found Genentech had not carried that burden. The scant evidence Genentech offered on

price erosion and lost market share reduce to its assertion that pharmaceutical pricing is "complicated" and "comple[x]." Appx1399-1400 (¶¶65, 66). Those vague statements regarding "'how the market will react to generic competition'" are precisely the sort of "'highly speculative'" evidence that this Court has held insufficient to establish irreparable harm. *Abbott*, 452 F.3d at 1348 (reversing grant of preliminary injunction). The district court was not required to credit them.[5]

Genentech's evidence, moreover, was directed to price erosion and lost market share that might occur *after trial*. Appx1356 (citing Appx1739-1748 (projecting that Herceptin's price will not begin to erode until *after* [redacted])); Appx1358 (citing Appx1739-1748 (alleging market share loss through 2022)). That evidence does not show that any harm *during the next* [redacted] could not be quantified. Appx8-9 (emphasis added).

As to the *relevant* time period, Genentech's internal forecasts predicted that competition from "biosimilar entries" during the remainder of 2019 (*i.e.*, before trial) would cause Genentech to lose "[c]onsiderably" less than [redacted] in sales, or only about [redacted] of Genentech's $23.608 billion in revenues for 2018.

[5] Genentech's purported evidence is a far cry from that presented in *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008) (cited Br. 45, 47), where the district court found Abbott would lose *90%+* of its market share before Abbott's licensees entered the market, and suffer substantial layoffs to boot. *See Abbott Labs. v. Sandoz, Inc*., 500 F. Supp. 2d 807, 843 (N.D. Ill. 2007).

Appx4231 (Oliger Dep. 110:12-25); Appx1468-1469 (¶17); Appx4252. The fact that Genentech was able to put its own number on the potential impact of new market entry only confirms that "[u]nder these facts, any potential damages for sales in the next four months should be quantifiable." Appx9; *see also Cordis*, 2003 WL 22843072, at *2 (denying preliminary injunction in part because infringement would affect less than 5% of total sales), *aff'd*, 99 F. App'x at 934 (approving such evidence as "part of the overall injunction calculus"). Harm that Genentech itself can measure in dollars is not irreparable.

2. *Effects on Other Products*

Genentech asserts that Kanjinti's launch will cause irreparable harm to *other* Genentech products. Genentech Br. 48-49. No evidence supports that claim. Melissa Abreu, Genentech's corporate designee on irreparable harm, was "unaware" of any internal forecasts predicting lost sales or price erosion for Genentech's non-Herceptin products (including Perjeta, Kadcyla, Rituxan, and Avastin) as a result of biosimilar market entry. Appx4139-4144 (Abreu Dep. 59:14-24, 69:24-70:12, 72:13-74:2). Likewise, Warner Biddle, Genentech's Vice President and Franchise Head for BioOncology Breast & Skin Cancer, testified that competition from Kanjinti will *not* cause Genentech to "reduce R&D expenditures" or "cance[l] future products." Appx4163-4165, Appx4166 (Biddle Dep. 84:5-86:6, 122:5-13).

Genentech *conceded* before the district court that it has no forecasts or data to substantiate its speculative assertions about "the effects of [Kanjinti's] launch on other Genentech products, layoffs, and R&D spending." Appx4731. Genentech's assertions on appeal are thus entitled no weight. *See Baxalta Inc. v. Genentech, Inc.*, No. 17-509-TBD, 2018 WL 3742610, at *11 (D. Del. Aug. 7, 2018) (disregarding speculative harms in irreparable harm analysis).

3. *Reputational Harm*

Finally, Genentech asserts that a preliminary injunction is needed because "*once a biosimilar competitor has launched*, the patentee cannot enforce its patents by removing the biosimilar product from the market without suffering reputational harm for being 'portrayed as taking a medicine off the market.'" Br. 49 (emphasis added). If Genentech genuinely feared such harm, it presumably would have raised that argument earlier, when asking this Court for an injunction pending appeal. But Genentech did not. *See* ECF #8-1 at 16-19 (raising only price erosion and lost market share); ECF #34-1 at 8-10 (same). And now that Kanjinti has fully launched, the argument is effectively moot. On Genentech's view, *granting* Genentech a preliminary injunction at this point would cause it the irreparable reputational harm it purports to fear by "portray[ing]" it—correctly—"as taking a

[competing] medicine off the market." If anything, this consideration weighs *against* Genentech's position.[6]

III. THE DISTRICT COURT PROPERLY FOUND THAT THE PUBLIC INTEREST WEIGHS AGAINST A PRELIMINARY INJUNCTION

The district court's findings about the public interest provided a third distinct basis for denying a preliminary injunction. Appx9 n.7. Genentech is thus mistaken when it contends that "the district court premised its denial of a preliminary injunction entirely on the theory that Genentech would not be irreparably harmed by Amgen's launch." Br. 2. The district court expressly found that public interest considerations "also weigh in favor of denying [Genentech's] motion." Appx9 n7. Genentech thus must show the district court abused its discretion in finding that the public interest weighed against a preliminary injunction. Genentech does not come close.

This Court has repeatedly made clear that the judiciary should not be in the business of restraining "lawful competitive activities." *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 777 (Fed. Cir. 1993). Accordingly, "injunctions in the patent

[6] Genentech has not raised, and therefore has waived reliance on, any other alleged reputational harm. Nor could it sustain such an argument. Genentech's corporate designee for irreparable harm testified that the only reputational harm that might result from market entry of trastuzumab biosimilars would occur if *Genentech abandons* the market for trastuzumab. Appx4145-4151 (Abreu Dep. 100:16-106:6). Because Genentech is *not* abandoning the market, that harm will not materialize.

context must be limited to restraints designed to prevent further infringement." *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 893 (Fed. Cir. 2011). A finding that "an injunction would have the effect of depriving the public of access to a large number of non-infringing features" weighs against granting it. *Apple, Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1372-73 (Fed. Cir. 2013).

That is exactly what the district court found here. The court correctly recognized that Genentech has already enjoyed the full exclusivity period for its composition-of-matter patents, the last of which expired on June 18, 2019. Appx9 n.7. The court also correctly noted that Genentech has *not* alleged infringement for "two of the four indications on the Kanjinti label." Appx9 n.7; *see* Appx4323-4363. Despite those concededly non-infringing indications, Genentech sought an order preventing Amgen from selling Kanjinti *altogether*—including for the indications that are wholly "free of any allegations of infringement." Appx10 n.7; Appx1324-1325; Appx1332-1333. The district court reasonably concluded that Genentech's demand for such an overbroad injunction—restraining lawful competitive activities in the provision of life-saving medicines—"weighs against granting an injunction," Appx10 n.7.

Genentech protests that the district court did not identify "any patient need for the non-infringing uses that cannot already be supplied by Herceptin." Br. 57. But Genentech's ability to supply its product for non-infringing uses does not

entitle it to keep others from competing to provide their products for those non-infringing uses too. And while Genentech complains that Kanjinti's concededly non-infringing indications constitute only about 25% of patient use, Br. 57, it fails to explain why it is in the public interest to constrain competition in breast cancer treatments for 25% of the relevant patient population.

Genentech would strike a different balance than the district court, giving dispositive weight to the public interest in "the enforcement of patent rights to encourage innovation." Br. 56. There is, of course, a strong public interest in maintaining a robust patent system that encourages investment in medical advances. And the district court did not suggest otherwise. It expressly recognized the "'public interest in protecting rights secured by valid patents.'" Appx9 n.7 (quoting *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988)).

On the particular facts of this case, however, the district court found that interest was outweighed by other concerns, including the interest in ensuring patients' access to Amgen's non-infringing treatments. That determination was well within the court's broad discretion. And the public interest in such access has grown since the district court ruled. Kanjinti has been in oncologists' hands since July. ECF #27-3 (Jacobson Decl. ¶¶7-8). Genentech thus seeks to have Kanjinti *taken away* from patients in the midst of receiving potentially life-saving treatments. *Id.* (¶8).

IV. GENENTECH HAS NOT SATISFIED THE REMAINING PRELIMINARY INJUNCTION FACTORS

The district court's findings that Genentech failed to meet its burden of showing irreparable harm (for two independent reasons), and that the public interest disfavored an injunction, are each sufficient to defeat a preliminary injunction. *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994). The district court thus was not required to decide—and, given the "hurried nature" of Genentech's last-minute motion, did not decide—whether Genentech had satisfied the likelihood-of-success and balance-of-hardships factors. Appx9. Genentech nonetheless argues that the "only reasonable conclusion" is that those factors "overwhelmingly support" a preliminary injunction. Br. 51. In fact, Genentech has failed to satisfy either factor.

A. Genentech Has Not Shown a Likelihood of Success on the Merits

Genentech has not shown it is likely to succeed on the merits on its infringement claims. Genentech relies entirely on the fact that its dosing patents survived inter partes review proceedings to which Amgen was not a party. Br. 52-53. But the patents barely escaped invalidation, based solely on the Board's doubts—on the record before it—about whether a skilled artisan would have reasonably expected the claimed dosing method to be effective. Through discovery in this case, Amgen has adduced evidence, unavailable to the Board, that eliminates any such doubt. New prior art also proves that the asserted claims were

anticipated—a theory the Board did not consider. Genentech is simply wrong to assert that Amgen's invalidity "arguments have been conclusively rejected by the PTAB," Br. 53, and it offers nothing more to contest Amgen's arguments.

1. *Evidence Not Considered by the Board Shows the Asserted Claims Are Obvious*

In the inter partes review proceedings, it was undisputed that the dosing patents differ from the prior art *only* in trastuzumab's dosing: The patents essentially claim tripling the known weekly dose, and then giving it once every three weeks. Appx3986; Appx1863. The Board therefore analyzed whether a skilled artisan (1) would have been motivated to "extend the weekly dosing interval taught in the prior art to a tri-weekly dosing interval," and (2) would have had a reasonable expectation of success in doing so. *Id.*

The Board concluded—over Genentech's arguments to the contrary—that a skilled artisan would have been motivated to arrive at the *exact* 3-weekly regimen claimed in the dosing patents. Appx3987-3993; Appx1864-1870. That was true for the "simple" yet "compelling" reason that fewer doses "would have been more cost effective and less burdensome for the patient." Appx3987-3988; Appx1864-1865. "'[A] relatively infrequent dosing schedule,'" the Board explained, "'has long been viewed as a potential solution to the problem of patient compliance.'" Appx1865 (quoting *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1329 (Fed. Cir. 2014)). And a skilled artisan would have been motivated to choose *3*-

weekly dosing in particular, the Board found, to synchronize trastuzumab treatment with the already-established 3-weekly schedule for chemotherapy. Appx3990-3991; Appx1867-1868.

The Board also concluded that a skilled artisan would have been motivated to use the *exact dosages* claimed in the dosing patents. Appx3991-3993; Appx1868-1870; *cf. Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1373 (Fed. Cir. 2005) (obvious to use a larger dose to extend dosing from daily to weekly). Those dosages "would have been the obvious starting point" and were "based on equations set forth in a basic pharmacokinetics textbook." Appx1869.[7]

Having found motivation to choose the claimed dosing regimen, the Board upheld the patents *solely* because the challengers had not shown that a skilled artisan would have had a reasonable "expectation of success" that the regimen would be efficacious. *See* Appx3993-4005; Appx1870-1882. The Board pointed to (1) uncertainty about whether the regimen would provide sufficiently high trastuzumab levels throughout treatment, given trastuzumab's non-linear

[7] The asserted claim of the '811 dosing patent, which has never been tested by an inter partes review, contains no "effective amount" limitation, and is not "narrower" than the other dosing patent claims, as Genentech argues. *Compare* Appx49 ('196 patent claim 11) *with* Appx139 ('811 patent claim 7). Because it does not recite any limitation for administration of an effective amount of Herceptin, the asserted claim of the '811 patent requires only administration of the recited dosing regimen—the same regimen that the Board held a skilled artisan would have been motivated to pursue. *See* Appx3980-3983, Appx3991-3993; Appx1857-1860, Appx1868-1870.

pharmacokinetics, and (2) uncertainty about efficacy in a small patient subpopulation exhibiting high levels of a "shed" form of the HER2 protein. *Id*. Amgen's new evidence shows those concerns were unfounded.

Non-Linear Pharmacokinetics. The Board identified uncertainty in the effect of trastuzumab's non-linear pharmacokinetics on drug concentrations over time. But Amgen's additional evidence shows that a variety of long-established modeling tools were available to confidently estimate trastuzumab dosing at higher levels and longer intervals, even if the drug's pharmacokinetics were non-linear. *See* Appx1793-1794; Appx1804-1807.

Those sophisticated models, however, were not necessary. Genentech argues that "the PTAB found that the prior art did not support the conclusion that a simple, linear model could be used." Br. 53. But new testimony from the dosing patents' inventors and Genentech's own consultants proves that simple mathematics, well within reach of a skilled artisan, was sufficient. Dr. Larry Norton, Genentech's own consultant and a renowned oncologist, testified that—prior to the dosing patents' priority date—he showed inventor Shak that 3-weekly dosing was likely to work using mathematics so simple he was able to scribble it on a napkin during a coffee break at a conference. Appx3841-3848. And the inventors actually used those trivial mathematics—based on an off-the-shelf *linear* computer model and pre-existing clinical trial data—to choose the claimed 3-

weekly dose. Appx3932, Appx3933-3935, Appx3939-3941, Appx3949 (Baughman Dep. 42:3-10, 46:11-48:3, 59:23-61:1, 111:5-23).

The inventors conceded that, in determining that the claimed regimen was likely to work, they relied only on information about trastuzumab that was published in the prior art. *Both* named inventors testified that the patents contain no experimental data actually evaluating the higher doses and longer intervals they claimed. Appx3949, Appx3950 (Baughman Dep.111:5-23, 126:5-24); Appx4379 (Shak Dep. 91:1-15). Instead, the entire basis for the inventors' belief that the claimed dosing regimens would be effective—and for their filing the patent—was the same prior-art disclosures and simple pharmacokinetics estimation techniques available to any skilled artisan.[8]

The inventors' routine mathematical modeling, combined with the lack of any clinical data in the patent testing "8/6—three weekly" dosing, compels a conclusion of obviousness. Where, as here, the patent discloses no scientific discovery beyond application of the existing knowledge of a skilled artisan, and no surprising result, the claims are obvious. *See Merck*, 395 F.3d at 1374 (less-than-

[8] Existing clinical trial data, disclosed in the prior art, showed that trastuzumab likely had a longer half-life than originally estimated. That meant pharmaco-kinetics estimates would *underestimate* the already strong likelihood of success with the regimen. *See* Appx3927, Appx3936-3938, Appx3943, Appx3946-3948, Appx 3954, Appx3963-3964 (Baughman Dep. 35:2-11, 53:16-55:20, 79:1-7, 89:8-91:18, 167:6-13, 240:6-241:25); Appx4370-4373, Appx4374-4376, Appx4377-4378 (Shak Dep. 44:3-47:12, 61:17-63:22, 65:10-66:1).

daily treatment obvious where the patent contains no clinical or laboratory data and thus adds nothing beyond the prior art).

The "Shed Antigen" Phenomenon. The Board also identified uncertainty as to the effect of "shed antigen" on maintaining trastuzumab levels over longer intervals. Appx3996-4000; Appx1873-1877. "Shed antigen" is a phenomenon—occurring in a small subpopulation of breast cancer patients—in which part of the HER2 protein "sheds" from the tumor surface and circulates in the patient's blood, where it can bind to trastuzumab. Appx3996-3997; Appx1873-1874. The Board believed this phenomenon caused additional "uncertainty" in trastuzumab's pharmacokinetics by potentially decreasing trastuzumab concentrations in patients with especially high "shed antigen" levels. Appx3997; Appx1874.

But the record on that issue in *this* case is different—the polar opposite. It shows that the prior art taught there was *no* correlation between shed HER2 antigen levels and responsiveness to trastuzumab treatment. Appx1808-1809. To the contrary, most patients with very high levels of shed HER2 antigen responded to therapy at *standard* trastuzumab doses. *Id.*

The inventors, moreover, conceded that they did nothing to account for, or try to mitigate, the shed antigen issue. Appx3950-3951, Appx3955-3956, Appx3957, Appx3965-3967 (Baughman Dep. 126:25-127:4; 175:23-176:7, 179:8-21, 254:9-256:1). That makes sense. "Shed antigen" affects only a small

subpopulation. Even setting aside the prior art's teaching that shed antigen has no effect, a skilled artisan would not have ignored the opportunity to provide a "more cost effective and less burdensome" regimen for large numbers of patients based on (unfounded) concerns about efficacy for a small minority. Appx1808-1809. The suggestion that the shed antigen phenomenon would have led a skilled artisan to abandon the entire project falls flat.

2. *Evidence Not Considered by the Board Shows the Asserted Claims Are Anticipated*

Genentech's dosing patents are also invalid because they are anticipated by another previously unconsidered prior-art reference: Genentech's own Hellmann patent. *See* Appx1815-1816; *see also* Appx4406-4535. Hellmann teaches *every single* limitation of the asserted claims. Appx4510-4535.

Genentech concedes the Board did not consider Hellmann. Br. 52 n.6. Yet Genentech addresses Hellmann only in a footnote, asserting that it "only discloses weekly dosing." *Id.* Not so. Hellmann explains that the combination of trastuzumab with paclitaxel—a chemotherapy drug with a known 3-week dosing interval—is "*favor[ed]*" because it "markedly increases the clinical benefit" of chemotherapy. Appx4532 (31:1-32:50) (emphasis added). And Hellmann leaves no doubt that its inventor anticipated higher doses of trastuzumab administered on paclitaxel's 3-weekly schedule: It *expressly discloses* ranges of trastuzumab doses covering the claimed 8/6 doses, Appx4530 (28:16-35), and *expressly teaches*

giving trastuzumab "simultaneously" with chemotherapy, Appx4529, Appx4532 (26:50-67, 31:1-17, 32:40-48). The range of doses disclosed in Hellmann covers a manageable number of intermediate dose amounts, Appx4530 (28:16-35), that a skilled artisan readily would have recognized as desirable, Appx3980-3993; Appx1857-1870.

Genentech offers no meaningful response. Rather than engage with Amgen's new invalidity evidence, Genentech parrots Board statements made *without* the benefit of that evidence. Br. 52-53. Because Amgen has offered an "invalidity defense that [Genentech] has not shown lacks substantial merit," an injunction is inappropriate. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010).

B. The Balance of Hardships Tilts Strongly Against Genentech

The balance of hardships also tips strongly in Amgen's favor. Fourteen months after providing Genentech with its notice of commercial marketing, eight months after the 180-day statutory notice period expired, after providing Genentech full discovery—and after having complied with the district court's emergency standstill order—Amgen made Kanjinti available to its customers, putting it into the stream of commerce and creating further obligations with patients, customers, and distributors. ECF #27-3 (Jacobson Decl. ¶¶5-8); *see also* Appx3771 (¶¶6-7). Since July 2019, Kanjinti has been in the hands of

oncologists, who have begun treating patients with Kanjinti to cure their cancers and prolong their lives. ECF #27-3 (Jacobson Decl. ¶¶5-8). To halt those activities a second time at this point would create substantial harms to Amgen, its reputation, its customers, and patients. *Id.* (¶9). By contrast, Genentech will not experience any disruption from sales of Kanjinti that is different from the impacts of the licensed sales that Genentech itself has allowed to commence in [redacted].

CONCLUSION

The district court's denial of Genentech's motion for a preliminary injunction should be affirmed.

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CERTIFICATE OF SERVICE

I certify that today, September 4, 2019, I electronically filed the foregoing document with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

September 4, 2019 /s/ Jeffrey A. Lamken

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE MOTIONS OR BRIEFS CONTAINING MATERIAL SUBJECT TO A PROTECTIVE ORDER

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/s/ Jeffrey A. Lamken
(Signature of Attorney)

Jeffrey A. Lamken
(Name of Attorney)

Appellee
(State whether representing appellant, appellee, etc.)

Sep 4, 2019
(Date)

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(b) and Fed. Cir. R. 32(a) because this brief contains 13,909 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

September 4, 2019 /*s*/ Jeffrey A. Lamken