IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant.*	:	Civ. No. 18-924-CFC

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MEMORANDUM OPINION

July 18, 2019

CONNOLLY, UNITED STATES DISTRICT JUDGE

This action arises under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111–148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.). Plaintiffs Genentech, Inc. and City of Hope have sued Defendant Amgen Inc. based on Amgen's submission of a Biologics License Application (BLA) for approval to market Kanjinti, a biosimilar of Genentech's drug product Herceptin.

On May 15, 2018, Amgen served Genentech a Notice of Commercial Marketing pursuant to § 262(*l*)(8)(A) of the BPCIA. Kanjinti was approved by the FDA on June 13, 2019. Four weeks later, on July 10, 2019, Genentech moved for a temporary restraining order and preliminary injunction to prevent Amgen from commercially launching, marketing, or selling Kanjinti until the Court renders a decision on the merits of Genentech's patent infringement claims following trial, and until the Court of Appeals for the Federal Circuit has adjudicated any appeal of that decision. D.I. 273; D.I. 274. That same day, I arranged an emergency teleconference with the parties and orally ordered a standstill until I received Amgen's response to Genentech's motions and had an opportunity to consider

fully the issues and rule on the merits. For the foregoing reasons, I will deny Genentech's motions for a temporary restraining order and preliminary injunction.

I. BACKGROUND

The non-proprietary names for Herceptin and Kanjinti are respectively trastuzumab and trastuzumab-anns.[1] For purposes of a trial scheduled for December 2019, the parties are litigating ten patents which cover: (i) the trastuzumab antibody itself (the Composition Patent)[2]; (ii) techniques for identifying patients who might benefit from trastuzumab therapy (the HER2 Diagnostic Patents)[3]; (2) various aspects of cell culture, purification, and antibody manufacturing purification (the Manufacturing Patents)[4]; and (3) methods of administration (the Dosing Patents). D.I. 44; D.I. 60 at 2-3; D.I. 75. Genentech's motions seek relief based on claims in the three Dosing Patents: U.S. Patent Nos. 6,627,196 (the "#196 patent"), 7,371,379 (the "#379 patent") and 10,160,811 (the "#811 patent"). All three patents relate to methods of treating cancer with a

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[1] The FDA employs a "naming convention" pursuant to which it gives a "core name" to the reference product (in this case, trastuzumab) and adds for each biosimilar a "distinguishing suffix that is devoid of meaning and composed of four lowercase letters ... attached with a hyphen to the core name" (in this case, "-anns").

[2] U.S. Patent No. 6,407,213 claims the trastuzumab antibody.

[3] The HER2 Diagnostic Patents at issue are U.S. Patent Nos. 7,993,834 and 8,076,066.

[4] The Manufacturing Patents at issue are U.S. Patent Nos. 6,620,918; 8,512,983; 8,574,869; and 9,714,293.

specific dosage regimen: intravenous ("IV") administration of an initial 8 mg/kg dose followed by one or more 6 mg/kg doses separated by three weeks. D.I. 279-1, Ex. 1, Cl. 11; Ex. 2, Cl. 11; Ex. 3, Cl. 6. The #379 patent further recites coadministration with a chemotherapy agent. *Id.*, Ex. 2, Cl. 6. The #811 patent further recites treatment of breast cancer. *Id.*, Ex. 3, Cl. 11.

II. LEGAL STANDARDS

A preliminary injunction is "a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). To obtain such extraordinary relief, the moving party must prove that: (1) it has a reasonable likelihood of success on the merits; (2) it would suffer irreparable harm in the absence of an injunction; (3) the balance of hardships tips in its favor; and (4) an injunction would have a favorable impact on the public interest. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Hybritech Inc. v. Abbott Lab.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). The grant or denial of a preliminary injunction is within the sound discretion of the district court. *Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996).

The standards for a preliminary injunction also apply to a motion for a temporary restraining order when, as here, the opposing party has notice of the motion. *See Takeda Pharm. USA, Inc. v. W.-Ward Pharm. Corp.*, 2014 WL 5088690, at *1 (D. Del. Oct. 9, 2014). Accordingly, Genentech's motion for a temporary restraining order rises and falls with its motion for a preliminary injunction.

III. DISCUSSION

"Central to the movant's burden are the likelihood of success and irreparable harm factors." *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996). "A court may decline to issue a preliminary injunction if the movant does not prove either of these factors." *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1380 (Fed. Cir. 2000). Here, I am denying the motion for preliminary injunction, because Genentech has failed to establish irreparable harm.

A patentee's undue delay in seeking a preliminary injunction "negates the idea of irreparability." *Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005); *Polymer Tech.*, 103 F.3d at 974 (same). Genentech has known of Amgen's intent to market Kanjinti since Amgen served its 180-day Notice of Commercial Marketing on May 15, 2018. In addition, Genentech received information through discovery that made clear Amgen's plan to launch its

marketing of Kanjinti in July 2019. Specifically, in February 2019, Amgen produced to Genentech documents showing that it filed a "resubmission" to the FDA in December 2018.[5] Given the known six-month regulatory timeline for the FDA to consider the resubmission (*see* D.I. 289-1, Ex. 11 at 4), Genentech would have understood at the time that the FDA would act on the resubmission by the end of June 2019. In April 2019, Amgen produced documents with its launch plan redactions removed, thus enabling Genentech to see that Amgen planned to launch in July 2019. *Id.* at Ex. 12. From late April through mid-June, five Amgen witnesses testified during depositions that Amgen was preparing to be ready to launch Kanjinti in July 2019. D.I. 289-1, Ex. 14 at 66:12-67:3, 83:9-12; Ex. 15 at 40:20-23; Ex. 16 at 79:6-10, 81:3-6; Ex. 17 at 18:5-10; and Ex. 18 at 32:11-33:18.

The FDA approved Kanjinti on June 13, 2019. But Genentech did not file its motion for a preliminary injunction until July 10, 2019—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.

[5] A resubmission is "a submission by the biologics license applicant or supplement applicant of all materials needed to fully address all deficiencies identified in the complete response letter." 21 C.F.R. § 600.3.

Genentech's actions are also contrary to the spirit and purpose of the BPCIA. As the Federal Circuit explained, the 180-day period triggered by the notice of commercial marketing "gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 591 (2016). Thus, the 180-day period is designed to prevent exactly the circumstances that Genentech has engineered in this case—a "race to court for immediate relief to avoid irreparable harm from market entry, and ... the hurried motion practice that (8)(A) is designed to replace."[6] *Id.* at 1065.

Genentech's undue delay in requesting a preliminary injunction, particularly in light of relevant provisions under the BPCIA, should be sufficient by itself to deny the motion. Nevertheless, a finding of no irreparable harm is also supported by the fact that Genentech has engaged in a pattern and practice of licensing the Dosage Patents.

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[6] Notably, Genentech demonstrated its ability to avoid hurried motion practice in a related case involving the same patents and the same reference product but a different defendant. With Amgen, however, Genentech represented to the Court as recently as May 16, 2019 that it was not seeking a preliminary injunction. *See* D.I. 289-1, Ex. 19 at 26:1-4.

An injunction is a form of equitable relief and, therefore, available only when there is no adequate remedy at law. *See N. Cal. Power Agency v. Grace Geothermal Corp.*, 105 S.Ct. 459, 459 (1984) ("A party seeking an injunction from a federal court must invariably show that it does not have an adequate remedy at law."); *Coca-Cola Bottling Co. of Shreveport, Inc. v. Coca-Cola Co.*, 769 F. Supp. 671, 713 (D. Del. 1991) ("The Court may only invoke its equity powers when there is no adequate remedy at law."). Thus, to establish irreparable harm, the movant must "clearly establish[] that monetary damages could not suffice." *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). The fact that "movants have engaged in a pattern of granting licenses under the patent" makes it "reasonable to expect that invasion of the patent right can be recompensed with a royalty rather than with an injunction." *Polymer Tech.*, 103 F.3d at 974; *see also High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (offering to license the patent "suggests that any injury suffered by [the patentee] would be compensable in damages"). Here, Genentech granted [redacted] licenses for the Dosing Patents to Mylan, Celltrion, and Pfizer that allow a biosimilar to enter the market in [redacted] D.I. 291-1, Exs. 37-39. In other words, Genentech has been able to place a value on the patents and has approved competitors entering the

market [redacted]. Under these facts, any potential damages for sales in the next four months should be quantifiable. *See King Pharm., Inc. v. Sandoz, Inc.*, 2010 WL 1957640, at *6 (D.N.J. May 17, 2010) (denying a preliminary injunction where any changes to the market from the non-movant's entry should be easy to calculate given the short period time).

The "absence of irreparable harm ... ma[kes] unnecessary a consideration of ... [the] likelihood of success in proving infringement." *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 682 n.3 (Fed. Cir. 1990); *Polymer Tech.*, 103 F.3d at 974 ("[T]he district court did not err by focusing its analysis solely on irreparable harm in denying [the movant's] motion."). Due to the hurried nature of this particular motion practice, I will not take additional time to set forth my analysis with respect to other preliminary injunction factors.[7] Genentech has failed to

[7] I will briefly make note of considerations under the fourth factor that also weigh in favor of denying the motion for a preliminary injunction. "[A]lthough there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech Inc.*, 849 F.2d at 1458. For pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs. Genentech itself acknowledges this public interest by stating that it is "committed to ensuring patient access by providing Herceptin free of charge to patients who are uninsured or cannot afford treatment." D.I. 275 at 18. In that context, I note that Genentech's exclusivity based on the Composition Patent expired on June 18, 2019, and only two of the four indications on the Kanjinti label allegedly infringe the Dosing Patents, meaning there are two recited methods of using Kanjinti that

establish irreparable harm and therefore its motions for preliminary and temporary injunctive relief must be denied.

IV. CONCLUSION

For the foregoing reasons, I will deny Genentech's motions for a temporary restraining order and preliminary injunction (D.I. 273; D.I. 274). The standstill ordered on July 10, 2019 is lifted.

The Court will issue an Order consistent with this Memorandum Opinion.

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are free of any allegations of infringement. "[T]he prospect that an injunction would have the effect of depriving the public of access to a large number of non-infringing features," weighs against granting an injunction. *Apple Inc. v. Samsung Elecs. Co. Ltd.*, 735 F.3d 1352, 1372–73 (Fed. Cir. 2013).