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

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