IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACCORD HEALTHCARE INC., ET AL., Defendants.	)	Civil Action No. 18-1043 (KAJ) **FILED UNDER SEAL**

MEMORANDUM OPINION

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JORDAN, Circuit Judge, sitting by designation.

I. Introduction

HEC has moved for a partial stay of final judgment, seeking to avoid the reset of the Food and Drug Administration's final approval of HEC's Abbreviated New Drug Application ("ANDA"). (D.I. 784 at 1.) HEC wishes to maintain its final approval status, rather than revert to preliminary approval, because it believes it will succeed on appeal and should not have to continue to wait, post-appeal, for the FDA's final approval. (D.I. 784 at 1.) I will deny the motion.

II. Background

Novartis's U.S. Patent No. 9,187,405 ("the '405 Patent") claims methods to treat Relapsing-Remitting multiple sclerosis ("RRMS") using the compound "fingolimod," at a 0.5 mg daily dosage. (D.I. 769 at 1.) Novartis manufactures a pharmaceutical product called Gilenya embodying its '405 Patent. HEC submitted ANDA No. 207939, seeking FDA approval of a generic version of Gilenya. (D.I. 1 at 28.) Novartis then sued HEC (and twenty-two other defendants) in this Court pursuant to the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2),[1] alleging that the defendants' ANDA applications infringe the '405 Patent. (D.I. 769 at 2.) In December 2019, HEC received FDA final approval for its generic fingolimod product. (D.I. 784 at 1.)

[1] "It shall be an act of infringement to submit an [ANDA] ... for a drug ... the use of which is claimed in a patent, ... if the purpose of such submission is to obtain approval ... to engage in the commercial manufacture, use, or sale of a drug ... before the expiration of such patent." 35 U.S.C. § 271(e)(2)(A).

Novartis ultimately prevailed in its patent infringement suit. First, it obtained a preliminary injunction on August 1, 2019. Then, following a bench trial from March 2 to 5, 2020, final judgment was entered in favor of Novartis on September 11, 2020, permanently enjoining HEC "from engaging in the commercial manufacture, use, offer for sale, and/or sale in the United States and/or importation into the United States of the fingolimod product that is the subject of HEC's ANDA No. 207939 until the expiration date of the '405 Patent[.]" (D.I. 780 at ¶ 4.) In my findings of fact and conclusions of law, I rejected HEC's invalidity attacks, finding adequate written description for the claim limitation "absent an immediately preceding loading dose" because a person of skill, reading the patent, "would not expect a loading dose to be used to treat RRMS with fingolimod." (D.I. 769 (FF) ¶¶ 49-66, (COL) ¶¶ 19-24.) I also found there was an adequate written description for the 0.5 mg daily dose, because a person of ordinary skill would understand the '405 Patent's Experimental Autoimmune Encephalomyelitis ("EAE") experimental results in rats, combined with the Patent's prophetic example,[2] to support a 0.5 mg daily dose to treat the human disease. (D.I. 769 (FF) ¶¶ 49-66, (COL) ¶¶ 19-24.) The result was consistent with a prior Patent Trial and Appeal Board ("PTAB") decision in an IPR proceeding on the '405 Patent. (D.I. 583 at 6.)

Having determined that the '405 Patent is valid and infringed, I ordered, pursuant to 35 U.S.C. § 271(e)(4)(A), that the approval date for HEC's ANDA "shall be a date not

[2] A prophetic example is a fictional experiment and expected results that is published in a patent. These can be accepted by the Patent Office. *See generally* Janet Freilich, *Prophetic Patents*, 53 UC DAVIS L. REV. 663 (2019).

earlier than the expiration date of the '405 Patent," which is set for June 25, 2027. (D.I. 780 at 2.) The parties agree that this order will cause the FDA to convert HEC's final approval to tentative approval. (D.I. 788 at 3.) Therefore, upon the expiration of the '405 Patent (or following a successful appeal), HEC will have to file an amendment with the FDA requesting that its tentative approval be changed back to final approval. (D.I. 788 at 9.)

HEC urges me to stay the judgment to the extent it causes this reset, arguing that the Federal Circuit is likely to overturn the judgment on appeal. HEC says it will be irreparably harmed if the order is not stayed, Novartis will not be unduly prejudiced or disadvantaged by a stay, and the public interest favors a stay. (D.I. 784 at 3.) I disagree.

III. Discussion

In deciding whether to grant a motion to stay final judgment, courts consider four factors, as described by the Supreme Court in *Hilton v. Braunskill*: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." 481 U.S. 770, 776 (1987). The application of these factors lies within my discretion. *See Crystallex Int'l Corp. v. PDV Holding Inc.*, No. 15-cv-1082-LPS, 2019 WL 6785504, at *2 (D. Del. Dec. 12, 2019).

Here, the four *Hilton* factors do not weigh in favor of a stay. HEC has not shown that it is likely to succeed on the merits. It merely repeats arguments already rejected after the bench trial. Nor has it shown that it will be irreparably harmed absent a stay.

Congress contemplated this kind of situation when it required the reset of final ANDA approval following final judgment by passing 35 U.S.C. § 271(e)(4)(A),[3] and I would undermine congressional intent and the public interest were I to grant HEC's motion. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) ("[T]he Hatch–Waxman Act struck a careful balance between encouraging the development of new drugs and enabling the marketing of low-cost generic drugs.").

A. Likelihood of Success on the Merits

HEC contends that it has "a reasonable chance" of success on appeal, arguing that the Federal Circuit may reverse my fact finding and conclusion that the '405 Patent is not invalid for lack of written description. (D.I. 784 at 3-4 (quoting *Singer Mgmt. Consultants, Inc. v. Milgram,* 650 F.3d 223, 229 (3d Cir. 2011) (*en banc*)).) HEC makes two primary arguments for why it will succeed in invalidating the patent.[4]

First, HEC alleges that the negative claim limitation, "absent an immediately preceding loading dose regimen," is inadequately disclosed in the '405 Patent's specification, because the specification fails to describe "a reason to exclude the relevant limitation." (D.I. 784 at 4 (quoting *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012)).) HEC notes that the limitation was "belatedly added" and suggests that I recognized that the patent "does not describe loading doses." (D.I. 784 at

[3] Section 271(e)(4)(A) states, "the court shall order the effective date of any approval of the drug ... involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed[.]"

[4] HEC reserves its full appellate rights but focuses for purposes of this motion on two invalidity issues. (D.I. 784 at 3 n.2.)

4 (quoting D.I. 769, ¶ 65).) HEC thus claims that the judgment is contradicted by my factual findings. Pointing to its expert testimony on the propriety of loading doses for fingolimod (D.I. 784 at 5-6), HEC says I also committed legal error by supplanting the patent disclosure with the knowledge of a person of ordinary skill. (D.I. 784 at 5 (citing D.I. 769, ¶ 61).) Lastly, HEC argues that a Federal Circuit panel, on appeal from an IPR proceeding wherein the PTAB also found the '405 Patent valid, "expressed strong skepticism that there is any support for the negative limitation in the specification." (D.I. 784 at 6 (citing D.I. 743 at 4; D.I. 696, Ex. 6).)

These same substantive arguments were made earlier, and I rejected them after a four-day bench trial, and consideration of substantial post-trial briefing. (*See* D.I. 788 at 5-8.) For the reasons already laid out in my findings of fact and conclusions of law, HEC's motion does not persuade me that its position has a reasonable chance of success on appeal.

Second, HEC argues that the patent should be invalidated because it lacks an adequate written description for a 0.5 mg daily dosage in humans. (D.I. 784 at 7 (citing D.I. 743 at 14).) HEC claims that the EAE experiment combined with the prophetic example did not adequately disclose the 0.5 mg daily human dosage because it at most represented actual or constructive disclosure of this dosage, not disclosure within the four corners of the specification. (D.I. 784 at 8.) Again, I rejected that argument before, having credited Novartis's expert testimony on how a person of ordinary skill would understand such disclosures. *Cf. In re 318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("[H]uman trials are not required for a therapeutic invention to be

patentable."). HEC has not persuaded me that it has a reasonable chance of showing that I erred by holding that it did not meet its burden of proving by clear and convincing evidence that the '405 Patent is invalid.

B. Irreparable Harm, Undue Prejudice, and the Public Interest

HEC argues it will be irreparably harmed if its motion is not granted. (D.I. 784 at 9.) It says that the delay in final approval of its ANDA product, following its hypothetical success on appeal, will cause it to lose significant profit, having been kept "off of the market for years." (D.I. 784 at 1.) HEC calls the re-approval process "a needless allocation of both HEC and the FDA's time and resources." (D.I. 784 at 9.) And HEC points out that its first final approval process took over five years. (D.I. 792 at 2-3.) Even if this hypothetical delay were briefer, HEC claims that it would still suffer irreparable harm because "quick entry of a generic upon invalidation of patents is a well-known core tenet of Hatch-Waxman litigations." (D.I. 784 at 9.) Further, HEC contends that Novartis will not be prejudiced because "unless and until the '405 patent is invalidated at the Federal Circuit, Novartis remains in exactly the same position whether or not this stay is granted." (D.I. 784 at 9.) Lastly, it claims "[t]he public interest is best served through making generic fingolimod available as soon as the legal barriers on Novartis' patent have been resolved." (D.I. 784 at 10.)

Novartis responds by explaining that, because HEC will not have to add any new data or information, the amendment it would have to submit is classified by the FDA

ANDA Guidelines as "minor" and those types of amendments are addressed promptly.[5] (D.I. 788 at 9-10, Ex. 1 (FDA ANDA Guidelines) at 7.) It characterizes HEC's description of harm as "conclusory and speculative." (D.I. 788 at 9 (quoting *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390-LPS-CJB, 2018 WL 395750, at *14 (D. Del. Jan. 8, 2018)).) Moreover, Novartis says that this alleged harm "is no different than any other Hatch-Waxman litigation where a patentee wins[,]" and the "normal result of a statutory command cannot ... form[ ] the basis of an argument to undo the statute." (D.I. 788 at 10.) Relatedly, Novartis contends that "[a] stay would shift the burden of policing HEC's market entry from [the] FDA (which can pursue civil and if necessary criminal enforcement remedies should HEC sell generic Gilenya without authorization) to Novartis and the Court under the Final Judgment's injunction." (D.I. 788 at 10.) This, Novartis asserts, would upend 35 U.S.C. § 271(e)(4), which intentionally "puts responsibility for policing the sale of infringing product back with FDA." (D.I. 788 at 10.)

I agree with Novartis that Congress intended for a final approval like that for HEC's ANDA be reset as a result of final judgment against the applicant. For the reasons described by Novartis, fulfilling congressional intent will not irreparably harm HEC, nor would it be in the public's interest to change the "careful balance" created by Congress,

[5] In reply, HEC calls the suggestion that approval will be speedy "speculation," and suggests that there could be COVID-19 related delays in approval. (D.I. 792 at 2-3.) It also claims that even a relatively speedy delay would cost HEC $4.4 million per day in lost sales. (D.I. 792 at 3.)

which includes entrusting enforcement of final judgments to the FDA. *Pharmaceutica, N.V*, 540 F.3d at 1361. A stay is not appropriate.

IV. Conclusion

For the reasons stated, HEC's motion for a stay will be denied.[6]

[6] I will also deny as moot Novartis's motion to file a sur-reply brief (D.I. 796) to respond to HEC's reliance on *Ferring B.V. v. Watson Labs., Inc.- Fla.*, C.A. No. 14-1416, Dkt. No. 22 (Fed. Cir. Apr. 28, 2014), first cited in HEC's Reply brief (D.I. 792 at 1).