UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. ET AL, Plaintiffs,	)	
v.	)	C.A. No. 15-10698-MLW 16-11117-MLW
CELLTRION HEALTHCARE CO. INC., ET AL., Defendants.	)	

MEMORANDUM AND ORDER

WOLF, D.J. September 26, 2016

I. SUMMARY

In 2015, plaintiffs Janssen Biotech, Inc. and New York University (collectively "Janssen") filed Civil Action No. 15-10698 (the "2015 Action") against defendants Celltrion Healthcare Co., Ltd., Celltrion Inc., and Hospira, Inc. (collectively "Celltrion"). The case was brought pursuant to the Biologics Price Competition Act (the "BPCIA"), 42 U.S.C. §262, 35 U.S.C. §271(e)(2)(C). In the 2015 Action, Janssen alleged infringement by defendants' biosimilar product of several of Janssen's patents, including U.S. Patent No. 6,284,471 (the "'471" patent") and U.S. Patent No. 7,598,083 (the "'083" patent"), used to produce Remicade. Remicade is prescribed for chronic pain and generates billions of dollars of sales in the United States annually. In addition, in the 2015 Action, Janssen alleged violations of the BPCIA.

In 2016, Janssen filed Civil Action No. 16-11117 (the "2016 Action"), pursuant to 35 U.S.C. §271(a), alleging infringement of the '083 patent relating to Celltrion's activities outside the United States. The two cases have been consolidated.

In August 2016, the court decided two Celltrion motions for summary judgment and held that the '471 patent is invalid due to obviousness-type double patenting. Celltrion has moved for entry of a final judgment on this issue pursuant to Federal Rule of Civil Procedure 54(b). Janssen opposes that motion.

For the reasons explained in this Memorandum, Celltrion's motion for final judgment concerning the '471 patent is being allowed. The court has decided all issues concerning the validity of the '471 patent. Its judgment is, therefore, "final" for the purposes of Rule 54(b). In addition, there is no just reason to delay the entry of final judgment concerning the '471 patent. The decisions concerning the '471 patent are separable from the remaining issues in these cases. This court finds that the results of the pending reexamination of the '471 patent by the Patent and Trademark Office (the "PTO") will not affect the decision that the '471 patent is invalid. Nor will the Federal Circuit be required to decide the same issues more than once.

The equities also favor an immediate appeal of the decisions that the '471 patent is invalid. Uncertainty concerning that question could delay the sale of Inflectra in the United States.

Even if Inflectra is sold in the United States, uncertainty about whether Inflectra will be removed from the market because it infringes the '471 patent could discourage doctors from prescribing it. In either case, the individuals suffering great pain could be unfairly deprived for some time of a more affordable alternative to Remicade if the '471 patent is found on appeal to be invalid. In any event, legitimate price competition may be delayed while Janssen reaps substantial monopoly profits that would be unjustified if the '471 patent is invalid.

The BPCIA established an expedited procedure to promote the prompt resolution of claims of patent infringement by biosimilar products. This process is intended to reduce uncertainty and thus encourage the sale of non-infringing, more affordable biosimilars which may be important to human health. Granting Celltrion's Rule 54(b) motion serves the purposes of the BPCIA.

II. THE FACTS AND PROCEDURAL HISTORY

Janssen holds patents employed to create the biologic product "Remicade," which is based on the antibody infliximab. Remicade is used to treat intense, chronic pain. It can cost up to $20,000 per person a year. It generates revenue from sales in the United States of about $4 billion a year for Janssen and its parent, Johnson & Johnson.

The '471 patent is a patent to a group of chimeric antibodies including the infliximab antibody in Remicade. It is referred to

by the parties as the "antibody patent." The '083 patent claims the liquid solution in which cells are grown, such as the cells that produce the infliximab antibody. It is referred to by the parties as the "soup patent." In contrast to the '471 patent, the '083 patent does not include any reference to infliximab.

Celltrion has developed a product named Inflectra that is biosimilar to Remicade. Celltrion invested more than $100 million to develop Inflectra. Hospira, which is owned by Pfizer, has an exclusive agreement with Celltrion to market Inflectra in the United States.

In April 2016, the United States Food and Drug Administration approved Inflectra for sale. Pursuant to the BPCIA, Celltrion may begin selling Inflectra in the United States in October 2016. See Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1066 (Fed. Cir. 2016).

In essence, the BPCIA: requires the developer of a biosimilar product to disclose promptly the information necessary for a patent holder to decide whether it believes its patent has been infringed; requires the patent holder to sue promptly for any alleged infringement; and limits a patent holder to recovering a reasonable licensing fee, rather than lost profits, if the alleged infringement is not prosecuted promptly. See Amgen Inc. v. Sandoz Inc., 794 F.3d 1347, 1351-52 (Fed. Cir. 2015); 35 U.S.C. §271(e)(6). The BPCIA seeks to "'ensure that litigation surrounding relevant patents will be resolved expeditiously and

prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.'" Amgen, 794 F.3d at 1363 (Newman, J. concurring in part, dissenting in part) (quoting Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On Courts and Competition Policy of the House Committee On the Judiciary, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo)). The BPCIA is based in part on the understanding that uncertainty concerning whether an innovative biologic infringes a valid patent can discourage development and sale of a product that may be helpful to human health and more affordable than the patented product.

In these consolidated cases, Janssen now alleges that Inflectra infringes the '471 patent and the '083 patent.[1] In addition, Janssen asserts that Celltrion has not satisfied the requirements of the BPCIA. Janssen seeks declaratory and injunctive relief, and damages as well.

Despite being offered by the court several opportunities to do so, Janssen did not move for a preliminary injunction to prohibit the sale of Inflectra in the United States pending the outcome of these cases. Janssen did, however, move for a stay of

[1] In the 2015 Action, Janssen originally alleged infringement of six of its patents. Based on stipulations of dismissal of certain contentions, only the '471 patent and the '083 patent remain in dispute.

the litigation until the PTO concluded the pending reexamination of the '471 patent. Celltrion opposed that request.

At a May 19, 2016 hearing, the court denied the motion for a stay. See May 19, 2016 Transcript at 54-57. In explaining its decision, the court noted that the case was at an early stage and the litigation would be simplified at the district court level if the PTO found the '471 patent invalid. Id. The court cited these factors as favoring a stay. Id. at 54-55.

However, the court found these considerations to be outweighed by the undue prejudice to Celltrion and the public if the stay were granted. It reasoned, in part, that a stay would undermine a primary purpose of the BPCIA--achieving the expeditious resolution of the issues of alleged infringement to promote certainty as to whether a biosimilar product could be sold without exposing an innovator to the risk of an award of lost profits, which could be hundreds of millions, if not billions, of dollars in the instant cases. Id. at 55-56 (citing Amgen, 794 F.3d at 1363).

More specifically, the court stated that:

> A stay would expose the defendant to enormous potential damages for lost profits if it markets its biosimilar product and loses the case.
>
> That risk could deter the defendant from selling . . . a biosimilar that it is or may be entitled to sell without infringing the '471 patent. The PTO has so far for the purposes relevant to this case found the '471

> invalid [because it is] not eligible for the safe harbor provisions of the relevant statutes.
>
> If the defendants' biosimilar is delayed in getting to the market, the public will be deprived of a cost-effective alternative to Remicade.

Id. at 55. The court also noted that eliminating uncertainty was a reason for the creation of the declaratory judgment remedy and for establishing the Federal Circuit, citing its analysis in In re Columbia University Patent Litigation, 330 F. Supp. 2d 12, 17-18 & n.2 (D. Mass. 2004). The court concluded that the interest of minimizing uncertainty inherent is every patent case was particularly compelling in a case arising under the BPCIA, which was enacted to minimize uncertainty. See id. at 55.

The request for a stay having been denied, Celltrion filed two motions for summary judgment seeking declaratory judgments that the '471 patent is invalid because of obviousness-type double patenting. Janssen opposed the motions. The parties refer to the first motion as the "Gilead Motion" and the second motion as the "Reexam Motion." The court heard extensive arguments on those motions on August 16 and 17, 2016. For reasons described in detail orally, the court allowed Celltrion's motions and found the '471 patent invalid for obviousness-type double patenting.[2]

[2] In view of the appeal being authorized in this Memorandum and Order, the court will convert the transcripts of its oral decisions to more formal Memoranda and Orders.

On August 19, 2016, the court issued a written Order summarizing its reasons for granting the motions for summary judgment and finding the '471 patent invalid. With regard to Celltrion's first motion, the court wrote:

> Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting (the "Gilead Motion") (Docket No. 127) is ALLOWED. Plaintiffs hold U.S. Patent No. 6,284,471 (the "'471 patent"). The '471 patent was issued on September 4, 2001. Standing alone, it would expire on September 4, 2018. Plaintiffs previously held U.S. Patent No. 6,790,444 (the "'444 Patent"). The '444 Patent was issued on September 14, 2004 and expired on July 11, 2011. The parties agree that the '471 patent is not patentably distinct from the '444 Patent. The Court of Appeals for the Federal Circuit held in Gilead Sciences., Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 1530 (2015), that a later-issuing, earlier-expiring patent can act as a double-patenting reference for an earlier-issuing, later-expiring patent. The court finds that the reasoning in Gilead applies where, as here, the later-issued patent expires earlier because of the change to patent terms resulting from the Uruguay Round Agreements Act, codified at 35 U.S.C. §154. In essence, the court concludes that the statute was not intended to alter the judicial doctrine of obviousness double-patenting. See Gilead, 753 F.3d at 1216. Therefore, claims 1, 3, 5, 6, and 7 of the '471 patent are invalid for obviousness-type double-patenting in light of the patentably indistinct, earlier-expiring '444 Patent.

August 19, 2016 Order at ¶1.

With regard to Celltrion's second motion for summary judgment, the Reexam Motion, the court wrote in most pertinent part:

> The '471 patent is not entitled to the protection of the 35 U.S.C. §121 statutory safe harbor (the "Section 121 safe harbor"). The Section 121 safe harbor applies only

> to applications filed as "divisional." See Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1362 (Fed. Cir. 2008). The '093 Application was filed as a continuation-in-part of U.S. Pat. App. No. 08/013,413 (the "'413 Application"). It was not filed as divisional of the '413 Application. The court does not have discretion to deem the '093 Application divisional. See id.; Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1354 (Fed. Cir. 2009).

Id. at ¶2(b). The court found that the "one-way test" for obviousness was applicable to deciding the Reexam Motion and that the asserted claims of the '471 patent were obvious in light of claims in the two other patents relating to infliximab, U.S. Patent No. 5,698,195 and U.S. Patent No. 5,656,272. Id. at ¶2(c). The court also found that the '471 patent would fail the "two-way test" if it applied. Id. at ¶2(d).

Therefore, this court has decided all of the issues concerning the '471 patent. The remaining matters for the trial scheduled for February 2017 relate to the '083 "soup patent" and whether Celltrion satisfied the requirements of the BPCIA.

Following the court's decisions finding the '471 patent invalid, the parties made publicly reported statements. Janssen's announcement stated that it "is disappointed with the court's ruling and plans to appeal to the Court of Appeals for the Federal Circuit." See Press Release, Johnson & Johnson Announces Ruling Related to REMICADE in the District of Massachusetts Federal Court Hearing (Aug. 17, 2016) (attached as Ex. 2 to Celltrion's Memorandum in Support of the 54(b) Motion). Celltrion stated that

it is "committed to bringing biosimilars to patients in the U.S. as quickly as possible, and continuing with the preparation of our launch plans for Inflectra in 2016." Associated Press, Judge Invalidates Patent for Johnson & Johnson Rheumatoid Arthritis Drug, N.Y. Times (Aug. 17, 2016), http://www.nytimes.com/aponline/2016/08/17/us/apusjohnsonjohnsonpfizerremicade.html?emc=eta1.

As indicated earlier, Celltrion has moved for entry of partial final judgment concerning the '471 patent pursuant to Federal Rule of Civil Procedure 54(b), and Janssen has opposed that motion.

III. ANALYSIS

Rule 54(b) states that:

> When more than one claim for relief is presented in an action, whether as a claim, counterclaim, cross-claim, or third-party claim, or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

Fed. R. Civ. P. 54.

In deciding a motion under Rule 54(b), this "court must first determine that it is dealing with a 'final judgment.'" Curtiss-Wright Corp. v. General Elec. Co., 446 U.S. 1, 7 (1980). A "final" judgment is "an ultimate disposition of an individual claim entered in the course of a multiple claim action." Id. (internal quotation and citation omitted).

In this case, the court's two decisions granting Celltrion's motions for summary judgment finding the '471 patent invalid are final. Celltrion challenged the validity of the '471 patent in two ways in the Gilead and Reexam Motions for summary judgment. The court granted both motions. Doing so resolved all issues concerning the validity of the '471 patent. With regard to the '471 patent, there is nothing left for the court to do except enter judgment. It is, therefore, final. See Catlin v. United States, 324 U.S. 229, 233 (1945); W.L. Gore & Associates, Inc. v. Int'l Med. Prosthetics Research Associates, Inc., 975 F.2d 858, 863 (Fed. Cir. 1992).

Accordingly, the court must exercise sound judicial discretion in deciding whether to find that there is no just reason for delay and, therefore, to authorize an immediate appeal of its decisions finding the '471 patent invalid. See Curtiss-Wright, 446 U.S. at 8. In doing so, the court "must take into account judicial administrative interests as well as the equities involved." Id.

Janssen's claimed infringement of the '471 is separate and distinct from its remaining claims. A trial will be necessary to decide whether the '083 patent is valid and, if so, whether Inflectra infringes it. However, the '471 patent and the '083 patent relate to different technologies. As explained earlier, the '471 patent claims chimeric antibodies including infliximab.

In contrast, the '083 patent claims the liquid solution in which cells are grown, such as the cells that produce the infliximab antibody. The '471 and '083 patents involve distinctly different inventions. They present no common questions of fact or law concerning claim construction, invalidity, or infringement. Therefore, an immediate appeal concerning this court's final decisions concerning the '471 patent would not create the risk that the Federal Circuit will "have to decide the same issues more than once if there [is] a subsequent appeal" concerning the '083 patent. Id.

Similarly, Janssen's claim that Celltrion has not satisfied the requirements of the BPCIA is separate and distinct from its claim that the '471 patent is valid and is infringed by Inflectra. The alleged violation of the BPCIA presents issues of statutory interpretation and fact concerning Celltrion's conduct that are unrelated to the court's findings that the '471 patent is invalid under the doctrine of obviousness-type double patenting. Once again, any future appeal concerning the BPCIA issue will not require the Federal Circuit to decide the same issue more than once. Id.

Janssen has announced its intention to appeal. The issues now ripe for appeal will have to be decided by the Federal Circuit sooner or later. Therefore, authorizing an immediate appeal

concerning the '471 patent will also not require unnecessary effort by the Federal Circuit.

Janssen, however, argues that an immediate appeal of this court's decisions concerning the '471 patent will deprive it--and the courts--of the benefit of the PTO's reasoning and decision in the pending reexamination proceeding. This is essentially a reiteration of the argument made in support of Janssen's motion to stay, which the court found to be unmeritorious.

As indicated earlier, Remicade generates more than $4 billion a year in revenue for Janssen. Janssen, therefore, has a financial incentive to try to delay the appeal of the finding that the '471 patent is invalid in the hope that uncertainty concerning the infringement issue will contribute to a delay in the sale of Inflectra or discourage doctors from prescribing it.

While Janssen has a financial reason to prefer having the validity of the '471 patent litigated after the PTO renders its reexamination decision, the BPCIA required that it present its infringement claim promptly to this court. Janssen's decision not to seek an immediate appeal itself, and its opposition to Celltrion's Rule 54(b) motion, essentially reflect a disagreement with a primary purpose of the BPCIA--to expedite patent litigation concerning biosimilar products in order to maximize certainty, and diminish the risk that innovators will be unnecessarily deterred from offering those products to the public because of the threat

of liability for a patentee's lost profits. See Amgen, 794 F.3d at 1363 (Newman, J. concurring in part, dissenting in part).

Janssen contends that if it prevails in the PTO reexamination, this court's invalidity analysis would have to be reconsidered and reversed. As the court explained in granting Celltrion's Reexam Motion, this contention is incorrect. See August 18, 2016 Hearing Tr. at 14.

The Federal Circuit's decision in G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349 (Fed. Cir. 2015) rejected an identical argument relating to a reissue patent. In that case, the patent applicant filed a continuation-in-part application, the '113 application, as a result of a restriction requirement imposed by the PTO. Id. at 1352. The resulting '068 patent was later invalidated for obviousness-type double patenting by the Federal Circuit in Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008), which found that the patent holder, Pfizer, was not entitled to protection under the §121 safe harbor because the '113 application was not filed as a divisional application. See id. Pfizer subsequently filed an application with the PTO for a reissue patent, arguing that the '113 application was improperly filed as a continuation-in-part instead of a divisional. See id. at 1353. The PTO allowed the amendment and issued the reissue patent with several changes including removing the new material that made the '113 application a

continuation-in-part and designating the '113 application as divisional. See id. Pfizer again sought protection under the §121 safe harbor for the reissue patent. See id. at 1354. The district court rejected Pfizer's argument. The Federal Circuit affirmed, stating in pertinent part:

> The '113 application for the '068 patent cannot be a divisional of the '594 application despite being designated as such in the reissue patent because it contains new matter that was not present in the '594 application. Simply deleting that new matter from the reissued patent does not retroactively alter the nature of the '113 application because neither of the '068 patent applications is a division of the original '594 application.

Id. at 1354-55.

Similarly, the application for the '471 patent was properly designated a continuation-in-part when it was filed because it contained new material. Under Searle, Janssen will not now be entitled to the protection of the §121 safe harbor even if the PTO retroactively characterizes the original application as divisional. Therefore, the PTO's decision will not affect the merit of this court's decisions that the '471 patent is invalid or be material to the Federal Circuit's review of them.

Accordingly, the court's decisions that the '471 patent is invalid are final and separable, and will not require duplication of effort or piecemeal consideration of related issues by the Federal Circuit. Nevertheless, the court recognizes that "[n]ot all final judgments on individual claims should be immediately

appealable even if they are in some sense separable from the remaining claims." Curtiss-Wright, 446 U.S. at 8. However, in this case the equities, including the public interest, favor authorizing an immediate appeal concerning the '471 patent.

As the seminal Curtiss-Wright case indicates, financial effects are among the equitable considerations a court may consider in deciding whether to authorize an appeal pursuant to Rule 54(b). Id. at 11 ("One of the equities which the District Judge considered was the difference between the statutory and market rates of interest."). In Curtiss-Wright, "the question before the District Court [] came down to which of the parties should get the benefit of the difference between the prejudgment and market rates of interest on debts admittedly owing and adjudged due while unrelated claims were litigated." Id. The Supreme court held that such financial consequences are cognizable in deciding a Rule 54(b) motion. Id. at 12-13.

In the instant cases, the risk of being required to pay Janssen for its lost profits if the '471 patent is valid and infringed could delay the sale of Inflectra in the United States. If so, Janssen would continue to have a monopoly generating more than $4 billion a year based on a patent this court has found to be invalid.

The court recognizes that Celltrion has said it is preparing to begin selling Inflectra in the United States in 2016. It is

not now certain whether it will do so. In any event, uncertainty relating to whether Inflectra infringes a valid '471 patent could affect decisions by potential investors in both Celltrion and Janssen. More significantly, uncertainty concerning whether Celltrion may be enjoined from selling Inflectra in the future could discourage doctors from prescribing it.

Most importantly, the public interest in making Inflectra available to doctors and their patients if it does not infringe a valid patent will be served by an immediate appeal. Remicade is prescribed for many people in great, chronic pain, which is why it generates billions in revenue annually. Remicade can cost up to $20,000 per patient per year. The cost may be unaffordable for some people. At a minimum, it makes their healthcare, and perhaps their insurance, more costly. A less expensive biosimilar alternative to compete fairly with Remicade would be in the public interest.

This public interest was recognized in the enactment of the BPCIA, with its expedited process for raising and resolving claims of infringement in cases involving biosimilar products. See Amgen, 794 F.3d at 1363 (Newman, J. concurring in part, dissenting in part). This court has given high priority to these consolidated cases in an effort to achieve the purposes of the BPCIA. Authorizing an appeal of the final decisions that the '471 patent

is invalid will further serve the purposes of the BPCIA. Therefore, Celltrion's Rule 54(b) Motion is being allowed.

IV. ORDER

In view of the foregoing, it is hereby ORDERED that:

1. Defendant's Motion for Entry of Final Judgment Pursuant to Federal Rule of Civil Procedure 54(b) Regarding U.S. Patent No. 6,284,471 (Docket No. 229) is ALLOWED.

2. A partial final judgment that U.S. Patent No. 6,284,471 is invalid shall enter for defendants as to Count 3 of Civil Action No. 15-10698-MLW

UNITED STATES DISTRICT JUDGE