UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY

Plaintiffs,

v.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.

Defendants.

Civil Action No. 1:15-cv-10698
Civil Action No. 1:16-cv-11117

DEFENDANTS' MOTION FOR ENTRY OF FINAL JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 54(b) REGARDING U.S. PATENT NO. 6,284,471

Defendants hereby move for entry of judgment pursuant to Federal Rule of Civil Procedure 54(b) on Count 3 of Plaintiffs' Janssen Biotech, Inc. and New York University's (collectively, "Janssen") Complaint. Count 3 alleges that Defendants infringe U.S. Patent No. 6,284,471 (the "'471 patent") under the Biologics Price Competition and Innovation Act ("BPCIA"). *See* No. 15-10698 Dkt. 1 at 31–32. On August 17, 2016 and August 18, 2016, the Court found the '471 patent invalid due to obviousness-type double patenting on two bases asserted in Defendants' motions for summary judgment. No. 15-10698 Dkt. 127, *et seq.*; No. 15-10698 Dkt. 176, *et seq*. The findings of invalidity were memorialized in the Court's written order dated August 19, 2016. No. 15-10698 Dkt. 226; No. 16-11117 Dkt. 7.

Entry of final judgment under Rule 54(b) on Count 3 is warranted for the reasons set forth in the accompanying memorandum of law. A proposed order is attached hereto as *Exhibit 1*.

Dated: August 22, 2016

Respectfully submitted,
Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc.
By their attorneys,

/s/Andrea L. Martin

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Attorneys for Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

LR 7.1(a)(2) CERTIFICATION

I, Andrea L. Martin, hereby certify that Defendants' counsel has conferred with Plaintiffs' counsel concerning the relief requested in this motion. Plaintiffs' counsel has stated that Plaintiffs will oppose this motion.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 22, 2016.

/s/Andrea L. Martin
Andrea Martin, Esquire

4825-3306-9879.1

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and
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Plaintiffs,

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CELLTRION HEALTHCARE CO., LTD.,
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Defendants.

Civil Action No. 1:15-cv-10698
Civil Action No. 1:16-cv-11117

[PROPOSED] **ORDER ENTERING FINAL JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 54(b) REGARDING U.S. PATENT NO. 6,284,471**

Having considered the parties' briefing regarding Defendants' Motion for Entry of Final Judgment Pursuant to Federal Rule of Civil Procedure 54(b) Regarding U.S. Patent No. 6,284,471, the Court finds as follows:

1. Plaintiffs Janssen Biotech, Inc. and New York University (collectively, "Janssen") filed Civil Action No. 15-cv-10698 (the "2015 Action") against Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively, "Defendants") on March 6, 2015, pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"). *See* No. 15-10698 Dkt. 1; 42 U.S.C. § 262; 35 U.S.C. § 271(e)(2)(C). The complaint in the 2015 Action included two counts (Counts 1 and 2) claiming violations of BPCIA, and six counts (Counts 3–8) of patent infringement on six different patents owned by Janssen, including U.S. Patent No. 6,284,471 (the "'471 patent") and U.S. Patent No. 7,598,083 (the "'083 patent"). No. 15-10698 Dkt. 1.

2. Janssen filed Civil Action No. 16-11117 (the "2016 Action") against Defendants on June 14, 2016, alleging infringement of the '083 patent under 35 U.S.C. § 271(a) and/or (b). No. 16-11117 Dkt. 1.

3. The 2015 Action and the 2016 Action were consolidated (No. 15-10698 Dkt. 226; No. 16-11117 Dkt. 7), and based on stipulations between the parties disposing of some of the claims in the 2015 Action, the following claims remain in the consolidated actions:

- 2015 Action Count 1: Janssen's claim that Defendants "failed to comply with the mandatory requirements of the BPCIA" provision 42 U.S.C. § 262(l);
- 2015 Action Count 3: Janssen's claim that Defendants infringe the '471 patent under the BPCIA;
- 2015 Action Count 6: Janssen's claim that Defendants infringe the '083 patent under the BPCIA; and
- 2016 Action Counts 1–3: Janssen's claims that Defendants infringe the '083 patent under 35 U.S.C. § 271(a) and/or (b).

4. Defendants have asserted no counterclaims in either the 2015 Action or the 2016 Action.

5. On August 17 and August 18, 2016, the Court granted, in oral orders, two motions filed by Defendants seeking summary judgment of invalidity of the '471 patent due to obviousness-type double patenting, after holding hearings related to the same. No. 15-10698 Dkt. 127, *et seq*.; No. 15-10698 Dkt. 176, *et seq*. The Court's oral orders were memorialized in a written judgment on August 19, 2016. No. 15-10698 Dkt. 226; No. 16-11117 Dkt. 7.

6. Defendants moved for entry of final judgment pursuant to Federal Rule of Civil Procedure 54(b) on the Court's order finding the '471 patent invalid due to obviousness-type double patenting. Dkt. 229, *et seq*.

7. The Court finds that entry of final, appealable judgment under Rule 54(b) on the Court's order finding the '471 patent invalid due to obviousness-type double patenting is warranted.

8. Rule 54(b) states, in pertinent part:

> When an action presents more than one claim for relief--whether as a claim, counterclaim, crossclaim, or third-party claim--or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay.

Fed. R. Civ. P. 54(b).

9. Rule 54(b) was enacted "to relax[] the restrictions upon what should be treated as a judicial unit for the purposes of appellate jurisdiction." *W.L. Gore & Assoc., Inc. v. Int'l Med. Prosthetics Research Assoc., Inc.*, 975 F.2d 858, 861 (Fed. Cir. 1992) (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 432 (1956)). The rule "allows a district court to sever an individual claim that has been finally resolved." *Id.*

10. Requests for final judgment pursuant to Rule 54(b) in patent cases are governed by Federal Circuit law. *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 830 (Fed. Cir. 2003); *see also State Contracting & Eng'g Corp. v. State of Florida*, 258 F.3d 1329, 1334 (Fed. Cir. 2001). The Federal Circuit has often looked to Supreme Court opinions interpreting Rule 54(b). *Gore*, 975 F.2d at 861.

11. There are two requirements for a judgment to be certified for appeal under Rule 54(b). *First*, the judgment in question must be "final with respect to one or more claims." *Gore*, 975 F.2d at 861. "Final" for the purpose of Rule 54(b) means "'an ultimate disposition of an individual claim entered in the course of a multiple claims action.'" *Id.* at 861–62 (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)) (emphasis omitted); *see also*

Curtiss-Wright Corp. v. Gen. Elec. Co., 446 U.S. 1, 7 (1980). *Second*, the Court must make a finding that there is "no just reason to delay the appeal" of the claim in question. *Gore*, 975 F.2d at 862. An inquiry into whether there is no just reason to delay involves looking at the "separateness of the claims for relief"—that is, the separateness of the claim sought to be certified as appealable, and the remaining claim or claims in the case. *Id*. The inquiry also involves consideration of "whether the nature of the claims already determined [i]s such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." *Id.* (quoting *Curtiss-Wright*, 446 U.S. at 8).

12. The Court's judgment that the '471 patent is invalid due to obviousness-type double patenting over U.S. Patent No. 6,790,444 (the "'444 patent"), over U.S. Patent No. 5,698,195 (the "'195 patent"), and over U.S. Patent No. 5,656,272 (the "'272 patent") is final with respect to Janssen's claim for infringement of the '471 patent, which is set forth at Count 3 in the complaint in the 2015 Action. The Court's order finding the '471 patent invalid is an "ultimate disposition" of an "individual claim"—that is, the claim asserting that all Defendants infringe the '471 patent. *Gore*, 975 F.2d at 861–62. It "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Id.* at 863 (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945)); *accord Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 407 F. App'x 481, 482 (Fed. Cir. 2011) ("[T]he District Court's grant of summary judgment of invalidity ended the litigation on the merits of Tyco's claim for patent infringement.") (citing *Catlin*, 324 U.S. at 233).

13. Additionally, there is no just reason to delay appeal of the Court's judgment regarding the '471 patent. Janssen's claim for infringement of the '471 patent is separable from

the remaining claims, and permitting appeal at this juncture does not pose any risk that the Federal Circuit will have to decide the same issues more than once.

14. Janssen's claims remaining in the consolidated actions fall into two categories: (1) Janssen's claim that Defendants violated the "patent dance" information-exchange procedures of the BPCIA; and (2) Janssen's claims that Defendants infringe the '083 patent. Both of these categories of claims are separable from the claim that Defendants infringe the '471 patent.

15. Janssen's claim that Defendants failed to abide by the "patent dance" requirements of 42 U.S.C. § 262(l) (Count 1 of the complaint in the 2015 Action) is separable from its claim asserting infringement of the '471 patent. The "patent dance" claim is unrelated legally and factually to Janssen's claim for infringement of the '471 patent. The "patent dance" claim raises questions of statutory interpretation of BPCIA, whereas the claim for infringement of the '471 patent raises questions of patent law, such as, for example, proper construction of claims in the '471 patent, and obviousness-type double patenting.

16. Courts have certified judgment on a patent-related claim under Rule 54(b) where a non-patent claim remains in the case. *See, e.g.*, *Schoenhaus v. Genesco, Inc*., 440 F.3d 1354, 1356 (Fed. Cir. 2006) (noting district court's entry of final judgment on noninfringement under Rule 54(b) where state law claims remained); *Gore*, 975 F.2d at 864 (certification of patent infringement claim under 54(b) was proper despite remaining antitrust counterclaim); *see also Amgen, Inc. v. Sandoz, Inc.*, No. 3:14-cv-04741-RS, Dkt. 111 at 2 (N.D. Cal. March 25, 2015) (entering judgment under rule 54(b) on claims related to BPCIA where the claims "all relate to the correct interpretation of the BPCIA and do not address the sole subject of the remaining claims and counterclaims…which relate to enforceability, infringement, and validity of the '427 patent").

17. Janssen's claims that Defendants infringe the '083 patent likewise are separable from its claim that Defendants infringe the '471 patent. The '083 patent and the '471 patent relate to different technologies. The '471 patent claims chimeric antibodies that bind the immune system molecule TNF-α, including the infliximab (cA2) antibody. No. 15-10698 Dkt. 1 at 8–9; No. 15-10698 Dkt. 1-1. The '083 patent claims soluble compositions suitable for producing cell culture media, and compositions comprising cell culture media—liquid in which cells that produce desirable antibodies or proteins can be grown. No. 15-10698 Dkt. 1 at 10–11; No. 15-10698 Dkt. 1-4. The '471 and '083 patents are not part of the same patent family; they have no common named inventors; and the priority date of the '471 patent is in March 1991, more than thirteen years before the October 2004 priority date of the '083 patent. No. 15-10698 Dkt. 1-1; No. 15-10698 Dkt. 1-4. The patents share no common questions of fact or law with respect to claim construction, infringement or invalidity.

18. Courts have issued Rule 54(b) judgments on patent infringement or other patent-related claims where claims related to a different patent or patents remained in the case. *See, e.g.*, *Medeva Pharma Suisse A.G. v. Par Pharm., Inc.*, 430 F. App'x 878, 880 (Fed. Cir. Jul. 7, 2011) (denying motion to dismiss appeal where district court had entered final judgment under 54(b) related to one of two patents); *Emhart Indus., Inc. v. Universal Instruments Corp.*, 925 F.2d 1480, at *1 (Fed. Cir. 1991) (per curiam) ("While other counts under other patents remain in the case for decision, we have jurisdiction at this time because the district court certified its judgment with respect to the '087 patent under Fed. R. Civ. P. 54(b)…"); *HTC Corp. v. IPCom GMBH & Co., KG*, 285 F.R.D. 130, 132 (D.D.C. 2012) (entering final judgment under Rule 54(b) as to one of two patents where they "deal with different technologies, the infringement evidence for each is unique, and HTC's invalidity argument for each is distinct"); *Augme Techs.*,

Inc. v. Yahoo! Inc., 305 F.R.D. 112, 114-115 (N.D. Cal. 2012), *aff'd*, 755 F.3d 1326 (Fed. Cir. 2014) (certifying under Rule 54(b) summary judgment on patent infringement claim where counterclaims for infringement of other patents were "separable"); *Decade Indus. v. Wood Tech., Inc*., 145 F. Supp. 2d 1075, 1079-80 (D. Minn. 2001) (certifying under Rule 54(b) summary judgment on counterclaim for infringement where remaining counterclaim for infringement of different patent on which "[t]he parties could easily conduct a separate analysis" remained).

19. Appeal of the Court's judgment finding the '471 patent invalid due to obviousness-type double patenting presents no risk of duplicate efforts by the Federal Circuit. The issues presented on appeal will focus on whether the '471 patent is invalid due to obviousness-type double patenting over the '444 patent, and whether it is invalid due to OTDP over the '195 and '272 patents. To the extent any separate, later appeals arise out of Janssen's "patent dance" claim or its claims for infringement of the '083 patent, they will not present the same issues. Defendants' obviousness-type double patenting defense is premised on the specific relationships between the term of the '471 patent and the terms of each of the '444, '195 and '272 reference patents, and is therefore unique to the '471 patent. *See, e.g., Gilead Sci., Inc. v. Natco Pharma, Ltd.*, Nos. 11-01455 and 11-04969, Dkt. 85 at 2 (D.N.J. May 9, 2013) (entering final judgment under Rule 54(b) on summary judgment of no OTDP where "there is no possibility that any appellate court will be obliged to consider the issue as to whether the '375 patent qualifies as a prior art reference against the '483 patent for purposes of obviousness-type double patenting raised in Defendants' appeal a second time, inasmuch as it presents a unique and dispositive issue of law controlling the outcome of this case").

20. Because the obviousness-type double patenting issues pertaining to the '471 patent are unique to the '471 patent, further proceedings by this Court will not moot appeal of the

Court's invalidity judgment, and appeal of the judgment will not complicate proceedings at the trial court level on Janssen's remaining claims.

21. The interests of justice favor certification of the Court's judgment for appeal, and support a finding of no just reason to delay the appeal. The stated goal of BPCIA is to "establish[] a simple, streamlined patent resolution process" for sellers of biologic drugs (often referred to as "reference products") and applicants for biosimilar approval that "will help 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." No. 15-10698 Dkt. 40-1 (Hearing Before Subcomm. on Courts and Competition Policy of the H. Comm. on the Jud., 111th Cong. at 9 (2009) (Test. of Rep. A.G. Eshoo)) at 14. The goal of BPCIA to resolve patent issues "expeditiously" and provide certainty to all involved would be frustrated if appeal of the '471 patent decision did not proceed promptly.

22. Defendants' biosimilar product INFLECTRA® was approved by the FDA in April 2016. Defendants have devoted substantial resources to the development of INFLECTRA®, and its entry to the market will provide the public with the benefits of price competition against REMICADE®. The interest in prompt resolution of the dispute over the '471 patent, which, as noted above, covers the infliximab antibody, weighs in favor of entering judgment pursuant to Rule 54(b). *Cf. Amgen, Inc. v. Sandoz, Inc.*, No. 3:14-cv-04741-RS, Dkt. 111 at 2-3 (N.D. Cal. March 25, 2015) (entering a Rule 54(b) judgment, noting that the adjudicated claims "raise[d] important legal issues that are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the Food and Drug Administration has now approved Sandoz's application for its biosimilar product (the first biosimilar that the FDA has approved),

implicating concerns about prejudice to the parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims").

23. For the foregoing reasons, Defendants' Motion for Entry of Final Judgment Pursuant to Federal Rule of Civil Procedure 54(b) Regarding U.S. Patent No. 6,284,471 is hereby GRANTED.

Dated: _____

_____
Hon. Mark L. Wolf
United States District Judge