IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1:15-cv-10698**
	)	**Civil Action No. 1:16-cv-11117**
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Janssen submits this Opposition to Celltrion's Motion for Entry of Final Judgment pursuant to Federal Rule of Civil Procedure 54(b) regarding U.S. Patent No. 6,284,471 (the "'471 Patent").

I. INTRODUCTION

Defendants' Rule 54(b) motion should be denied because there is a just reason to delay entry of judgment until after the Patent and Trademark Office ("PTO") renders its impending decision in the reexamination of the '471 Patent. Fairness demands that the parties have an opportunity to brief and argue, and that this Court retain its ability to make the initial determination, on the effect of the decision by the PTO on the double patenting issue that was the subject of this Court's prior '471 Patent invalidity ruling. Janssen has consistently maintained that a favorable PTO ruling will supersede this prior ruling because it will have the effect of retroactively denominating the '471 Patent as a "divisional," thus unquestionably entitling it to the protection from double patenting afforded by 35 U.S.C. § 121. While in this Court's prior decision, the Court has questioned whether this would be the case (Hr'g Tr., Aug. 18, 2016, Dkt. 234, at 14:8–22), it would be unfair to the parties, and to the Federal Circuit, for this Court to deprive itself of jurisdiction over this issue by prematurely entering judgment without having fully and fairly rendered a final decision in view of the PTO's upcoming decision, which is now expected as early as two months from now.[1]

In seeking entry of judgment now, defendants fail to address this important issue, instead disingenuously characterizing their Rule 54(b) motion as an attempt to obtain "certainty and prompt resolution" of Janssen's patent rights prior to launching their biosimilar version of

[1] The Patent Trial and Appeal Board has now scheduled Janssen's '471 reexamination appeal for September 28, 2016, and its decision is expected shortly thereafter, typically within about a month of the hearing.

Janssen's biological medicine Remicade. But defendants have no intention of voluntarily waiting until after resolution of Janssen's appeal to launch their biosimilar product. To the contrary, defendants have publicly announced that in light of this Court's decision granting them summary judgment on the '471 Patent, they expect to begin marketing their Remicade biosimilar in the United States during the fourth quarter of 2016. That is long before a Federal Circuit appeal could possibly be decided under any scenario.

Given that defendants have publicly committed to launch at risk of reversal on appeal, pre-launch certainty is not the reason for this motion. Rather, the unstated reason defendants seek to force Janssen to take an early appeal of this Court's summary judgment rulings is to prevent Janssen from having a full and fair opportunity to defend the validity of the '471 Patent in the reexamination proceeding. As defendants have repeatedly asserted, they believe that a final judgment in this case will moot the reexamination proceeding, even though it is still pending before the PTO. Defendants' motion to accelerate Janssen's appeal, in the absence of any bona fide intention to await the result of the appeal before launching their product, is an attempt to interfere with the ongoing reexamination proceeding that defendants themselves originally initiated.

Defendants' attempt to short-circuit the reexamination process is not "just," Fed. R. Civ. P. 54(b), and this Court should not endorse it. Entry of partial judgment pursuant to Rule 54(b) is not routine. On the contrary, it is disfavored where, as here, the party trying to accelerate the appellate process *prevailed* at the district court level and seeks to deprive the appellant of the ability to control the timing of its own appeal. Nothing about the present circumstances calls for certifying an early appeal. With trial on Janssen's remaining claims only five months away, it would be inefficient to split this action into two appeals rather than one. More importantly,

granting defendants' motion would be highly inequitable because its consequence (and intent) would be to threaten Janssen's ability to see the pending reexamination proceeding through to its conclusion. Defendants' motion should be denied.

II. PROCEDURAL HISTORY

In 2013, defendants filed a request for *ex parte* reexamination in the PTO, contending that the '471 Patent is invalid for obviousness-type double patenting ("OTDP"). The PTO decided to institute such a reexamination, during the course of which the PTO examiner rejected the claims of the '471 Patent on OTDP grounds based, among other reasons, that the '471 Patent was denominated as a "continuation in part." Subsequently Janssen was authorized by a decision of the Director of the PTO to amend the '471 Patent to make it a divisional. This change in status of the '471 Patent is of course highly material to this Court's invalidity ruling, as this Court's determination rests on its conclusion that the safe harbor protection is categorically unavailable to patents that are not denominated as divisionals, as the '471 Patent was, but is no longer as amended in the PTO. While the '471 Patent currently stands rejected, Janssen's appeal to the Patent Trial and Appeal Board ("PTAB") to reverse this determination has been fully briefed and will be argued on September 28, 2016. A decision is expected within about a month and at the latest by Thanksgiving.

In March 2015, after defendants' biosimilar application was accepted for review, Janssen filed Civil Action No. 1:15-cv-10698, alleging (in addition to other since-mooted counts) violations of the Biologics Price Competition and Innovation Act ("BPCIA") (Count I) and technical acts of infringement of Janssen's '471 Patent covering the antibody used in Janssen's Remicade biologic (Count III) and another patent (the "'083 Patent") relating to the manufacture of cell culture media used to produce defendants' biosimilar product (Count VI). As Janssen

describes in the complaint, defendants effectively forced Janssen to assert the '471 Patent at the risk of losing valuable remedies. More recently, Janssen filed Civil Action No. 1:16-cv-11117, alleging actual, rather than technical, infringement of the '083 Patent. The two actions were consolidated by this Court on August 19, 2016. Trial is scheduled for February 2017.

Apparently recognizing that the reexamination proceeding was not going as they had hoped, a year after the original case was filed defendants sought summary judgment on Count III. In their motions, defendants contended that the '471 Patent was invalid for OTDP on two grounds: (1) that it was invalid over an later-filed but earlier-issued patent pursuant to the Federal Circuit's ruling in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014) (the "*Gilead* Motion"); and (2) that it was invalid over two other earlier-issued patents because it was not entitled to the statutory safe harbor created in 35 U.S.C. § 121 (the "Reexam Motion"). The Reexam Motion largely tracks the OTDP issues that are pending in the reexamination, with one important difference: while amendments made in the reexamination to the specification of the '471 Patent will be treated for all purposes as if they had been made during the original examination, *see* 35 U.S.C. §§ 252 & 307(b), these amendments will not become effective until the PTO issues its reexamination certificate, which occurs shortly after the final merits determination. As such, the PTO's decision, including the amendments made during the reexamination, was not, and could not have been, directly at issue during consideration of the Reexam Motion.

After a hearing, on August 19, 2016, the Court granted summary judgment in favor of Celltrion on both the *Gilead* Motion and the Reexam Motion. (Dkt. 226.) Counts I and VI remain in the case and will be tried. After the Court's ruling, counsel for defendants attempted to move orally pursuant to Federal Rule of Civil Procedure 54(b) for the Court to direct entry of the

judgment on Count III to start the running of Janssen's appeal clock. The Court asked for a written motion and brief, which Celltrion filed on August 22, 2016.

III. ARGUMENT

A. Legal Standards

Federal Rule of Civil Procedure 54(b) provides that a court "*may* direct entry of a final judgment as to one or more, but fewer than all, claims" in a suit but "only if the court expressly determines that there is no just reason for delay." Fed. R. Civ. Proc. 54(b) (emphasis added). "Otherwise, any order or other decision, however designated, that adjudicates fewer than all the claims . . . does not end the action as to *any* of the claims . . . and may be revised at any time before the entry of a judgment adjudicating all the claims . . . ." *Id.* (emphasis added).

As its text indicates, Rule 54(b) permits – but does not require – a district court to enter partial final judgment when there is no just reason for delay. "It is left to the sound judicial discretion of the district court to determine the 'appropriate time' when each final decision in a multiple claims action is ready for appeal." *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 8 (1980). In evaluating a Rule 54(b) motion, a court should consider "judicial administrative interests" including "whether the claims under review were separable from the others remaining to be adjudicated and whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once." *Id.* The court should also consider "the equities involved." *Id.* "Plainly, sound judicial administration does not require that Rule 54(b) requests be granted routinely." *Id.* at 10.

Federal Circuit (and Supreme Court) law applies to Rule 54(b) issues in patent cases. *State Contracting & Eng'g Corp. v. State of Florida*, 258 F.3d 1329, 1334 (Fed. Cir. 2001). However, where the Federal Circuit has not addressed a given "subissue" under Rule 54(b), it

"look[s] to the law of all circuits equally for persuasive reasoning." *W.L. Gore & Assocs. v. Int'l Med. Prosthetics Research Assocs.*, 975 F.2d 858, 861 (Fed. Cir. 1992).

B. The Equities Call for Denying the Motion

Here, both the equities and the interests of judicial administration counsel against entering partial final judgment and forcing Janssen to file an immediate appeal. Granting defendants' motion would be inequitable because they prevailed at the trial court level and are effectively seeking to require Janssen, the prospective appellant, to bring *its* appeal on the *defendants*' preferred timetable. That is particularly inappropriate here because Janssen may be severely prejudiced by the entry of a final judgment. An accelerated appeal in this action may deprive Janssen of its ability to pursue the pending reexamination proceedings to their conclusion on the merits. In contrast, the lack of an immediate appeal by Janssen will cause no harm to the defendants, because Janssen is not seeking a preliminary injunction based on the '471 Patent, and under any scenario defendants intend to launch their biosimilar product long before Janssen's appeal would be resolved.

1. Rule 54(b) Motions By Prevailing Parties Are Disfavored

Defendants prevailed on their summary judgment motions. They bring this motion not to obtain the right to file their *own* appeal, but rather to require *Janssen* to appeal the Court's rulings before it would prefer to do so. This fact strongly weighs against granting the motion.

A "district judge ordinarily should not enter a Rule 54(b) document unless the *losing* party requests it." *Exch. Nat'l Bank v. Daniels*, 763 F.2d 286, 291 (7th Cir. 1985) (emphasis added). This is because "there is no pressing reason why a party should be *compelled* to proceed with an immediate appeal on one part of the case under Rule 54 if he is willing to wait for the end." *Id.* (emphasis in original). A Rule 54(b) motion by the prevailing party "invert[s] the purpose of Rule 54(b) from one of enhancing the appellate rights of a losing party . . . to one in

which a prevailing party could prematurely force an appeal of part of a case by a losing party, who must comply with timeliness requirements for exercising appellate rights." *Stewart v. Gates*, 277 F.R.D. 33, 36 (D.D.C. 2011); *see also Onyx Props. LLC v. Bd. of County Comm'rs*, 916 F. Supp. 2d 1191, 1211 (D. Colo. 2013) (denying Rule 54(b) motion where "[t]his is not the usual case of the losing party requesting the entry of final judgment under Rule 54(b), but rather the prevailing party seeking to force the losing party to seek (or not seek) appellate relief"); *Patriot Mfg. LLC v. Hartwig, Inc.*, No. 10-1206-EFM-KGG, 2014 U.S. Dist. LEXIS 127229, at *6 (D. Kan. Sept. 11, 2014) (similar).

The right to appeal vests in the losing party, and if it chooses to wait and take a single appeal of all appeal issues, the Court "should require a powerful reason to override this decision." *Exch. Nat'l Bank*, 763 F.2d at 291.[2] As discussed below, no such "powerful reason" to grant defendants' motion is present here. On the contrary, the circumstances strongly call for denying the motion.

2. Being Forced to File an Early Appeal Would Prejudice Janssen

An early entry of judgment and appeal of the Court's grant of summary judgment would threaten Janssen with extreme prejudice. If this Court grants defendants' motion, it will be divested of jurisdiction over the '471 Patent. *See Marrese v. Am. Acad. of Orthopaedic Surgeons*, 470 U.S. 373, 379 (1985). If Janssen exhausts all its appellate rights in this action while the reexamination proceeding is still pending, the reexamination may be terminated, thus depriving Janssen of the opportunity to defend its patent in both forums in which defendants

[2] An exception to this principle, not at issue here, is when the prevailing party is entitled to a money judgment that will not be recoverable until the entry of final judgment. Then, the equities may call for a partial final judgment – not in order to accelerate the losing party's time to appeal but rather to speed the prevailing party's ability to execute on the judgment. *See Curtiss-Wright Corp.*, 446 U.S. at 3 (describing this situation). Here, in contrast, where the defendants are not entitled to a remedy upon the entry of judgment, the consequence of granting their Rule 54(b) motion would simply be to force Janssen to bring an early appeal.

have challenged it. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 (Fed. Cir. 1988) ("[I]f a court finds a patent invalid, and that decision is either upheld on appeal or not appealed, the PTO may discontinue its reexamination."); MPEP § 2286 ("[A] final federal court holding of invalidity or unenforceability (after all appeals), is binding on the Office. . . . If *all* of the *claims being examined in the reexamination proceeding* are *finally* held *invalid or unenforceable*, the reexamination will be vacated . . . ." (emphasis in original)).

In contrast, if the Court were to deny the motion, its rulings on the '471 Patent "may be revised at any time before the entry of a judgment adjudicating all the claims." Fed. R. Civ. P. 54(b). The Court would thus retain the ability to hear additional argument and make the initial determination as to the impact of the PTO decision on Janssen's claims in this action. That determination would then become part of the record on appeal, allowing the Federal Circuit to address the full range of the parties' disputes regarding the validity of the '471 Patent. This would be both more just and more efficient than immediately enabling an appeal that may impact (or be impacted by) the PTO's subsequent decision. *Cf. Blanchard v. Teledyne Movible Offshore, Inc.*, 612 F.2d 971, 972 (5th Cir. 1980) (holding that Rule 54(b) order was inappropriate where Supreme Court had granted certiorari in a case whose outcome could have resolved the issue).

Even if for some reason this Court does not end up addressing the PTO decision, allowing Janssen's appeal to proceed after a final judgment rather than on an accelerated schedule would allow Janssen to rely on the record in the PTO proceedings on appeal to the Federal Circuit. That is highly significant because, as discussed above, the PTO has granted amendments to the specification of the '471 Patent that Janssen believes are relevant to its OTDP case. The amendments were not before this Court in the Reexam motion and may not be before the Federal Circuit in Janssen's appeal of the Court's ruling on that motion. If Janssen's appeal

in the present action is accelerated, Janssen may never have the opportunity to litigate the validity of the '471 Patent in light of the amendments that have already been entered by the PTO.

Indeed, defendants' counsel incorrectly advised the Court at oral argument on the Reexam motion that this Court's judgment invalidating the '471 Patent would end the reexamination proceeding. (Hr'g Tr., Aug. 16, 2016, Dkt. 232, at 118:12–14 ("THE COURT: Will the reexamination continue if I find this invalid? MR. HURST: I believe that it would not.").) In fact, the reexamination proceeding would not end until there is a final court judgment "after all appeals." MPEP § 2286. As such, while this Court's decision alone does not end the reexamination, there is a risk that forcing an early appeal of the decision would do so, as it could lead to a final determination by the Federal Circuit before the reexamination proceeding were final. *See id.*; *Ethicon, Inc. v. Quigg*, *supra*.[3] The Court should not impose this risk on Janssen by granting defendants' motion.

3. An Early Appeal Will Not Provide Defendants With Pre-Launch "Certainty"

Throughout this case, defendants have argued that they needed early resolution of Janssen's claims in order to obtain "certainty" prior to the launch of their Remicade biosimilar. Whatever the merits of that argument before now, it has no relevance whatsoever to the present motion.

No further pre-launch certainty can be forthcoming because defendants have repeatedly indicated that they will *not* await a final ruling from the Federal Circuit before deciding to launch their Remicade biosimilar. In a statement issued just after the Court's ruling on August 17th, a

[3] Janssen believes, and would contend in the future, that any disposition that prevents consideration of the record in the reexamination proceeding, including the amendments entered therein, would be inequitable and inappropriate. Janssen recognizes, however, that there is a risk that a final appeal in this action would end the reexamination proceeding, depending on the circumstances.

Pfizer spokesperson said that Pfizer is "continuing with the preparation of our launch plans for Inflectra for 2016."[4] Similarly, in response to the ruling, Celltrion's CEO stated that the biosimilar will be on the shelf "in the fourth quarter of this year," and Celltrion shipped the first batch to the United States on August 19th.[5] These statements directly belie any suggestion that the defendants are seeking pre-launch "certainty" by moving to force Janssen to file an early appeal. Even if the Court enters the final judgment immediately, the resolution of any appeal by the Federal Circuit would likely take at least a year, well beyond when defendants have already pledged to begin marketing their product in the United States.

"Judgments under Rule 54(b) must be reserved for the unusual case in which the costs and risks of multiplying the number of proceedings and of overcrowding the appellate docket are outbalanced by pressing needs of the litigants for an early and separate judgment. . . ." *Morrison-Knudsen Co. v. Archer*, 655 F.2d 962, 965 (9th Cir. 1981) (Kennedy, J.); *cf. Spiegel v. Trs. of Tufts Coll.*, 843 F.2d 38, 42 (1st Cir. 1988) ("Clearly the purpose of the rule is not to encourage broadly piecemeal appeals just because an appellant may be in a hurry." (quotation omitted)). Because defendants have quite clearly made the decision to launch their biosimilar before the possibility of any final judgment from the Federal Circuit, they have no legitimate need for an immediate appeal.

Indeed, given that an immediate appeal will not generate the pre-launch certainty that defendants assert is the basis for their motion, the *only* apparent reason defendants seek to expedite an appeal is to prejudice Janssen by terminating the reexamination proceeding before it

[4] *Judge Invalidates Patent for Johnson & Johnson Rheumatoid Arthritis Drug*, N.Y. Times, Aug. 17, 2016, *available at* http://www.nytimes.com/aponline/2016/08/17/us/ap-us-johnson-johnson-pfizer-remicade.html (last accessed August 29, 2016)

[5] Kim Tae-gyu, *Celltrion Ships Biosimilar Medicine to US*, The Korea Times, August 19, 2016, *available at* http://m.koreatimes.co.kr/phone/news/view.jsp?req_newsidx=212329 (last accessed August 29, 2016)

can conclude. That objective is inequitable and should lead to the rejection of defendants' motion. Interfering with parallel proceedings is not a valid use of Rule 54(b) and amounts to gamesmanship that this Court should not facilitate.

C. The Interests of Judicial Administration Call for Denying the Motion

The interests of judicial efficiency also weigh against granting defendants' motion. An immediate appeal would present the disfavored possibility of the Federal Circuit having to decide the same issues twice, and would serve little legitimate purpose in light of the fact that trial on the remaining claims is scheduled for February.

In considering the interests of judicial administration the Court, a primary concern is whether there is a possibility that an appellate court "would have to decide the same issues more than once." *Curtiss-Wright Corp.*, 446 U.S. at 8. Here, if an immediate appeal is taken, the Federal Circuit may have to consider many of the same issues surrounding the reexamination more than once. If Janssen's appeal in the reexamination proceeding does not succeed, it has the option to appeal to the Federal Circuit. *See* 35 U.S.C. § 141. As the issues in the reexamination proceeding and the reexamination summary judgment motion are essentially identical, the Federal Circuit will be required either to consider the same issue twice, or to consolidate the two appeals, in which case the premature entry of the judgment will have been purposeless. This is disfavored as "[m]ultiple appeals occupy in the aggregate more time of counsel and appellate courts than single appeals raising multiple issues." *Exch. Nat'l Bank*, 763 F.2d at 291.

Directing entry of the judgment under Rule 54(b) will also only marginally advance the timeline of the appeal. The Court scheduled the trial on the remaining claims to begin on February 13, 2017, and a final judgment on liability will be rendered at the end of that trial. If Celltrion wins, Janssen will take its appeal soon thereafter. If Janssen wins, the decision will still

be immediately appealable. *See* 28 U.S.C. § 1292(c)(2) (allowing immediate appeal of a judgment for patent infringement if judgment is final except for damages). Requiring Janssen to appeal immediately will advance the ultimate resolution of these issues by only a few months, while also requiring the Federal Circuit to consider piecemeal, overlapping appeals involving common facts and legal issues.

Additionally, if the '471 Patent is finally invalidated by the PTO (and affirmed by the Federal Circuit), Janssen's '471 case in this action will be mooted entirely, sparing the parties and the Federal Circuit the need to brief and consider the appeal. *See Slip Track Sys., Inc. v. Metal Lite, Inc.*, 159 F.3d 1337, 1341 (Fed. Cir. 1998) ("[I]f the [patentee's] claims were canceled in the reexamination, [it] would eliminate the need to try the infringement issue."); *Gould v. Control Laser Corp*., 705 F.2d 1340, 1342 (Fed. Cir. 1983) (noting that "[o]ne purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled)"). The possibility that the need for an appeal might become moot is "a major negative in the Rule 54(b) equation." *Spiegel*, 843 F.2d at 45; *see also Horn v. Transcon Lines, Inc.*, 898 F.2d 589, 592 (7th Cir. 1990) ("The possibility that developments in the litigation may moot a claim suggests that appellate resolution be deferred.").

Finally, the Court should also consider whether the "claims under review [are] separable from the others remaining to be adjudicated." *Curtiss-Wright Corp.*, 446 U.S. at 8. Here, Count I of the complaint seeks a declaration that Celltrion violated the BPCIA by failing to engage in the requisite exchange of information and insisting that Janssen file suit to preserve its claim to lost-profits damages and injunctive relief. Though Janssen complied with this unreasonable demand, Celltrion has repeatedly insisted that Janssen has not prosecuted this case in good faith and therefore still may not be entitled to lost profits and an injunction if it ultimately prevails on

the '471 Patent infringement count.[6] Janssen's BPCIA claim is intertwined with the '471 Patent infringement count because the resolution of the BPCIA claim will determine the extent of available damages under the infringement count.[7]

IV. CONCLUSION

For the reasons explained above, defendants' Rule 54(b) motion is an invitation to unfairness, which this Court should decline. Because defendants prevailed at trial, Janssen, not defendants, should choose when to appeal. Janssen believes that an appeal of the Court's '471 rulings is premature because it is concerned that an early appeal might interfere with the ongoing reexamination proceeding before the PTO. Defendants, for their part, purport to seek pre-launch certainty, but are in truth trying to the cause the very interference that Janssen seeks to avoid. Strategically undermining a related proceeding is not an appropriate use of Rule 54(b). This Court should deny defendants' motion.

[6] *See, e.g.*, Defendants' Cross Motion to Limit Plaintiffs' Remedy Dkt. 190 (arguing that Janssen's request for a discovery schedule showed a lack of prosecution in good faith and requesting a limitation of Janssen's remedy); Defendants' Opposition to Plaintiffs' Motion to Stay, Dkt. 41, at 17 (arguing that a grant of Janssen's motion for stay should be conditioned on a stipulation that it will not seek lost-profits damages); Defendants' Sur-Reply to Plaintiffs' Motion to Stay, Dkt. 94, at 1–3 (arguing that Janssen's remedy is limited to a reasonable royalty).

[7] For that reason, this case is distinguishable from *Amgen, Inc. v. Sandoz, Inc.*, No. 3:14-cv-04741-RS, Dkt. 111 (N.D. Cal. March 25, 2015) (Def. Ex. 2), which raised the issue of whether a biosimilar application is obligated to engage in the BPCIA's procedures at all. *Id.* at 2. In addition, the parties in that case stipulated to the entry of judgment under Rule 54(b), and Sandoz agreed not to challenge the validity of the subject patent while the appeal was pending. *Id.*, Dkt. 106, at 2 (Pl. Ex. 1). Finally, this case does not present the same time sensitivity that the court in Amgen referenced because defendants have committed to launch before even an expedited appeal in the Federal Circuit could be decided.

Dated: August 29, 2016

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CERTIFICATE OF SERVICE

I certify that on August 29, 2016, this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing and if not so registered, that copies will be electronically mailed to such parties or their counsel.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH,

Defendants.

Case No. 3:14-cv-04741-RS

NOTICE OF MOTION AND JOINT MOTION FOR FINAL JUDGMENT UNDER RULE 54(B), ORDER ESTABLISHING SCHEDULE FOR RULE 62(C) PROCEEDINGS, AND STAY OF FURTHER PROCEEDINGS

Date: May 14, 2015
Time: 1:30 p.m.
Crtrm: 3, 17th Floor

The Honorable Richard Seeborg

NOTICE OF MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD: PLEASE TAKE NOTICE that on May 14, 2015, at 1:30 p.m., Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") and Defendant Sandoz Inc. ("Sandoz") will and hereby do move this Court for entry of final judgment under Rule 54(b) of the Federal Rules of Civil Procedure, a scheduling order, and a stay as set forth in the motion below.

MOTION

On March 19, 2015, the Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction. (ECF No. 105.) The Court's Order dismissed with prejudice the first and second causes of action brought by Amgen and entered judgment in favor of Sandoz on Sandoz's first, second, third, fourth, and fifth counterclaims insofar as they were consistent with the Court's interpretation of the Biologics Price Competition and Innovation Act ("BPCIA"). The Order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for judgment on the pleadings (or alternatively for partial summary judgment) on Sandoz's sixth and seventh counterclaims, allowing those counterclaims to proceed. Consistent with the parties' agreement to expedite appeal of the Court's March 19, 2015, Order, Amgen and Sandoz hereby jointly move for the following, and respectfully request entry of the requested Order by March 25, 2015:

1. Entry of final judgment under Rule 54(b) of the Federal Rules of Civil Procedure, in favor of Sandoz and against Amgen on Amgen's first and second causes of action, as well as on Sandoz's first, second, third, fourth, and fifth counterclaims in accordance with the Court's March 19, 2015, Order. As grounds therefor, there is no just reason to delay entry of final judgment on the adjudicated claims and counterclaims. *See, e.g.*, *e.Digital Corp. v. Futurewei Techs., Inc.*, 772 F.3d 723, 727 (Fed. Cir. 2014). These claims and counterclaims, which relate to the correct interpretation of the BPCIA, are separable from and not intertwined with the remaining claims and counterclaims, which relate to alleged patent infringement and invalidity. Moreover, as the parties have agreed, expeditious appellate review of the judgment as to the BPCIA-related claims and counterclaims is warranted to avoid prejudice to the parties that may

result from delay, in light of the fact that the Food and Drug Administration has now approved Sandoz's biologic license application.

The parties have agreed that if the Court grants this motion and enters a Rule 54(b) judgment, Amgen will file its notice of appeal from the Rule 54(b) judgment and this Court's March 19, 2015, Order on the same date that the Court enters the Rule 54(b) judgment, or early the next morning if the judgment is entered after 5:00 p.m. P.T. The parties have agreed to seek an expedited briefing schedule in the Federal Circuit and to seek to have the Federal Circuit schedule oral argument for its June 2015 oral argument calendar. The parties thus respectfully request that this Court enter the requested final judgment under Rule 54(b) by March 25, 2015. The parties have further agreed that if the Court has not ruled on the pending Rule 54(b) judgment by close of business on March 26, 2015, Amgen will, on March 27, 2015, file its notice of appeal as to this Court's March 19, 2015, denial of Amgen's motion for a preliminary injunction and, if the Court thereafter issues a Rule 54(b) judgment, the parties will jointly seek to consolidate an appeal from that judgment with Amgen's appeal from the Court's denial of its motion for a preliminary injunction.

2. Entry of a scheduling order for Amgen's contemplated motion under Rule 62(c) of the Federal Rules of Civil Procedure for an injunction pending appeal. Amgen intends to file a motion under Rule 62(c) for an injunction pending appeal, and Sandoz intends to oppose that motion. To facilitate the expeditious and orderly briefing of that motion, the parties have agreed to a briefing schedule as follows: Amgen will make any motion for an injunction under Rule 62(c) no later than Tuesday, March 24, 2015. Sandoz will file its response to any such motion no later than Tuesday, March 31, 2015. Amgen will file its optional reply no later than Thursday, April 2, 2015.

3. Entry of an order staying all remaining proceedings in this Court, other than Amgen's contemplated Rule 62(c) motion, until issuance of the Federal Circuit's mandate in the appeal from this Court's March 19, 2015, order and the Rule 54(b) judgment, if any. During the pendency of the stay, Sandoz will not challenge the validity of U.S. Patent No. 6,162,427 (which has been asserted in this litigation), and the two patents that have been identified but not asserted

in this litigation (U.S. Patent No. 7,781,395 and U.S. Patent No. 8,273,707) in connection with the manufacture or use of filgrastim. During the pendency of the stay, Amgen will not try to enforce the '427, '395, or '707 patent against Sandoz in connection with the manufacture or use of filgrastim. Should Amgen try to enforce any of those patents during the stay, Sandoz is free to challenge, including but not limited to commencing inter partes review against, all three identified patents. As the sole exception to the stay, the parties agree that Amgen may continue efforts to effect service on Sandoz International GmbH and Sandoz GmbH, provided, however, that the time to move, answer, or otherwise respond to the complaint for either entity so served is tolled until twenty days after the expiration of the stay sought by this paragraph.

The parties agree that this Court would continue to have jurisdiction over Amgen's contemplated Rule 62(c) motion even after Amgen files a notice of appeal. *See* Fed. R. Civ. P. 62(c) ("While an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights."). The parties respectfully request that this Court issue a ruling on Amgen's contemplated Rule 62(c) motion as soon as practicable after it is fully briefed.

To allow this Court to consider Amgen's Rule 62(c) motion and, if denied, to allow Amgen time to seek an injunction pending appeal from the Federal Circuit under Federal Rule of Appellate Procedure 8, Sandoz has agreed that it will not launch its biosimilar filgrastim product in the United States until the earlier of May 11, 2015, or a ruling by the Federal Circuit on Amgen's Rule 8 motion for an injunction pending appeal.

For the reasons stated, the parties jointly respectfully request that, on March 25, 2015, or as soon thereafter as practicable, the Court enter final judgment under Rule 54(b) and issue an order setting a briefing schedule for Amgen's contemplated Rule 62(c) motion and staying the remainder of the proceedings.

A proposed Judgment and Order accompanies this Motion.

Dated: March 24, 2015

Respectfully submitted,

By: /s/Rachel Krevans
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ATTESTATION

I, Rachel Krevans, am the ECF user whose user ID and password are being used to file the foregoing document. Pursuant to Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of this document has been obtained from Vernon M. Winters.

Dated: March 24, 2015

/s/ Rachel Krevans
Rachel Krevans