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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

SANDOZ INC.'S OPPOSITION TO AMGEN'S MOTION FOR AN INJUNCTION PENDING APPEAL

Date: April 30, 2015
Time: 10:00 a.m.
Crtrm: 3, 17th Floor

The Honorable Richard Seeborg

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INTRODUCTION

Amgen cannot meet the high burden for the extraordinary relief it seeks. Amgen is asking this Court to grant under Rule 62(c) the very relief this Court just denied on both likelihood-of-success and irreparable-harm grounds. The same four factors apply to this motion as to Amgen's preliminary injunction motion, and nothing in Amgen's current motion changes this Court's previous conclusions. Those rulings preclude the relief Amgen seeks.

First, Amgen cannot demonstrate a strong likelihood of success. This Court correctly concluded that the BPCIA is an integrated statutory regime that, when considered as a whole, does not mandate a biosimilar applicant to participate in all circumstances in a statutory process for disclosing and negotiating patent disputes. The Court also correctly held that Section 262(*l*)(8) is a notice provision and does not provide an extra 180 days of exclusivity. Rather than address this Court's decision, Amgen argues that it only needs to show that its appeal will raise "serious questions" on the merits. That is not the standard in the Supreme Court or the Federal Circuit, which is the law that governs Amgen's motion. Even if that were the standard, this Court has already held that Amgen "cannot demonstrate serious questions as to the merits, let alone a likelihood of success." (ECF No. 105 ("Order") at 17.) That conclusion is correct, and Amgen offers nothing that suggests otherwise.

Second, as this Court already concluded, Amgen cannot establish irreparable harm. Amgen repeats its argument that a launch by Sandoz will cause it irreparable harm due to price erosion, harm to goodwill, and effects on its sales force. This Court correctly rejected each of these arguments as "at best highly speculative." (Order at 18.) Amgen offers nothing new that would warrant reconsideration of this Court's holding.

Even if Amgen's alleged irreparable harms were not speculative, there would be no basis for the requested injunction. The broad injunction Amgen seeks – prohibiting Sandoz from marketing, selling, offering to sell, or importing into the United States its filgrastim product – is the injunction Amgen ***might*** be able to obtain ***if*** it could show that Sandoz's filgrastim product would infringe a valid patent. Amgen has not attempted to make that showing. Instead, Amgen bases its request solely on California-law claims, predicated on its argument that Sandoz

supposedly "violated" procedures of the BPCIA. But as this Court correctly held, the BPCIA expressly contemplates what Sandoz did here, and in this circumstance, allows Amgen to file suit immediately to attempt to show infringement of any valid patent claim. (Order at 11-12.) Because Amgen made no such showing, and because Amgen's exclusivity period expired long ago, this Court correctly held that no legal bar precludes Sandoz from launching. (*Id.* at 18.) Amgen fails to address this independent ground for denial of an injunction.

Third, the balance of equities heavily favors Sandoz. Sandoz is poised to launch the first biosimilar filgrastim in the United States. An injunction would jeopardize the first-to-market advantage that Sandoz has invested years of effort and tens of millions of dollars to attain. Denying the injunction would impose no undue hardship on Amgen, [redacted].

Fourth, the public interest factor weighs against an injunction. The BPCIA expressly seeks to balance two key public purposes: innovation and consumer interests. Amgen already has been amply rewarded for its innovation, enjoying more than twice the period of exclusivity Congress determined is sufficient to meet the public's interest in innovation for biologics. But the consumer interest in the availability of lower-priced biosimilar drugs would be substantially harmed by awarding Amgen an injunction stopping public access to biosimilar filgrastim. And patients and payors in this State would be the most negatively affected because the requested injunction could apply only in California.

Finally, there is no need for this Court to enter an injunction while the Federal Circuit considers Amgen's motion to that Court for an injunction pending appeal. To allow Amgen time to seek such an injunction, 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 motion for an injunction pending appeal. (ECF No. 106, at 3.)

ARGUMENT

I. Amgen's Motion Should Be Denied For The Same Reasons This Court Denied The Preliminary Injunction Motion.

Amgen seeks an affirmative injunction against Sandoz pending appeal, not simply a stay

of this Court's Order. Because this Court ruled against Amgen on the merits, Amgen faces a "very heavy burden of persuasion" for its motion. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. CIV.A. 07-2762 (JAP), 2009 WL 1968900, at *2 (D.N.J. July 1, 2009). An injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 22 (2008). An injunction pending appeal requires a court to consider "(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." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). Amgen has not sustained its burden of establishing ***any*** of the four required factors, much less ***all*** of them.

A. This Court Correctly Concluded That Amgen Has Neither Made A "Strong Showing" Of Likelihood Of Success On The Merits Nor Even Raised A "Serious Question."

1. A "Serious Question" On The Merits Is Insufficient, And This Court Correctly Held Amgen Cannot Meet Even That Standard.

Amgen does not attempt to make the requisite "strong showing" of a likelihood of success on the merits. *Hilton*, 481 U.S. at 776. Instead, Amgen asserts that Ninth Circuit law governs its motion and that under that standard, it need only show the existence of "serious legal questions" if the balance of hardships tips "sharply toward the movant." (Mot. at 5.) That is not the right standard.[1] As the Supreme Court has made clear, even where (unlike here) the harm absent an injunction is grave and certain (*e.g.*, deportation of an asylum applicant), the movant must make a "strong showing that he is likely to succeed on the merits" of his appeal. *Nken v. Holder*, 556 U.S. 418, 434 (2009) (citation omitted). Satisfying one factor does not lessen the requirement to establish the others. *See Winter*, 555 U.S. at 21-22.

[1] Indeed, the Ninth Circuit itself applies the Supreme Court's *Winter* standard in some cases. *See, e.g.*, *Haskell v. Harris*, 669 F.3d 1049, 1053 (9th Cir. 2012); *DISH Network Corp. v. FCC*, 653 F.3d 771, 776 (9th Cir. 2011).

Amgen cannot set aside governing Supreme Court law, and it is Federal Circuit, not Ninth Circuit, law that applies to Amgen's motion. The BPCIA provisions at issue concern matters unique to patent law – *i.e.*, patent-dispute resolution between reference product sponsors and biosimilar applicants. Because Federal Circuit law governs those issues, the question whether injunctive relief should be granted is governed by Federal Circuit law. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc). Since the Supreme Court's decision in *Winter*, the Federal Circuit has held that "the Supreme Court's current statement of the test is the definitive one." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (discussing *Winter*); *see also Duramed Pharms., Inc. v. Watson Labs., Inc.*, 426 F. App'x 905, 906 (Fed. Cir. 2011) (applying *Hilton*).[2]

In any event, the standard makes no difference here. Amgen cannot satisfy any formulation. As this Court correctly concluded, because Amgen "cannot demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is foreclosed from injunctive relief under either formulation of the test for injunctive relief." (Order at 17.) Even if some lower showing of a likelihood of success were the correct standard (which it is not), Amgen would still have to show that the balance of interests tips "sharply" toward it. (Mot. at 5.) It cannot. As explained below, Amgen cannot show irreparable harm, and the balance of interests favors Sandoz. *See* Parts I.B-I.D, *infra*.

Additionally, although the Federal Circuit has not yet interpreted the BPCIA, there is nothing "novel" (Mot. at 5) about the need for Amgen to make a clear showing that it has a valid, infringed patent claim before it could prevent Sandoz from launching its biosimilar filgrastim,

[2] In a pre-*Winter* decision, the Federal Circuit stated that, absent a "strong showing" on the merits, the Court may issue a stay pending appeal if the movant shows "a *substantial case* on the merits" and the other factors weigh in the movant's favor. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990). This articulation of the stay standard (which Amgen cannot meet) is more exacting than the "serious question" standard relied on by Amgen (Mot. at 5). In *Standard Havens* itself, the Federal Circuit issued a stay only after concluding that the movant showed "a substantial chance of prevailing when our court decides this appeal." *Id.* at 516. Moreover, while some unpublished orders after *Winter* have cited *Standard Havens* without any discussion, no precedential Federal Circuit opinion since *Winter* has cited it.

given that "the twelve-year exclusivity period for Neupogen long ago expired." (Order at 18.) The injunction Amgen seeks tracks the language of the patent statute. *See* 35 U.S.C. § 271(a) (making it unlawful to "make[], use[], offer[] to sell, or sell[] any patented invention, within the United States or import[] into the United States any patented invention"). But as this Court correctly observed, Amgen has made no attempt to show that Sandoz's filgrastim product would infringe any valid patent claim. (Order at 18.) Instead, it seeks this injunction based solely on California-law claims, based on supposed "violations" of the BPCIA. But the BPCIA expressly provides that Amgen's remedy is to commence a suit for patent infringement, as it did here. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). If Amgen had a valid patent claim on filgrastim, it could have tried to obtain an injunction under the traditional four-factor test by showing a likelihood of success on validity and infringement. Even then, an injunction would not be automatic. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006). But Amgen has never attempted to make that showing. That is reason enough to conclude that Amgen has no likelihood of succeeding in its quest for injunctive relief. As this Court correctly concluded, it must be presumed that Amgen has no valid, infringed patent claim and that there thus "exists no substantive bar to market entry for Sandoz's biosimilar filgrastim – and, consequently, no basis on which Amgen is entitled to injunctive relief." (Order at 18.)

2. Under The Correct Standard, Amgen Failed To Make A Strong Showing That It Is Likely To Prevail.

Amgen is likewise not entitled to an injunction under the correct standard, which it tellingly does not try to meet. Amgen argues at best only that "[t]he Federal Circuit has not yet addressed" the interpretation of the BPCIA and that, once it does so, it "***might*** reach a different conclusion." (Mot. at 6-7 (emphasis added).) But the Supreme Court has held that such a "'possibility' standard is too lenient," and that "[i]t is not enough that the chance of success on the merits be 'better than negligible.'" *Nken*, 556 U.S. at 434-35 (citations omitted).

In fact, Amgen is unlikely to win on appeal, because this Court correctly held that Sandoz's decision not to provide Amgen with Sandoz's application within 20 days of being notified of FDA acceptance was not unlawful conduct under 42 U.S.C. § 262(*l*)(2)(A). As this

Court concluded, in the context of the BPCIA as a whole, an applicant that opts not to take advantage of the benefits of the patent-exchange process does not violate the BPCIA. The BPCIA expressly contemplates that situation and provides that the sponsor may commence patent litigation immediately, just as Amgen did here. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). If an applicant chooses an approach provided by the BPCIA, it can hardly be said that it is in violation of the BPCIA.

Contrary to the Court's holistic reading of the BPCIA, Amgen's interpretation requires reading the word "shall" in Section 262(*l*)(2)(A) in isolation. But as this Court recognized, that approach conflicts with the principle that a statutory provision must be read "in context and with regard to its role in the overall statutory framework." (Order at 8-9.)

Not one of Amgen's objections to this Court's reasoning can withstand scrutiny. Amgen argues that the Court's reading of Section 262(*l*)(2)(A) "renders the obligations illusory and does not distinguish between the statute's use of 'shall' and 'may.'" (Mot. at 6.) Not so: the Court's interpretation gives full effect to both "shall" and "may" in Section 262(*l*)(2)(A) and the difference between them. The "shall" provision specifies a condition precedent to participating in the patent-exchange process: the applicant "shall" provide its application within 20 days after FDA acceptance. 42 U.S.C. § 262(*l*)(2)(A). Under the "may" provision, once the patent-exchange process is commenced, the applicant "may" provide certain additional information (42 U.S.C. § 262(*l*)(2)(A)), but doing so is not a condition precedent to engaging in that process or to anything else.

Amgen incorrectly states that Sandoz is arguing "that the BPCIA contemplates two optional, parallel procedures." (Mot. at 6.) To the contrary, the BPCIA provides what the sponsor or applicant must do at each step of the patent-exchange process to continue the process, and it carefully details the precise consequences if the sponsor or applicant opts to exit the process at any particular point. (*See* Declaration of Erik J. Olson in Support of Sandoz's Opposition to Amgen's Motion for an Injunction Pending Appeal ("Olson Decl."), Ex. A.)

Amgen also suggests that the Court misread *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014). (Mot. at 6.)

Amgen argues that the statute there "imposed no duty to record mortgages; it simply informed a mortgagee how to record a mortgage to protect it against subsequent purchasers." (*Id.* at 6.) But the Court correctly concluded that the statute there is parallel to the provisions here. While the statute imposed no duty to record mortgages, it stated the consequences for not doing so: "[e]very conveyance of real estate ***shall*** be recorded in the office of the county recorder of the county where such real estate is situated; and ***every such conveyance not so recorded*** shall be void as against any subsequent purchaser in good faith and for a valuable consideration of the same real estate, or any part thereof, whose conveyance is first duly recorded." *Ramsey*, 962 F. Supp. 2d at 1086 (emphasis added). So too here: Section 262(*l*) imposes no duty to engage in the patent-exchange process; it informs applicants and sponsors what steps they must take to invoke and enjoy the benefits of each phase of the process.

3. Amgen Does Not Try To Make Any Showing That Section 262(*l*)(8)(A) Is An Exclusivity Extension Rather Than A Notice Provision.

Far from establishing a strong likelihood of success – or even a serious question – Amgen completely ignores the Court's interpretation of Section 262(*l*)(8)(A). That simply confirms the correctness of the Court's interpretation. As the Court held, Section 262(*l*)(8)(A) requires notice of commercial marketing. It does not extend the sponsor's exclusivity period beyond the 12-year period specifically provided by Congress. *See* 42 U.S.C. § 262(k)(7)(A). If Congress had intended an exclusivity extension, it would have said so.

In short, Amgen does nothing to undermine this Court's previous conclusion that Amgen has shown neither a strong likelihood of success nor even a serious question on the merits. That alone warrants denial of Amgen's motion.

B. This Court Already Correctly Held That Amgen Cannot Establish Irreparable Harm.

Amgen's request for injunctive relief should likewise be denied for the independent reason that it cannot establish irreparable harm. As this Court already correctly concluded, not only are Amgen's alleged harms "at best highly speculative; they are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." (Order at 18.) Amgen offers no basis for reconsidering that conclusion.

1. Amgen Still Has Not Asserted Any Irreparable Harm Based On Alleged Infringement Of Any Valid Patent Claim.

Amgen still makes no showing that any claim of the sole patent it has asserted is valid and infringed, nor does it seek an injunction on that basis. "It must, therefore, be assumed that no such infringement has occurred." (Order at 18.) That is consistent with Amgen's verified SEC filings: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013." (ECF No. 74-7, Ex. G, Amgen Form 10-Q at 27.) The Court correctly concluded that, unless Amgen establishes that a valid patent claim would be infringed, Amgen has no basis for an injunction. (Order at 18.) Amgen ignores this holding, which was correct: as explained above, the BPCIA provisions on which Amgen relies are directed toward resolving and adjudicating patent disputes, and until Amgen offers proof of a valid, infringed patent claim, there can be no irreparable harm.

2. This Court Correctly Concluded That Amgen's Claims Regarding The Neupogen Market Do Not Demonstrate Irreparable Harm.

Amgen instead tries to establish irreparable harm by relying on its already-disproved allegation that it would drop its prices for Neupogen® and Neulasta® in the face of competition from Sandoz's filgrastim product. But as the record evidence demonstrates, [redacted] Amgen's own expert admitted that any possible price erosion was "very uncertain" and "highly uncertain." (ECF No. 74-4, Ex. D, Philipson Depo. at 119:7-11; 119:21-120:2.) Even if price erosion were to occur, it would be readily remedied by money damages. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009). The Court correctly rejected Amgen's price-erosion claim.

Nothing Amgen offers warrants reconsidering that conclusion. [redacted] The other pricing-

related documents Amgen alleges its expert did not have were ***Amgen's own documents***. (Mot. at 8 (citing Exs. B & C).) [redacted] Sandoz's expert considered these documents in analyzing the actual data and concluded the price-erosion claim was unfounded. (ECF No. 71-9, Rausser Decl. ¶¶ 62-67; *id.* Ex. C at 9.)

3. This Court Correctly Rejected Amgen's Asserted Irreparable Harm To Goodwill.

Likewise, Amgen's previously rejected theory of alleged harm to goodwill does not improve with repetition. First, Amgen's theory depends on proof of a significant price reduction by Amgen, which the record does not support. Second, Amgen claims that the supposed harm is not remediable because "there is already one alternative G-CSF product on the market, Granix®, and others expected this year." (Mot. at 9.) Because Amgen admits that it is responding to present and future competition from products other than Sandoz's, Amgen cannot blame any alleged harm to goodwill solely on Sandoz. Finally, Amgen's alleged harm to goodwill assumes that Amgen will be able to enforce patent rights in the future to remove Zarxio® from the market, a premise for which there is no evidence. (ECF No. 72, at 20.)

4. This Court Correctly Concluded That Amgen Has Not Proven Any Irreparable Harm Relating To Its Sales Force.

Amgen offers nothing new to support its theory that it would be irreparably harmed by supposedly having to divert its sales force from other oncology products to defend Neupogen® against competition from Zarxio®. Amgen still fails to cite a single decision holding that this could amount to irreparable harm. Nor would it: if Amgen believed it needed a larger sales force [redacted] it has had ample time and vast resources to hire and train new salespeople. [redacted]

[redacted]

C. Considering The Balance Of Hardships, Injunctive Relief Is Unwarranted.

The balance of hardships strongly disfavors an injunction pending appeal. Sandoz already has FDA approval. Amgen speculates that an injunction pending appeal would delay Sandoz's launch only by 6-7 weeks. (Mot. at 10-11.) But even in expedited appeals, the Federal Circuit is under no obligation to issue a decision at any specified time after oral argument, which has not yet been scheduled in this case. There is no reason for patients (and those subsidizing their care) to wait any longer for biosimilar filgrastim.

Moreover, ***any*** delay of Sandoz's launch would cause Sandoz substantial losses. (ECF No. 71-9, Rausser Decl. ¶¶ 84-98.) Through its considerable investment, Sandoz currently enjoys a significant head start over two other biosimilar filgrastim applicants, Apotex and Hospira, which are expected to receive approval and launch their products later this year or in early 2016. (*Id.* ¶ 89.) An injunction pending appeal would cause Sandoz to lose that head start. By contrast, Amgen will not incur any cognizable hardship unless it has a valid, infringed patent claim – of which it has provided ***no*** proof. Amgen is thus unlike the patentee in the decision it cites, where the Federal Circuit noted that without a preliminary injunction, "Glaxo would lose the value of its patent." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003).

D. The Public Interest Would Not Be Served By An Injunction.

Amgen's request for an injunction also should be denied because it is contrary to the public interest. The purpose of the BPCIA is to balance the interests of innovators ***and consumers*** by expediting the public's access to more affordable medical treatments, such as Sandoz's biosimilar filgrastim, while ensuring that sponsors receive clearly defined exclusivity periods and always have the right to initiate patent litigation. *See* BPCIA § 7001(b), Pub. L. No. 111-148, 124 Stat. 804 (2010). Congress decided that, apart from any exclusivity due to a valid patent claim, a 12-year period of exclusivity meets the public's interest in rewarding innovation for biologics. *See* 42 U.S.C. § 262(k)(7)(A). Amgen has already enjoyed double that exclusivity period. As permitted by the BPCIA, Sandoz chose not to initiate the patent-exchange process because that would necessarily have delayed resolution of patent disputes until after it

expected FDA approval. It wanted to have all patent issues resolved before approval if possible, so that it could launch immediately thereafter, thereby serving the public interest by bringing its product to market sooner. Entry of an injunction would be contrary to the public interest and undermine the goals of the statute.

II. If The Court Were To Grant An Injunction, The Scope Should Be Limited, And The Injunction Should Be Conditioned On Amgen's Posting A Substantial Bond.

Amgen's motion should be denied for the same reasons this Court denied its preliminary-injunction request. But were an injunction pending appeal to be issued, the scope of the enjoined activities should match the alleged harms. First, as Amgen has never disputed (*see* ECF No. 57, at 19), any injunctive relief must be limited to conduct occurring in California. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-60 (Fed. Cir. 2013).

Second, the only act for which Amgen alleges any potential irreparable harm is launching. (*See, e.g.*, Mot. at 2-3 ("Amgen will be irreparably harmed by Sandoz's having launched.").) That alleged harm cannot support the broad injunction Amgen seeks, which would prohibit Sandoz from "marketing, selling, offering to sell, or importing into the United States" its biosimilar product. (*Id.* at 12.) Rather, any injunction pending appeal should prohibit Sandoz only from launching its biosimilar filgrastim product – *i.e.*, shipping its product to customers in commercial quantities – in California, and nothing more.

Finally, Amgen does not dispute that, if any injunction were granted, it must post a substantial bond. Fed. R. Civ. P. 65(c). Without a bond, Sandoz would be deprived of relief for being wrongfully enjoined. *Russell v. Farley*, 105 U.S. 433, 437 (1882); *W.R. Grace & Co. v. Local Union 759, Int'l Union of United Rubber, Cork, Linoleum & Plastic Workers of Am.*, 461 U.S. 757, 770 n.14 (1983). Thus, "[w]hen setting the amount of security, district courts should err on the high side." *Mead Johnson & Co. v. Abbott Labs.*, 201 F. 3d 883, 888 (7th Cir. 2000).

Amgen incorrectly asserts that a bond need only cover a 6-7 week delay in launch. But as of March 31, 2015, the Federal Circuit has not yet scheduled oral argument and, even in expedited appeals, there is no set time by which the Federal Circuit must rule. Accordingly, Sandoz requests that any injunction be conditioned upon the posting of a bond protecting Sandoz

from the risk of an erroneous injunction for the maximum duration that an injunction could last, which, under Amgen's interpretation of the BPCIA, is 410 days. The harm to Sandoz from an erroneous injunction of 410 days would be in excess of [redacted]. (ECF No. 71-9, Rausser Decl. ¶¶ 84-99 & Figs. 20, 22-23, Table 21.) To ensure that the bond is sufficient to protect Sandoz, any bond should be set at 120% of the total: [redacted].

III. Amgen's Alternative Request Also Should Be Denied.

As an alternative to an injunction pending appeal, Amgen requests an injunction until the Federal Circuit rules on its contemplated motion to that Court for an injunction pending appeal. (Mot. at 2.) That request also should be denied. The parties have agreed that Sandoz will not launch its biosimilar filgrastim product until May 11, 2015, to give sufficient time for this Court and the Federal Circuit to rule on Amgen's motions. (ECF No. 106-1, at 2.) The parties also have stipulated that they will inform the Federal Circuit of this agreement and that each party will request that Court to rule by May 11. (*Id.*) That allows ample time for decisions on Amgen's motions. In any event, Amgen's alternative request should be denied for all the reasons above – Amgen cannot demonstrate any of the four factors necessary to warrant injunctive relief.

CONCLUSION

For the above reasons, Amgen's motion should be denied. Moreover, because Amgen simply repeats arguments this Court already rejected after full briefing and argument, Sandoz respectfully suggests that no oral argument is needed to deny Amgen's motion.

Dated: March 31, 2015

MORRISON & FOERSTER LLP

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Rachel Krevans

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Attorneys for Defendant
SANDOZ INC.

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

DECLARATION OF ERIK J. OLSON IN SUPPORT OF SANDOZ INC.'S OPPOSITION TO AMGEN'S MOTION FOR AN INJUNCTION PENDING APPEAL

Date: April 30, 2015
Time: 10:00 a.m.
Crtrm: 3, 17th Floor

The Honorable Richard Seeborg

I, Erik J. Olson, hereby declare as follows:

1. I am a member of the bar of the state of California and a partner with Morrison & Foerster LLP, counsel of record for Defendant Sandoz Inc. ("Sandoz") in the above-captioned action. I am admitted to practice before this Court. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently as to these facts.

2. Attached hereto as **Exhibit A** is a true and correct copy of a demonstrative that Sandoz submitted to the Court during the March 13, 2015, hearing on the parties' cross-motions for judgment on the pleadings and Amgen's motion for preliminary injunction.

3. Attached hereto as **Exhibit B** is a true and correct copy of excerpted pages from a presentation entitled "OBU Q4 14' QBR Review," produced by Amgen in this litigation and bearing Bates numbers beginning at AMG-NEUP-00002616.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 31st day of March, 2015, at Palo Alto, California.

/s/ Erik J. Olson
Erik J. Olson

ECF ATTESTATION

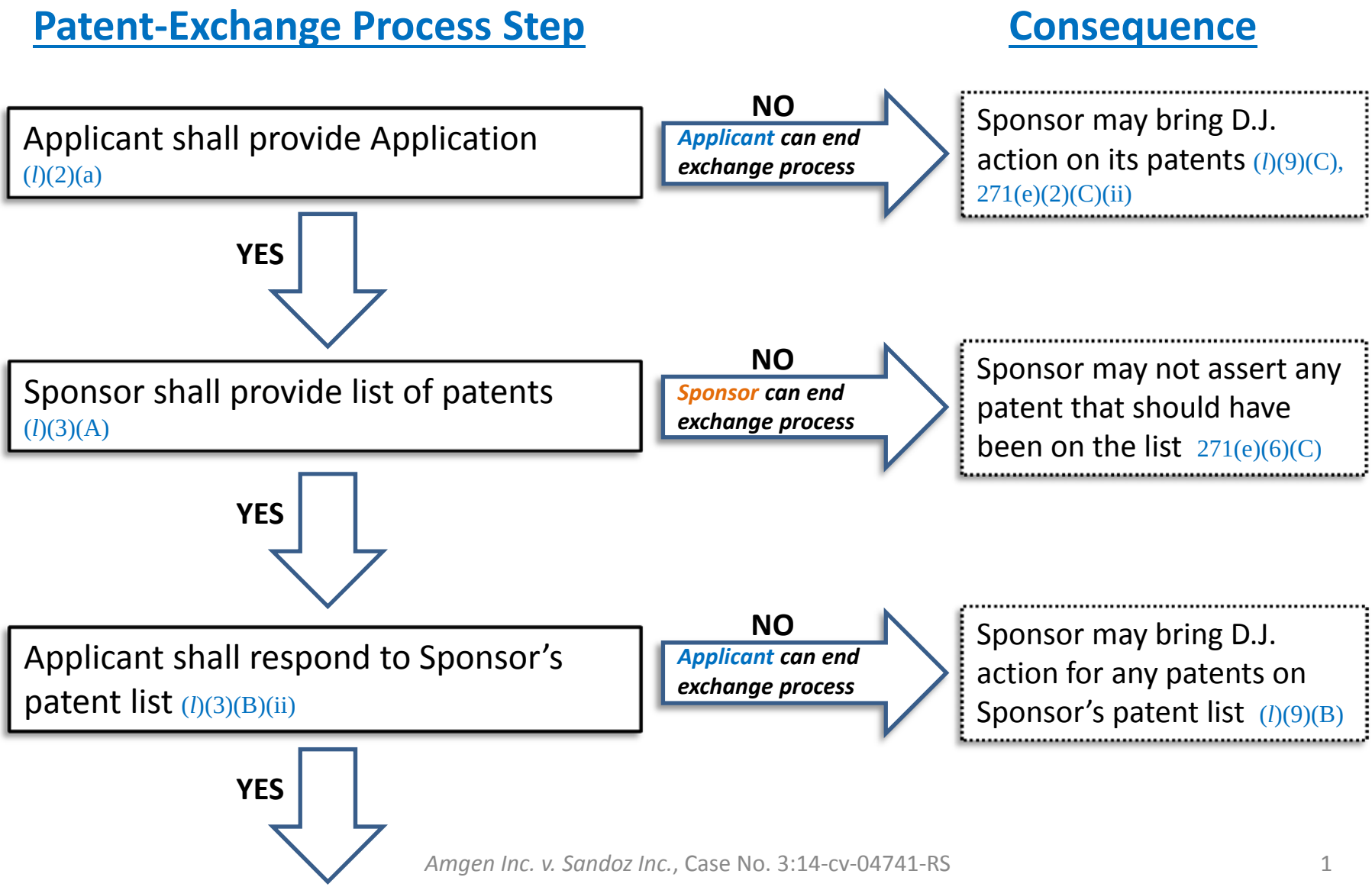
I, Rachel Krevans, am the ECF User whose ID and Password are being used to file this document. I attest that concurrence in the filing of this document has been obtained from the signatory.

Dated: March 31, 2015

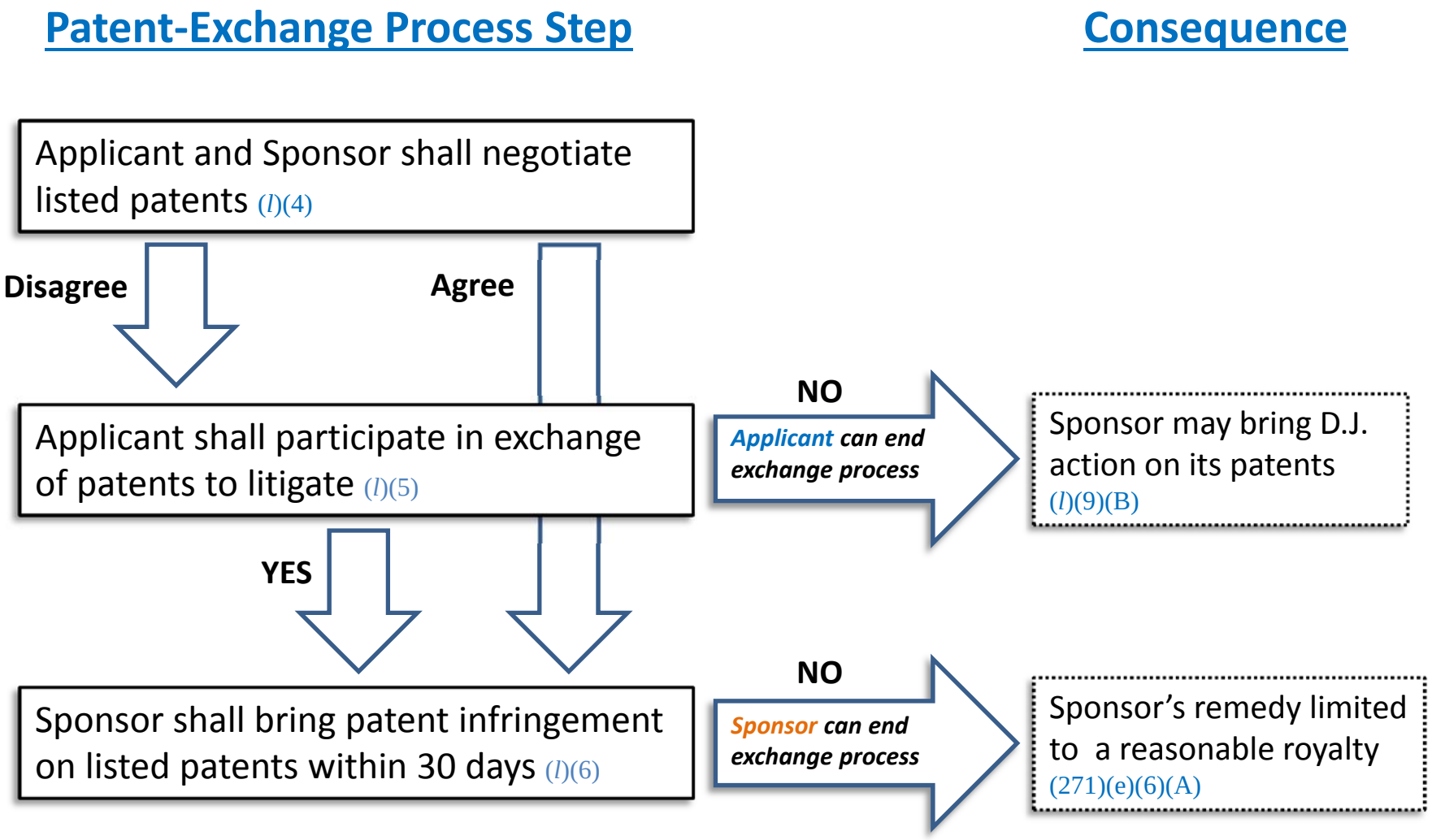
By: /s/Rachel Krevans
Rachel Krevans

EXHIBIT A

BPCIA Section (*l*) Exchanges and Scenarios



BPCIA Section (*l*) Exchanges and Scenarios



Patent-Exchange Process	Non-Patent-Exchange Process
• Sponsor gets immediate copy of Application. 262(*l*)(2)	• Sponsor can sue immediately and get copy of Application
• Sponsor gives Applicant list of patents it may assert. 262(*l*)(3)	• Sponsor can assert any patents without prior notice.
• Applicant can limit number of patents that Sponsor may assert. 262(*l*)(5)	• No limit on number of patents.
• Applicant can control what patents are litigated. 262(*l*)(3)-(*l*)(5)	• Sponsor decides what patents to assert.
• Certainty regarding timing of litigation. 262(*l*)(6)	• Sponsor decides when to sue and can force Applicant to launch at risk.
• Disclosure of BLA to a competitor without court supervision. 262(*l*)(1)(B)	• Discovery of BLA in lawsuit with court-enforced protective order
• Where Sponsor's exclusivity period has expired, litigation unnecessarily delayed. 262(*l*)(2)-(*l*)(6)	• Sponsor can choose to sue immediately.

(Blue = Benefit to Applicant, Orange = Benefit to Sponsor, White = Neutral)

EXHIBIT B

(REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED)