UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and NEW YORK UNIVERSITY Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC. Defendants.	Case No. 1:15-cv-10698-MLW

NOTICE OF SUPPLEMENTAL AUTHORITY

In connection with their Motion for a Preliminary and Permanent Injunction (Dkt. Nos. 34, 72), Plaintiffs Janssen Biotech Inc. and New York University (collectively, "Janssen") provide this notice of supplemental authority. In *Amgen Inc. et al. v. Apotex Inc. et al.*, Case No. 15-61631-CIV-Cohn/Seltzer (ECF No. 71), the United States District Court for the Southern District of Florida ruled on an issue that is central to Janssen's Motion for a Preliminary and Permanent Injunction: whether the 2009 Biologics Price Competition and Innovation Act requires a biosimilar maker to give the biologic manufacturer 180 days' notice of its intent to market a biosimilar product after the biosimilar is licensed by FDA. In that case, Judge James I. Cohn ruled, as Janssen has argued here, that the 180 days' notice provision is mandatory regardless of whether the biosimilar maker provides its aBLA. Judge Cohn therefore granted Amgen's motion for a preliminary injunction. A copy of Judge Cohn's decision and Order is attached as Exhibit A.

Dated: December 11, 2015

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY,

By their attorneys,

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CERTIFICATE OF SERVICE

I certify that on December 11, 2015 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.

/s/ Heather B. Repicky

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Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 15-61631-CIV-COHN/SELTZER

AMGEN, INC., and AMGEN MANUFACTURING LIMITED,,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

THIS CAUSE has come before the Court upon the Motion of Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively "Amgen") for a Preliminary Injunction DE [42]. Amgen seeks a preliminary injunction enjoining the Defendants, Apotex Inc. and Apotex Corp. (collectively "Apotex") from marketing its pegfilgrastim product until 180 days after it notifies Amgen of approval by the Federal Drug Administration ("FDA"). Amgen's Motion for Preliminary Injunction is based upon the Biologics Price Competition and Innovation Act of 2009 ("BCPIA"), 42 U.S.C.A. § 262 *et seq.*, in particular § 262(*l*)(8)(A).

For purposes of this motion, the parties have stipulated that three of the four elements needed for the issuance of a preliminary injunction are met: Apotex does not contest the elements of irreparable harm, balance of hardships or the public interest being served by an injunction. *See Bryan v. Hall Chem. Co.,* 993 F.2d 831, 835 (11th Cir. 1993)(discussing the showing needed for issuance of a preliminary injunction). The

parties have presented evidence and argument on the final element: the likelihood of Amgen's success on the merits, and the Court heard oral argument on December 3, 2015. The only issue before the Court is whether the BCPIA requires a company such as Apotex to give a company such as Amgen 180 days notice of its intent to market a licensed biosimilar product (as Amgen claims) or whether (as Apotex argues) the BCPIA merely makes the 180 days notice provision optional at the discretion of the applicant.

The BCPIA is a complex statute that attempts to establish "an abbreviated pathway for regulatory approval of follow-on biological products that are 'highly simliar' to a previously approved product ('reference product')." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015). Typically, the maker of a biological product must obtain licensing from the Food and Drug Administration ("FDA") through the submission of clinical data that prove the safety and efficacy of its product. *Id.* In an attempt to "balance innovation and price competition," the BCPIA allows the filing of abbreviated applications ("aBLA" or "subsection (k) application") for approval of biological products that are "biosimilar" or "interchangeable" with a previously approved reference product. *Id.* This process allows a biosimilar or interchangeable product to be approved using publicly available clinical data that was produced and obtained by the sponsor of the reference product ("reference product sponsor" or "RPS"). 42 U.S.C. § 262(k)(2)-(5). The innovator RPS is protected through a statutory 12-year period of exclusivity and the right to file "infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product." *Sandoz*, 795 F.3d at 1352.

As part of this abbreviated process, a subsection (k) applicant submits an aBLA to the FDA, and then provides the RPS with a copy of the aBLA and information about the product's manufacturing. 42 U.S.C. § 262(*l*)(2). The parties then exchange lists of patents they believe may be impinged by the biosimilar product and the RPS has 30 days within which to file a patent infringement action on the listed patents. *Id.* § 262(*l*)(6). If and when the biosimilar product is approved by the FDA for sale and use, § 262(*l*)(8) provides that the biosimilar applicant "shall" provide the RPS with 180 days notice of approval before marketing the biosimilar product for sale and use in the United States. *Id.* § 262(*l*)(8). This 180-day period "allows the RPS a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly listed or licensed patents (collectively, 'non-listed patents'), *Id.* § 262(*l*)(7)-(8)." *Sandoz,* 794 F.3d at 1352. If the biosimilar applicant fails to comply with certain provisions of subsection (*l*), including § 262(*l*)(8), the RPS (but not the applicant) may seek declaratory relief. 42 U.S.C. § 262(*l*)(9)(B) and (C).

Amgen is an RPS that developed, manufactures and markets a biologic therapy known as Neulasta, which is approved by the FDA for use in treating certain cancer patients receiving chemotherapy. Apotex submitted an aBLA to the FDA, seeking approval of a biosimilar version of Neulasta. Apotex complied with the BCPIA and disclosed its aBLA and information about its manufacturing process to Amgen, pursuant to § 262(*l*)(2). Based upon the list of patents compiled by the parties, Amgen filed this action to enforce two of its patents. Apotex has informed Amgen that it will not notify

Amgen when and if it obtains FDA approval for its biosimilar product and it will not provide the 180 days commercial marketing notice as required in § 262(*l*)(8). Amgen requests injunctive relief in the form of an order requiring Apotex to provide Amgen with notice of FDA approval of Apotex's pegfilgrastim product and to refrain from marketing its licensed product for at least 180 days from the date of such notice.

As previously stated, the issue is whether the commercial marketing notice and 180 day period in § 262(*l*)(8) is mandatory. Paragraph 262(*l*)(8) provides that "[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A) (emphases added). "The word 'shall' is ordinarily the language of command." *In re Tennyson*, 611 F.3d 873, 877 (11th Cir. 2010), *quoting Alabama v. Bozeman*, 533 U.S. 146, 153, 121 S.Ct. 2079, 2085, 150 L.Ed.2d 188 (2001) (quotation omitted). However, in the realm of statutory construction, "shall" may sometimes mean "may." "Use of the word "shall" generally indicates a mandatory intent unless a convincing argument to the contrary is made." *Sierra Club v. Train*, 557 F.2d 485, 489 (5th Cir. 1977). And that is where the parties lead us: Amgen argues that "shall" means shall in all cases, while Apotex argues that "shall" means shall only in some cases.

The Federal Circuit addressed the meaning of "shall" as used in § 262(*l*)(8)(A) in the *Sandoz* case, 794 F.3d 1347, but left some ambiguity which this Court must now address. In *Sandoz,* the subsection (k) applicant submitted the abbreviated application allowed by the BCPIA, but did not provide the RPS with its aBLA or manufacturing process as contemplated by § 262(*l*)(2). Even though § 262(*l*)(2) contained the word

"shall," the Federal Circuit, in a two-person majority, ruled that "shall" in the context of § 262(*l*)(2) is not mandatory. *Sandoz,* 794 F.3d at 1355-57. The court then stated that the word "shall" in the context of § 262(*l*)(8)(A) *does* mean "mandatory." 794 F.3d at 1359. "Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*), and Sandoz concedes as much. . . . . The purpose of paragraph (*l*)(8)(A) is clear: requiring notice of commercial marketing be given to allow the RPS a period of time to assess and act upon its patent rights." *Id.* at 1359-60. However, the *Sandoz* decision was limited to situations where the subsection (k) applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline . . . ." *Id.* at 1360. Because the situation was not before it, the court did not address whether the notice provision of § 262(*l*)(8)(A) applies where the applicant , like Apotex, *did* share the information required by § 262(*l*)(2).

Apotex would have this Court limit the *Sandoz* decision, and the mandatory nature of § 262(*l*)(8)(A), to instances where the applicant did not comply with § 262(*l*)(2) and make the notice provision of § 262(*l*)(8)(A) optional in instances where the applicant did comply with § 262(*l*)(2). This scenario was addressed by Judge Chen in his dissent to the *Sandoz* decision: "While the result in the latter scenario comes from the plain language of the statute, not so with the former. Nothing in the statute supports this peculiar outcome." *Sandoz*, 794 F.3d at 1371 (Chen, J., dissenting). This Court agrees. The scenario proposed by Apotex would result in confusion and uncertainty, as well as inconsistent results, depending on which route a subsection (k) applicant chooses to travel. Nothing in the statute or the *Sandoz* decision leads to or supports

such a result; neither the statute nor the *Sandoz* decision condition the 180 day notice provision of § 262(*l*)(8)(A) upon a subsection (k) applicant's compliance with § 262(*l*)(2).

The BCPIA is intended to provide an orderly process for evaluating patent claims in the context of biosimilar products. Indeed the *Sandoz* court (in the unanimous portion of the decision) recognized that "[g]iving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court. Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." *Id.* at 1358. That defined statutory window exists for all biosimilar products that obtain FDA licenses, regardless of whether the subsection (k) applicant complies with § 262(*l*)(2).

The *Sandoz* court also discounted Apotex's argument that the notice provision of § 262(*l*)(8)(A) unfairly gives the RPS an additional 180 days of exclusivity. Noting that Sandoz filed its aBLA 23 years after the RPS's product was initially approved, the *Sandoz* court agreed that the RPS received an "extra" 180 days, but stated "that is apparently the way the law, business, and the science evolved. That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity

period for other products. A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case." *Id.*

Indeed, the "extra" 180 days afforded to Amgen by the injunction it seeks will likely result in a more crystallized patent litigation before this Court. As Amgen concedes, depending on when the FDA grants Apotex's product a license, one of the patents Amgen has filed suit on in this Court may well expire before the 180 day period ends; under Apotex's construction of § 262(*l*)(8)(A), the Court would be forced to rule on the validity of that patent now, even though that patent claim may be moot by the end of the 180 day period. This fact helps illustrate the value and the purpose of applying the 180 day notice provision to all biosimilar applicants.

Finally, the Court disagrees with Apotex's argument that making § 262(*l*)(8)(A) mandatory for all subsection (k) applicants would render the penalty provisions of § 262(*l*)(9) superfluous. Subsection 262(*l*)(9) gives the RPS the option to file a declaratory judgment action if the subsection (k) applicant fails to comply with § 262(*l*)(8)(A) , but it is not an exclusive remedy. As the *Sandoz* court ruled, an injunction to compel compliance with the 180-day notice provision of § 262(*l*)(8)(A) is another remedy. The BCPIA simply does not give the subsection (k) applicant the power to nullify the RPS' statutory right to 180 days notice of approval prior to marketing based on whether or not the subsection (k) applicant complies with § 262(*l*)(2). As Judge Newman stated in her dissent in *Sandoz,* "[s]ubsection 262(*l*)(9) provides jurisdiction in the district court when a subsection (k) applicant fails to comply with subsection (*l*), but it does not ratify non-compliance; While 'a party may waive any provision, either of a

contract or of a statute, intended for his benefit' . . . . the party cannot waive or disregard a provision that benefits those in an adverse position." *Sandoz*, 794 F.3d at 1366 (Newman, J., dissenting), quoting *United States v. Mezzanatto*, 513 U.S. 196, 201 (1995).

On the record before the Court, Amgen has established (1) that Apotex does not intend to comply with § 262(*l*)(8)(A) of the BCPIA; (2) that it would suffer irreparable harm if Apotex were to commence marketing its product without complying with § 262(*l*)(8)(A) ; (3) that the balance of hardships weighs in favor of Amgen; (4) that the public interest will be served by an injunction; and (5) that Amgen has a substantial likelihood of prevailing on the merits. The Court finds that the requested injunctive relief is appropriate. *See, Sandoz*, 794 F.3d at 1360 (enjoining Sandoz from marketing its biosimilar product before 180 days from the date it gave notice of FDA approval).

Rule 65(e), Federal Rules of Civil Procedure, requires the Court to establish an amount of a bond to secure the costs and damages the enjoined party may sustain if the injunction is wrongfully issued. Nevertheless, "it is well-established that 'the amount of security required by the rule is a matter within the discretion of the trial court . . . [,and] the court may elect to require no security at all.'" *City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981); *BellSouth Telecomms., Inc. v. MCImetro Access Transmission Servs.,* 425 F.3d 964, 971 (11th Cir. 2005).

The Court finds that no bond is necessary. There are no factual disputes before the Court. It is undisputed that Apotex is not currently approved by the FDA to market

its biosimilar product and is not conducting such marketing. The requested preliminary injunction will require Apotex to notify Amgen when and if it receives FDA approval and will prohibit Apotex from marketing the approved product for 180 days after the notice is provided. This injunction maintains the status quo and leaves the parties in the position mandated by § 262(*l*)(8)(A). Apotex presented evidence of its projected income during the first 180 days of marketing its biosimilar product and requests a bond in that amount, but as the Court has found, Apotex is prohibited by statute from marketing its product for 180 days after it obtains FDA licensure. Apotex will lose nothing to which it is otherwise entitled by the entry of this injunction. Therefore, for the reasons discussed herein, it is hereby

ORDERED AND ADJUDGED that Amgen's Motion for Preliminary Injunction DE [42] be and the same is **GRANTED**. If the FDA approves Apotex's Biologics License Application for its pegfilgrastim product, Apotex must provide Amgen with at least 180 days notice before the date of the first commercial marketing of the biological product approved by the FDA. 42 U.S.C. § 262(*l*)(8)(A). Apotex and those acting in concert with it are enjoined from any commercial marketing of its biosimilar pegfilgrastim product, including selling that product or offering it for sale for use in the United States, until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before its pegfilgrastim biosimilar product is licensed by the FDA, and the 180-day notice period is exhausted. No bond is required to be posted by Amgen.

DONE AND ORDERED in Chambers, Fort Lauderdale, Florida, this 9th day of December, 2015.

JAMES I. COHN
United States District Judge