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A review of developments in Intellectual Property Law


Standing Alone– The Current Status of the BPCIA's Notice of Commercial Marketing

By Paula S. Fritsch, Ph.D. and Andrew W. Williams, Ph.D.

In March 2015, the FDA approved the first biosimilar application, which was for a follow-on biologic drug of Amgen's reference product NEUPOGEN® (filgrastim).[1] Yet, before the applicant, Sandoz, could launch its biosimilar under the brand name ZARXIO®, it had to wait for the Federal Circuit to interpret the controlling statute, the Biologics Price Competition and Innovation Act ("BPCIA"). This year, a different applicant with an approved biosimilar drug is in a very similar situation. On April 5, 2016, the FDA approved its second biosimilar application, this time Celltrion's application for a biosimilar therapeutic antibody related to Janssen Biotech Inc.'s REMICADE® (infliximab).[2] Celltrion had already agreed not to launch until at least June 30, 2016.[3] However, as this date rapidly approaches, Celltrion is similarly waiting for the Federal Circuit to rule on an issue that was not squarely addressed in the Federal Circuit's *Amgen v. Sandoz* decision from last year[4] – whether the 180-day Notice of Commercial Marketing period is mandatory for parties that participate in the disclosure and patent exchange provisions of the BPCIA – the so-called "patent dance."[5] Resolution of this issue in Celltrion's favor could provide a valuable approach for biosimilar applicants wishing to reach the market six months earlier than they otherwise could.

Interestingly, even though the outcome of this issue will greatly impact Celltrion, it was not the party to bring this issue to the attention of the Federal Circuit. Instead, Apotex did so when it appealed a preliminary injunction issued by Judge Cohn of the Southern District of Florida requiring Apotex to "provide Amgen with at least 180 days notice before the date of the first commercial marketing of the biological product approved by the FDA."[6] Apotex had filed an application with the FDA to market a biosimilar version of NEULASTA® (pegfilgrastim). But, unlike Sandoz before it, Apotex had participated in the patent dance. The question before the Federal Circuit in the *Amgen v. Apotex* appeal rests on the status of the 180-day notice requirement as a stand-alone provision of the BPCIA. The Federal Circuit heard arguments in the *Apotex* appeal on April 4, 2016. This article analyzes the status of the *Apotex* and *Celltrion* cases, the issue the Federal Circuit faces in the *Apotex* appeal, and the implications for all biosimilar applicants in the future.

The BPCIA

Congress passed the BPCIA in 2009 to facilitate the entry of biosimilar drugs into the market by allowing the biosimilar applicant to submit an abbreviated Biologics License Application ("aBLA") that relies in part on the approved license of a reference product.[7] The BPCIA consists of two parts – the first, found at 42 U.S.C. § 262(k), addresses regulatory aspects

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of the new regime, and the second, found at 42 U.S.C. § 262(l), addresses patent resolution issues. This latter section lays out the steps of the patent dance, which begins within 20 days of the FDA's notification to the biosimilar applicant that the aBLA has been accepted.[8] According to the language of the statute, the biosimilar applicant "shall" provide to the reference product sponsor ("RPS") the aBLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."[9] This disclosure begins a cascade of information exchanges regarding patents that the RPS could assert against the biosimilar applicant if it were to launch before patent expiration.[10]

The culmination of this process is a (potential) two-phase litigation, where the parties agree that the RPS will only initially assert a subset of the identified patents. After that, the RPS holds any remaining identified patents in reserve until the biosimilar applicant provides notice that it intends to market the biosimilar product sometime after 180 days from the date of that notice (the so-called "Notice of Commercial Marketing").[11] When the biosimilar applicant provides that notice, the RPS can seek a preliminary injunction with respect to the second-phase patents.[12] Importantly, the statute provides that "[i]f a [biosimilar] applicant fails to complete an action required" by this patent resolution mechanism – including providing the Notice of Commercial Marketing – the RPS "may bring an action . . . for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)."[13] In other words, the RPS can immediately sue the biosimilar applicant with respect to any patent identified during the patent dance.

Amgen v. Sandoz

The Federal Circuit provided its first interpretation of the BPCIA in the *Amgen v. Sandoz* case. The first issue decided was whether the patent dance is even mandatory. Amgen had asserted that the kick-off step of the dance, in which the biosimilar applicant provides the RPS with a copy of the aBLA and other information,[14] is not optional because the statute specifies that the biosimilar applicant "shall" provide such information to the RPS. The Federal Circuit disagreed, holding that because the statute provides a remedy for failure to comply with that provision, the biosimilar applicant can voluntarily choose not to participate in the patent dance.[15] That statutory remedy allows the RPS to bring a declaratory judgment suit for "any patent that claims the biological product or a use of the biological product."[16] Congress presumably provided this broad remedy ("any patent") because there would be no list of identified patents in such situations.

The second issue was whether the "Notice of Commercial Marketing" provision was also mandatory, and if so, in which situations? Sandoz had provided notice shortly after its application had been accepted for review by the FDA, which Amgen argued was too soon to be of any practical use. The Court agreed, holding that a Notice of Commercial Marketing could only be effective after the FDA has licensed the product – in other words, after FDA approval.[17] Importantly, the majority of the Court (in this instance Judges Lourie and Newman) held that the Notice provision was a standalone provision, independent of the patent dance.[18] Judge Chen disagreed in his dissent-in-part.[19] He believed that the Notice provision was "part and parcel to, and contingent upon" the patent dance.[20]

The BPCIA consists of two parts–the first, found at 42 U.S.C. § 262(k), addresses regulatory aspects of the new regime, and the second, found at 42 U.S.C. § 262(l), addresses patent resolution issues.

Stand-Alone Provision?

This "stand-alone" dichotomy in the *Amgen v. Sandoz* panel stems from the panel members' differential reading of the interplay between the Notice provision and the remainder of the patent dance provisions. The majority acknowledged that paragraph (l)(9)(B) specifically provides a remedy for violations of the Notice of Commercial Marketing provision (paragraph (l)(8)(A)) "*after the applicant has complied* with paragraph (l)(2)(A)['s requirement to share the aBLA and other manufacturing information] . . . ."[21] The majority also noted, in contrast, that the BPCIA does ***not*** specify the consequence for noncompliance with the Notice of Commercial Marketing provision in the situation where the biosimilar applicant does not share the aBLA and other manufacturing information.[22] Therefore, the Court concluded that "Paragraph (l)(8)(A) is a standalone notice provision in subsection (l),"[23] and:

> where, as here, a [biosimilar] applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the [notice] requirement of paragraph (l)(8)(A) is mandatory. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, i.e., September 2, 2015.[24]

This, of course, left unanswered the questions of whether notice is mandatory if the biosimilar applicant provides its aBLA and the required manufacturing information to the RPS, and what happens if that applicant does not provide the requisite notice.

Judge Chen, on the other hand, found that "[t]he interwoven structure of subsection (l) indicates that Congress viewed the procedures of (l)(8) as inseverable from the preceding steps in (l)."[25] To reach this conclusion, he looked to the purpose behind the Notice provision: "the entirety of (l)(8), including (l)(8)(A)'s notice provision, serves to ensure that an RPS will be able to assert all relevant patents before the [biosimilar] applicant launches its biosimilar product."[26] As such, "the most logical conclusion when reading (l)(8) in context is that (l)(8)'s vitality is predicated on the performance of the preceding steps in subsection (l)'s litigation management process."[27] Indeed, according to Judge Chen, "[w]ithout first engaging in these procedures, (l)(8) lacks meaning."[28] Therefore, according to him:

> The most persuasive reading of subsection (l) as a whole is that Congress provided two paths to resolve patent disputes: (1) the intricate route expressed in (l)(2)-(l)(8); and (2) the immediate, more flexible route provided in (l)(9), should the [biosimilar] applicant falter on any of its obligations recited in (l)(2)-(l)(8).[29]

With such a reading, the Notice provision

should be as optional as the patent dance, with paragraph (l)(9) providing the requisite remedy should the biosimilar applicant choose not to comply.

However, because the majority viewed the Notice provision as standing alone, biosimilar applicants would be advised to view the Notice provision as mandatory in all cases, at least until the Federal Circuit or Supreme Court says differently. Moreover, until there is further clarification from the courts, as explained by Judge Chen in his dissent-in-part, the majority's logic could result in different consequences for non-compliance with the Notice provision, depending on whether the biosimilar applicant had engaged in the patent dance.[30] A non-patent dancer who refuses to provide notice would face an 180-day injunction, whereas a patent dancer would likely face an immediate second lawsuit on the second-phase patents.[31]

Amgen v. Apotex

As suggested above, the issue of whether the notice is required in all cases is at the forefront of an appeal pending before the Federal Circuit. Apotex is appealing the grant of a preliminary injunction resulting from Apotex's warning that it would not provide a notice of commercial marketing when it receives approval. Apotex believes that *Amgen v. Sandoz* does not control because Apotex provided its aBLA and other relevant information to Amgen, and otherwise participated in the patent dance. On the other side, Amgen argued that the Federal Circuit's *Amgen v. Sandoz* opinion provided no leeway for such an interpretation. The District Court agreed with Amgen, stating that "[t]he scenario proposed by Apotex would result in confusion and uncertainty, as well as inconsistent results, depending on which route a [biosimilar] applicant chooses to travel."[32]

During the April 4, 2016, hearing at the Federal Circuit, it was unclear from the questioning which way the judges were leaning. Importantly, the panel consisted of Judges Bryson, Wallach, and Taranto, none of whom was on the panel that decided the *Amgen v. Sandoz* appeal. The court expressed an interest in an issue highlighted in the *amicus* briefs – the fact that this case might be distinct because all of the patents identified during the dance were part of the initial litigation. In other words, a second round of litigation was not necessary because there were no patent issues remaining to be resolved. Amgen thought this was irrelevant, because the purpose of the 180-day notice period is to allow the RPS to seek a preliminary injunction. Amgen argued that, without the certainty of these six months to resolve those remaining patent issues, an RPS would seek an early preliminary injunction in all cases. This would be a potential waste of resources, according to Amgen, because all of the patent issues might be resolved before the applicant ever receives approval, thereby rendering the injunction unnecessary.

Apotex, for its part, focused on the same canons of statutory construction that dictated the outcome in the *Amgen v. Sandoz* case with regard to whether the patent dance was mandatory. In fact, Apotex argued that the majority opinion in that case was limited to cases where there had been no patent exchange. Because that distinction did not apply in the present case, Apotex argued that the statutory remedy – the ability to bring an immediate declaratory judgment action – was the only remedy to which Amgen was entitled.

The parties were also in disagreement about whether the Notice provision acted as a *de facto* extension of the twelve-year exclusivity granted to the RPS.[33] The concern is that because a biosimilar applicant cannot give effective notice until the FDA has licensed the biosimilar product, and because the FDA cannot license the product until the twelve-year exclusionary period has run, an RPS would always gain an extra six months of exclusivity. The majority opinion in *Amgen v. Sandoz* suggested that this was not an issue because the statute contemplated aBLA filings during the twelve-year period. This conclusion, however, assumes that a biosimilar applicant could provide notice after the FDA provides "tentative licensure." It is not clear, though, if the FDA will "tentatively" approve/license any biosimilar application. Not surprisingly, Amgen and Apotex had different responses when questioned about this potential problem. Amgen pointed to 42 U.S.C. §262(k)(7)(A), which states in part that "[a]pproval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed…."[34] As such, according to Amgen, approval and effectiveness are two distinct events, with approval serving as a "tentative licensure," potentially before the expiration of the 12-year period. Not surprising, Apotex did not agree, noting that the FDA has not indicated that it will provide an early, non-effective "approval" if warranted. Of course, the outcome of this case may influence what the FDA does in the future.

A decision in this case is expected within the next few months.

Janssen v. Celltrion

Although the *Janssen v. Celltrion* case was filed before the *Amgen v. Apotex* case, the *Amgen v. Apotex* case leap-frogged the *Janssen* case to the Federal Circuit. However, the decision in the *Amgen v. Apotex* case could very well determine the date Celltrion launches its infliximab biosimilar product, even though it may not address all the issues raised in the *Janssen* case.

Celltrion provided an initial Notice of Commercial Marketing in February 2015, and at the same time it provided Janssen with a copy of its aBLA. The 180-day period triggered by that notice passed without Celltrion securing licensing approval for its biosimilar product. In February 2016, the FDA's Arthritis Drugs Advisory Committee recommended that the FDA approve Celltrion's biosimilar application, and on April 5, 2016, that license was granted.[35] In the meantime, however, Janssen and Celltrion entered an agreement in which Celltrion agreed that it would not sell its biosimilar product in the U.S. before June 30, 2016, following the expiration of one of the patents at issue in the parties' pending patent infringement litigation, in exchange for Janssen dismissing that patent from the suit.[36]

In light of that agreement, Celltrion could not launch on the date of approval. Moreover, it was still facing a claim from Janssen that its February 2015 Notice of Commercial Marketing was premature and thus violated paragraph (l)(8)(A) of the BPCIA.[37] Indeed, Janssen had filed a motion for a preliminary injunction to prevent Celltrion from launching its biosimilar product within 180 days of its FDA approval.[38] That motion was eventually dismissed without prejudice after a conference with the court, during which it was acknowledged that the *Amgen v. Apotex* case might resolve the issue.[39]

Celltrion provided another Notice of Commercial Marketing on the day its biosimilar product was licensed,[40] presumably to comply with the Federal Circuit's decision from *Amgen v. Sandoz* that a notice is not effective unless provided after the FDA has licensed the

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Changes to Trademark Registration in the European Union

By James M. McCarthy and Eric R. Moran

On March 23, 2016, new rules came into effect substantially amending the Community trademark system in the European Union (the "amended Regulations").[1] Below we discuss a number of points potentially relevant to U.S. brand owners, including (1) changes in terminology, (2) changes in fees, and, perhaps most important, (3) potential changes to the scope of protection of existing trademark registrations in the European Union.

Changes in Terminology

As of March 23, 2016, the amended Regulations simplified and made some terminology more intuitive (especially to non-European brand owners). The Community Trade Mark ("CTM") will now be known as the European Union Trade Mark ("EUTM"). In addition, the office that oversees the system, the Office for Harmonization in the Internal Market ("OHIM"), will now be known as the European Union Intellectual Property Office ("EUIPO"). And references to "the Community" will be updated to "the Union."

Changes in Fees

Also as of March 23, EUIPO has instituted a new fee system. Important to U.S. brand owners, the new system makes application filing fees—for applications with three or more classes—more expensive:

Application Filing Fees	***Old Fees***	***New Fees***
First class	€900 covered up to three classes	€850
Second class		+ €50
Third class		+ €150
Fourth and subsequent classes	+ €150 per class	+ €150 per class

Also important to U.S. brand owners, the new system makes renewal fees quite a bit less expensive:

Renewal Fees	***Old Fees***	***New Fees***
First class	€1350 covered up to three classes	€850
Second class		+ €50
Third class		+ €150
Fourth and subsequent classes	+ €400 per class	+ €150 per class

Goods and Services Descriptions—Significant Changes

A. Class Headings As Goods/Services Identifications

Traditionally, Community Trade Mark applications could be filed with broad goods and services identifications that consist of "class headings." Such "class headings" correspond to goods classes 1-34 and services classes 35-45, and are set forth in an agreement often referred to as the "Nice Agreement."[2]

Class headings are generally considered to be broad recitations of the types of goods or services included within each class. As one example, the "Class 8" class heading is "Hand tools and implements (hand-operated); cutlery; side arms; razors." Accordingly, class 8 includes goods such as, for example:

- "hammers," "pliers," and "screw drivers" (all "hand tools and implements");
- "knives," "forks," and "spoons" (all "cutlery");
- "swords" ("side arms"); and
- "shaving blades" ("razors").

Under the Nice Agreement, however, class 8 also includes some goods that do not literally fall within the class heading. For example, class 8 also includes the following goods:

- "tool belts" (not literally "hand tools and implements");
- "boxes specially adapted for the storage of cutlery and flatwear" (not literally "cutlery");
- "sword scabbards" (not literally "swords"); and
- "shaving cases" (not literally "razors").

In U.S. practice, the U.S. Trademark Office will not allow an applicant to use a class heading as an identification of goods or services.[3] Instead, the U.S. Trademark Office generally requires much more specific goods and services identifications.[4] Accordingly, in the U.S., if an applicant tries to, for example, submit as a goods description: "hand tools and implements;" the U.S. Trademark Office will require a narrowing amendment along the lines of: "hand tools and implements, namely, hammers, pliers, and screw drivers."

Such narrowing amendments would limit the identifications to the specific goods identified and would not cover goods not specifically identified.

Some non-U.S. jurisdictions, however, allow much broader identification of goods and services, including, in some cases, the use of class headings for broad coverage of goods or services in a particular class. OHIM allowed such class heading identifications in CTM applications, and now the EUIPO allows such class heading identifications in EUTM applications.

B. Changes to Past Practices

Under previous Community Trade Mark practice, trademark applications including "class headings" as goods or services descriptions were deemed to cover ***all*** goods and services within that particular class. Accordingly, an identification of "hand tools and implements (hand-operated); cutlery; side arms; razors" in class 8 of a CTM registration would be deemed to cover, for example:

- "hammers," "pliers," and "screw drivers," *as well as "**tool belts**;"*
- "knives," "forks," and "spoons," *as well as "**boxes specially adapted for the storage of cutlery and flatwear**;"*
- "swords," *as well as "**sword***

scabbards; and
- "shaving blades," *as well as* ***"shaving cases."***

Under the amended Regulations, however, only goods and services that fall within the literal meaning of class headings will be covered. Accordingly, in the above example, under the amended Regulations, the highlighted goods above would not be covered as they would likely be deemed to fall outside of the literal meaning of the class heading.

C. Strategies Going Forward

Owners of EUTMs (formerly CTMs) filed before June 22, 2012, and designating the entire heading of a class will have some formal procedural recourse, however. Counsel for such owners may submit an "Article 28(8) Declaration" to the EUIPO no later than September 24, 2016.[5] Such a declaration would state the owner's intention to seek protection for goods and services beyond those covered by the literal meaning of the class heading.

Accordingly, an owner of a CTM/EUTM registration (including an international registration designating the European Union) should work with counsel and take the following steps:

- review the owner's trademark portfolio to determine whether any class headings are included in identifications of goods or services;
- if so, evaluate whether the literal construction of the class heading covers all goods or services of interest; and
- if not, consider:
  - if the application was filed before June 22, 2012, preparing and filing an Article 28(8) declaration before September 24, 2016; or
  - if the application was not filed before June 22, 2012, preparing and filing a new application to cover goods falling outside of the "literal meaning" of class headings.

An Article 28(8) declaration, however, may only specify goods and services that go beyond the literal meaning of the class heading of that class, provided that those goods and services are included in the alphabetical list for that class in the edition of the Nice Classification in force at the date of filing. In addition, an Article 28(8) declaration may not clarify "general indications lacking in clarity and precision."[6] To make such a clarification, an owner must file a "Partial Surrender," as under past practices.[7]

Lastly, national trademark offices for countries in the European Union are also adopting a "literal meaning" interpretation of class headings used as an identification of goods and services. Accordingly, an owner of any trademark registration in the European Union should also work with counsel to review its portfolio for use of class headings. Unfortunately, no "Article 28(8) declaration" is available for national registrations in the European Union, and owners may have to file new applications to cover goods falling outside of the "literal meaning" of class headings.

* * *

The above points are not exhaustive of all potential issues raised by the amended Regulations or changing trademark laws in the European Union. They do highlight some issues likely to be of concern to U.S. brand owners that have sought or are seeking to protect their interests in the European Union. Please consult counsel regarding further or specific questions on the topics discussed.

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Endnotes

1 Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 amending Council Regulation (EC) No 207/2009 on the Community trade mark and Commission Regulation (EC) No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community trade mark, and repealing Commission Regulation (EC) No 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trade Marks and Designs).

2 *International Classification of Goods and Services for the Purposes of the Registration of Marks* (10th ed. 2011), published by the World Intellectual Property Organization ("WIPO").

3 See Trademark Manual of Examining Procedure ("TMEP") § 1402.01(a). According to section 1402.01(a) of the TMEP (emphasis added):

> With few exceptions, an identification of goods and services will be considered acceptable if it:
>
> Describes the goods and/or services so that an English speaker could understand what the goods and/or services are, even if the grammar or phrasing is not optimal;
>
> Meets the standards (not necessarily the language) set forth in the ID Manual;
>
> ***Is not a class heading***; and
>
> Is in the correct class, i.e., there is no language in the identification that makes classification difficult or ambiguous; each class lists goods or services that are clearly in a single class.

4 *See, e.g.*, TMEP § 1402.01 ("The identification of goods and/or services must be specific, definite, clear, accurate, and concise.").

5 Article 28(8) of the amended Regulations.

6 *See* Guidelines for Examination in the Office for Harmonization in the Internal Market (Trade Marks and Designs) on Community Trade Marks, Part B, Examination, Section 3, Classification, paragraph 4.2.

7 *See* Guidelines for Examination in the Office for Harmonization in the Internal Market (Trade Marks and Designs) on Community Trade Marks, Part E, Register Operations, Section 1, Changes in a Registration, paragraph 1.3.5, Partial Surrender.

Pre-AIA and Post-AIA Issues Presented by the On-Sale Bar

By Joseph A. Herndon and James L. Korenchan

The "on-sale" bar to patentability refers to a sale or offer for sale of an invention that can invalidate the patent for that invention. The America-Invents-Act (AIA), which altered the language in the statutes that apply to the on-sale bar, has made it difficult to determine what actions might constitute a "sale" or an "offer for sale" under current law. Nevertheless, a clear understanding of the on-sale bar is necessary to enable entities of all sizes—from single inventors to large corporations—to effectively monitor activities surrounding their inventions, and to enable attorneys to provide such entities with accurate and useful advice.

Pre-AIA On-Sale Bar

According to the pre-AIA on-sale bar, a patent cannot be obtained if the invention was on sale in the U.S. before a date exactly one year before the patent application was filed.[1] This date is known as the application's "critical date." An inventor's activities trigger the pre-AIA on-sale bar when two conditions are satisfied before the critical date (an analysis known as the *Pfaff* test): (1) the invention must be the subject of a commercial offer for sale, not primarily for experimental purposes; and (2) the invention must be ready for patenting.[2]

Generally, both public and private offers/sales can trigger the pre-AIA on-sale bar. An offer/sale may be considered "public" when information regarding the offer/sale is made known or sufficiently available to the public, or when the sale itself results in the claimed invention being made known or sufficiently available to the public. On the other hand, a "private" offer/sale is one not known or available to the public, such as when the offer/sale is subject to a formal or informal confidentiality agreement.

To determine whether there has been a commercial offer, courts look to see whether the actions of the inventor satisfy the standards of an offer under the Uniform Commercial Code. Offers/sales may not be considered commercial if the seller controls the buyer such that the invention remains out of the public's hands.[3] Examples of offers/sales that qualify as "commercial" include, but are not limited to: (i) offers/sales made even where delivery occurs after the critical date[4]; (ii) offers/sales on consignment or otherwise subject to approval of customer; (iii) offers/sales made, but rejected or unreceived; (iv) offers/sales made without the product on hand; (v) offers/sales by an independent third party with or without authorization; and (vi) offers/sales involving oral or written purchase orders[5] provided by a customer, supplier, or the like, even if such orders are not accepted.

The America-Invents-Act (AIA), which altered the language in the statutes that apply to the on-sale bar, has made it difficult to determine what actions might constitute a "sale" or an "offer for sale" under current law.

There are notable exceptions that do not constitute bar-triggering commercial offers/sales. For instance, the sale by a first party of an unpatented product does not trigger the bar for another party to patent the method used to produce the unpatented product, if the method is kept secret and remains secret after the sale.[6] The most notable exception is when the primary purpose of the offer/sale is experimental.[7] Some courts have acknowledged that, in certain circumstances, a sale with an experimental purpose "may be necessary to legitimately advance the experimental development of an invention;"[8] thus, experimental offers/sales signify inventions that have not yet been commercialized.

The MPEP helpfully provides numerous factors courts have considered when determining whether the primary purpose of a pre-AIA offer/sale is experimental.[9] One factor is whether the offer/sale was necessary for public testing. Courts have acknowledged that, in certain circumstances, a sale with such a purpose "may be necessary to legitimately advance the experimental development of an invention."[10] Note, however, that "public testing" does not include testing to gauge a consumer's subjective needs and interests. Another factor is whether there was a low or merely incidental degree of commercial exploitation. For this factor, courts often consider payment made (if any) and contacts made with existing or potential customers. Yet another important factor is the degree of control the inventor/patentee had over how the testing party tested the invention. For instance, if the patentee continually monitored the invention and the testing party throughout the testing period, courts are more likely to find an experimental purpose.

For the second prong of the *Pfaff* test, there are two ways to satisfy the test of whether an invention is "ready for patenting." First, one can show proof of a reduction to practice.[11] Second, one can show "proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."[12] The Federal Circuit has found that an offered/sold product—whether in the form of a sample, working prototype, CAD drawing, public or private presentation, or the like—is ready for patenting if the product meets each of the claimed limitations, even if the product does so inherently.[13] In this manner, if a product is "ready for patenting" at the time the product is offered or sold, the on-sale clock starts once the offer/sale is made, even if the product is not yet patented.

Several important Federal Circuit cases have dealt with pre-AIA on-sale activities. Perhaps most notable is the rule from *Special Devices, Inc. v. OEA, Inc.* that there is no "supplier exception" with respect to a patentee-supplier relationship, provided the offer/sale was not for experimental use.[14] This rule arose from a situation in which a patentee had secretly stockpiled his invention more than one year before filing a patent application in order to ensure adequate supplies upon launch. The Federal Circuit held that such behavior nevertheless qualifies as a sale, objecting

to the practice of patentees "stockpil[ing] commercial embodiments of their patented invention via commercial contracts with suppliers more than a year before they file their patent application," regardless of whether done publically or in secret.[15]

The Federal Circuit has applied the "no supplier exception" rule various times since *Special Devices*. Most recently, in *The Medicines Company v. Hospira*, the Federal Circuit cited the rule in their holding that a private order placed with a pharmaceutical supplier constitutes an invalidating sale.[16] The supplier in this case was to prepare batches of a drug for the plaintiff using an embodiment of a patented method. The preparation consisted of marking batches of the drug with commercial product codes and customer lot numbers, and sending the batches back to the plaintiff for commercial and clinical packaging, all of which the Court noted was consistent with commercial sale of pharmaceutical drugs. Interestingly, however, the Court then granted an *en banc* rehearing, and requested the parties to file new briefs addressing various issues including (i) whether the private order constituted a sale for experimental use and (ii) whether the Federal Circuit should overrule or revise the "no supplier exception" rule of *Special Devices*.[17] Other parties have weighed in as amici, such as the American Intellectual Property Law Association (AIPLA), which argued in its brief that not all transactions between inventors and suppliers should trigger the on-sale bar, and that a supplier-to-inventor transaction is not necessarily a commercial offer for sale because the inventor does not place the invention on sale to the general public and also does not profit from the invention.[18]

The forthcoming *en banc* decision in *Hospira* may have a huge impact on how courts analyze pre-AIA sale activities. At a minimum, the decision is likely to provide a framework for pre-AIA private offers/sales, including a further distinction between commercial and experimental offers/sales in the context of private commercial dealings with suppliers. In addition, courts may even consider this framework in the future when dealing with post-AIA offer/sale activities.

Post-AIA Changes to the On-Sale Bar

According to the post-AIA on-sale bar, a patent cannot be obtained if the invention was "on sale, or otherwise available to the public" anywhere in the world one year or more before the effective filing date of the claimed invention.[19] There is notable ambiguity surrounding the post-AIA bar because the statutory language implies that only public offers/sales can trigger the bar ("on sale, or otherwise available to the public"). It remains unclear as to whether the bar applies to private offers/sales, and as to whether the experimental use exception has survived the AIA.

MPEP sections pertaining to the post-AIA bar merely reference pre-AIA case law such as *Pfaff* for defining pre-AIA on sale activity and for designating pre-AIA exceptions, including experimental use. The legislative history surrounding AIA, however, supports the interpretation that private offers/sales do not trigger the post-AIA bar, stating, for instance: "An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute [prior] art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art."[20] Sen. Patrick Leahy has stated that AIA § 102(a) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States" constitute prior art.[21]

To date, the Federal Circuit has not interpreted the new statutory language. However, a district court judge in the Third Circuit very recently interpreted the post-AIA on-sale bar. In *Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories Ltd*., Judge Mary L. Cooper agreed with the plaintiff's argument that private offers/sales do not trigger the post-AIA bar and stated in her supplemental opinion that "[t]he new requirement that the on-sale bar apply to public sales comports with the plain language meaning of the amended section, the USPTO's interpretation of the amendment, the AIA Committee Report, and Congress's overarching goal to modernize and streamline the United States patent system."[22]

Still, applicants engaged in private offers/sales are sure to be concerned with the ambiguity surrounding the post-AIA bar. Because the statute has indeed changed, courts might not apply the same pre-AIA analysis to post-AIA patents, and may instead agree with Judge Cooper's decision that private offers/sales do not trigger the bar. Alternatively, applicants can play it safe and proceed with caution by assuming that courts may end up applying the *Pfaff* test to post-AIA patents. Of course, applicants who file post-AIA patents run the risk that courts could end up interpreting the new statute to include private offers/sales and maintaining the "no supplier exception" rule. It is yet to be seen what impact the *Hospira en banc* decision will have on the post-AIA bar, if any, and it is also yet to be seen whether the Federal Circuit will agree with Judge Cooper's opinion on the scope of the post-AIA bar.

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Endnotes

1 *See* 35 U.S.C. §102(b) [pre-AIA].
2 *See* Pfaff v. Wells Electronics, 525 U.S. 55, 67-68 (1998).
3 *See* Netscape Commc'ns Corp. v. Konrad, 295 F.3d 1315, 1324 (Fed. Cir. 2002).
4 *See, e.g.*, Buildex Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1464 (Fed. Cir. 1988).
5 *See* Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc., 726 F.3d 1370 (Fed. Cir. 2013).
6 *See* In re Caveney, 761 F.2d 671, 675 (Fed. Cir. 1985).
7 *See* MPEP § 2133.03(e).
8 *Id*.
9 *See* MPEP § 2133.03(e)(4).
10 MPEP § 2133.03(e)(1).
11 *Pfaff*, 525 U.S. at 67-68.
12 *Id*.
13 *See, e.g.*, Atlanta Attachment Co. v. Leggett & Platt, Inc., (Fed. Cir. 2008); Scaltech, Inc. v. Retec/Tetra, LLC, 269 F.3d 1321, 1329 (Fed. Cir. 2001).
14 *See* Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353 (Fed. Cir. 2001).
15 *Id*. at 1354.
16 791 F.3d 1368 (Fed. Cir. 2015).
17 *See* The Medicines Company v. Hospira, 805 F.3d 1357 (Fed. Cir. 2015).
18 *See* Brief of Amicus Curiae American Intellectual Property Law Association, 2016 WL 325470 (C.A.Fed.).
19 35 U.S.C. § 102(a)(1) [AIA]; 35 U.S.C. § 102(b)(1) [AIA]
20 *See* 157 Cong. Rec. S5320 (daily ed. Sept. 6, 2011)
21 *See* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy)
22 No. CV 11-3962 (MLC) (D.N.J. Mar. 3, 2016), *supp. op.*, page 100.

(continued from page 3)

product.[41] However, Celltrion has characterized the later notice as a "***conditional*** 180-day notice of commercial marketing that applies only "***if***" required by the anticipated decision in *Amgen Inc. v. Apotex Inc*., No. 16-1308 (Fed. Cir.)."[42] Under that second notice, Celltrion could not launch before October 2, 2016. However, since the *Amgen v. Apotex* case could result in a decision that exempts biosimilar applicants who have engaged in the patent dance from the notice requirements, Celltrion "expressly '***reserved [the] right to void this notice and to launch***'" before the 180-day period started by the second notice.[43] That is, Celltrion has poised itself to launch as early as June 30, 2016, should the *Amgen v. Apotex* court side with Apotex (and biosimilar applicants that engage in the patent dance) on the notice issue.

But that leads to the second issue in the *Janssen* case – did Celltrion engage in the patent dance? While Celltrion said yes, Janssen's answer was a resounding no. Celltrion did not go as far as Sandoz and refuse to provide Janssen with a copy of its aBLA. However, Celltrion also did not go as far as Apotex either, at least according to Janssen. Celltrion provided Janssen with a copy of its aBLA, but not any additional manufacturing information called for in paragraph (l)(2)(A).[44] When pressed by Janssen to provide manufacturing information, Celltrion indicated that "[a]ll relevant information needed to generate a list of patents for which a claim of patent infringement can reasonably be asserted by Janssen is included in Celltrion's [a]BLA"[45] and later, that "Celltrion does not have the authority" to share certain manufacturing information with Janssen.[46]

After receiving Janssen's paragraph (l)(3)(A) patent list, Celltrion provided the paragraph (l)(3)(B)(ii) statement of defenses.[47] But rather than provide its own patent list as contemplated by paragraph (l)(3)(B)(i), Celltrion informed Janssen that it "consented to Janssen's patent list" and considered moot the remaining steps in the patent dance, namely Janssen's paragraph (l)(3)(C) response to Celltrion's defenses, the paragraph (l)(4) patent resolution negotiations, and the further paragraph (l)(5) negotiations to identify patents to be immediately litigated.[48] Celltrion also asserted that Janssen was required to file suit against Celltrion on all of the patents on Janssen's paragraph (l)(3)(A) patent list within 30 days of receipt of Celltrion's paragraph (l)(3)(B)(ii) statement of defenses.[49]

Janssen alleged that Celltrion's failure to provide manufacturing information at the start of the patent dance, and its refusal to engage in the BPCIA's subsequent patent dispute resolution procedures, are violations of the mandatory procedures under section (l) of the BPCIA.[50] That claim remains pending.[51] And if faced with a decision in *Amgen v. Apotex* that exempts patent dancers from the notice requirement, Janssen will almost certainly argue that Celltrion failed to engage in the patent dance, thereby precluding Celltrion from qualifying for such an exemption.

The time has not yet come for the *Janssen v. Celltrion* court to address these issues. At some point, though, the court may be called upon to decide whether a biosimilar applicant can be deemed to have complied with the "shall provide" provision of paragraph (l)(2)(A) if it does not provide manufacturing information beyond that found in the aBLA, or whether the "shall" provisions of paragraphs (l)(3)(C), (l)(4), and (l)(5) are prerequisites to a finding that the biosimilar applicant has engaged in the patent dance.

Thus, the *Janssen* case is destined to play a role in defining the contours of what qualifies as having engaged in the patent dance. If the federal courts accept Celltrion's approach to the patent dance, it is unlikely that any biosimilar applicant will ever provide manufacturing information, other than what is included in the aBLA. And future biosimilar applicants may accept an RPS's complete list of patents in order to accelerate the filing of the eventual patent litigation.

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Endnotes

1 Press Release, U.S. Food and Drug Admin., FDA Approves First Biosimilar Product Zarxio (Mar. 6, 2015), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm.
2 Press Release, U.S. Food and Drug Admin., FDA Approves Inflectra, a Biosimilar to Remicade (April 5, 2016), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm.
3 *See* Stipulation of Voluntary Dismissal at 2, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 1:15-cv-10698 (D. Mass. filed Mar. 22, 2016).
4 Amgen Inc. v. Sandoz, Inc., 794 F. 3d 1347 (Fed. Cir. 2015).
5 As discussed in more detail later, the patent dance is a series of exchanges between the biosimilar applicant and the reference product sponsor designed to result in the orderly resolution of patent issues. *See* 42 U.S.C. § 262(l).
6 Amgen, Inc. v. Apotex Inc., No. 15-61631-CIV-COHN/SELTZER, slip op. at 9 (S.D. Fla. Dec. 9 2015).
7 *See* 42 U.S.C. § 262(k), (l). The BPCIA addresses both biosimilar and interchangeable biological products. See 42 U.S.C. § 262(i). Applications for licensure of both types of biological products are governed by 42 U.S.C. § 262(k). To date, the FDA has only approved applications for biosimilar biological products. Thus, for ease of reference, we refer to applications under 42 U.S.C. § 262(k) as "biosimilar applications" (and the applicants filing such applications as "biosimilar applicants"), but the term also encompasses applications for biological products that are so biosimilar that they are interchangeable with their reference biological products.
8 42 U.S.C. § 262(l)(2).
9 *Id.*
10 42 U.S.C. § 262(l)(2)-(l)(3).
11 42 U.S.C. § 262(l)(4)-(l)(6).
12 42 U.S.C. § 262(l)(8). The RPS can also assert newly issued or licensed patents that it brings into the patent dance. 42 U.S.C. § 262(l)(7).
13 42 U.S.C. § 262(l)(9)(B).
14 42 U.S.C. § 262(l)(2).
15 Amgen Inc. v. Sandoz, Inc., 794 F. 3d 1347, 1357 (Fed. Cir. 2015).
16 42 U.S.C. § 262(l)(9)(C).
17 *Sandoz, Inc.*, 794 F. 3d at 1358.
18 *Id.* at 1359.
19 *Id.* at 1367.
20 *Id.* at 1370.
21 *Id.* at 1359 (emphasis in original).
22 *Id.*
23 *Id.*
24 *Id.* at 1360.
25 *Id.* at 1369.
26 *Id.*
27 *Id.*
28 *Id.*
29 *Id.* at 1370.
30 *Id.* at 1371.
31 *Id.*
32 Amgen, Inc. v. Apotex Inc., No. 15-61631-CIV-COHN/SELTZER, slip op. at 5 (S.D. Fla. Dec. 9 2015).
33 42 U.S.C. § 262(k)(7)(A).
34 *Id.*
35 Press Release, Celltrion Health Care, FDA's Arthritis Advisory Committee Recommends Approval of Celltrion's CT-P13, a Proposed Biosimilar Infliximab, for All Indications, *available at* http://www.businesswire.com/news/home/20160209006848/en/; Press Release, U.S. Food and Drug Admin., FDA Approves Inflectra, a Biosimilar to Remicade (April 5, 2016), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm.
36 *See* Stipulation of Voluntary Dismissal at 2, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 1:15-cv-10698 (D. Mass. filed Mar. 22, 2016).
37 *See* Complaint at 26-29, 31, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 1:15-cv-10698 (D. Mass. filed Mar. 15, 2015) [hereinafter Complaint].
38 *See* Plaintiff's Motion for Summary Judgment at 2, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-cv-10698 (D. Mass. Filed April 8, 2015).
39 *See* Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-10698-MLW, slip op. at 1-2 (D. Mass. Feb. 10, 2016); Plaintiff's Letter of April 27, 2016 at 2, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-cv-10698 (D. Mass. Filed April 27, 2016). Janssen recently requested that the Court set "a tentative schedule for proceedings on a potential renewed motion for a preliminary injunction" to prevent Celltrion from launching within 180 days of approval if the *Amgen v. Apotex* case is not decided before June 30, 2016, or if the case is decided but does not resolve the parties' dispute. *Id.*
40 *See* Plaintiff's Letter of April 12, 2016 at 1, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-cv-10698 (D. Mass. filed April 12, 2016).
41 Amgen Inc. v. Sandoz, Inc., 794 F. 3d at 1358.
42 *See* Defendant's Letter of April 18, 2016 at 2, Janssen Biotech, Inc. v. Celltrion Healthcare Co., No. 15-cv-10698 (D. Mass. filed April 18, 2016). (emphasis in original).
43 *Id.* (emphasis in original).
44 Before Celltrion's aBLA was accepted by the FDA and before providing any information about it to Janssen, Celltrion and its marketing partner, Hospira, sought to bypass the BPCIA altogether by filing declaratory judgment actions against Janssen seeking declarations of noninfringement or invalidity of patents they identified as relevant to the biosimiar product. *See Complaint, supra note 35*, at 20-21. Hospira's action was dismissed, and Celltrion's action was voluntarily withdrawn. *Id* at 21.
45 *Id*. at 22.
46 *Id*. at 23.
47 *Id*.
48 *Id*.
49 *Id*. at 23-24.
50 *Id*. at 29-30.
51 Also still pending are Janssen's claim for violation of the paragraph (l)(8)(A) notice provision, and two of its patent infringement claims.

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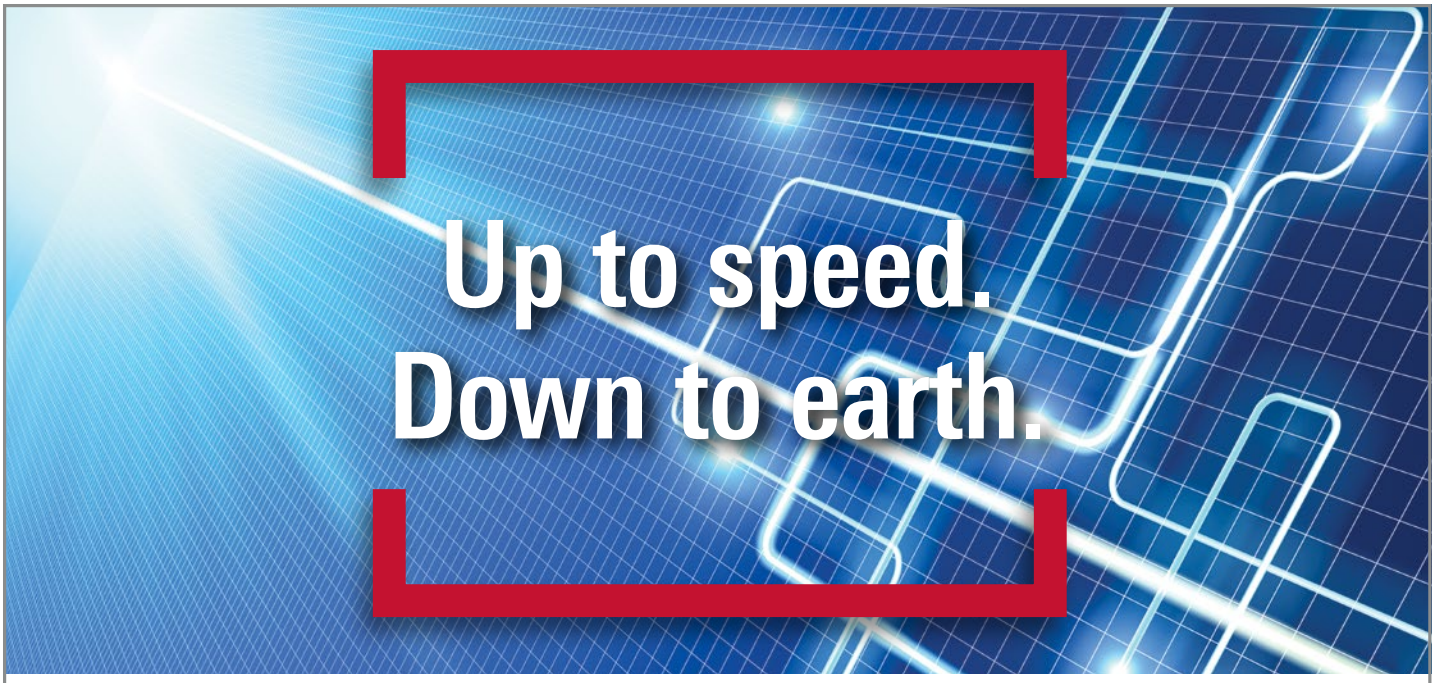

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