Nineteen Hundred and Twenty-two

A Publication of the New York Intellectual Property Law Association

NYIPLA®

February/March 2016

The Report

In This Issue

Special Biologics & Biosimilars Issue

The Biosimilar Patent Dance: The Steps We Can Skip, The Steps We Must Follow, The Steps We Still Need To Learn

*By Courtenay C. Brinckerhoff**

In March 2010, President Obama signed the Biologics Price Competition and Innovation Act ("BPCIA")[1] into law as part of the Patient Protection and Affordable Care Act. The aim of the BPCIA was to create an abbreviated pathway for biosimilar product approval, similar to the existing Abbreviated New Drug Application ("ANDA") pathway for generic versions of drugs. The BPCIA includes provisions for resolving patent infringement disputes, but these provisions are vastly more complicated than the ANDA litigation framework. Indeed, before the U.S. Food and Drug Administration ("FDA") even had approved the first biosimilar product, parties had disputed the meaning of various provisions in district court litigation. To date, the U.S. Court of Appeals for the Federal Circuit has decided two issues, but many others remain. This article will review the Federal Circuit's interpretation of two key provisions of the BPCIA and highlight significant issues that remain unresolved.

I. The Biosimilar Framework

The BPCIA's abbreviated FDA approval pathway allows a biosimilar applicant to rely on the FDA's previous approval of an original biologic product (the "reference product") when seeking approval of a biosmilar product. For example, 42 U.S.C. § 262(k) provides that a biosimilar applicant is not required to produce clinical data demonstrating safety and efficacy, as long as it submits data showing that its product is "biosimilar" to the reference product. In effect, the BPCIA permits a biosimilar applicant to rely on and benefit from the clinical trials conducted by the reference product sponsor, so that biosimilar products can be approved at a significantly reduced cost and in a shorter period of time than an original biologic product.

II. The Patent Dance

The patent dispute resolution procedures of the BCPIA are set forth in 42 U.S.C. § 262(*l*). In the first step, the biosimilar applicant shares its biosimilar application and other information with the reference product sponsor:

> (2) Subsection (k) application information. Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

cont. on page 2

cont. from page 1

> (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.[2]

In the next steps, the parties identify which patents they believe should be litigated. First, the reference product sponsor "shall provide … (i) a list of patents for which the … sponsor believes a claim of patent infringement could reasonably be asserted… and (ii) an identification of the patents on such list that the… sponsor would be prepared to license to the subsection (k) applicant."[3] In response, the biosimilar applicant "may provide" its own list of patents, and "shall provide" a detailed statement describing "the factual and legal basis" for the applicant's opinion that the patents on the sponsor's list are "invalid, unenforceable, or will not be infringed."[4] The applicant also "shall provide … a response" to any offer to license.[5] Then, the sponsor "shall provide" its own detailed statement describing "the factual and legal basis" for its opinion that the patents will be infringed and responding to the applicant's assertions regarding invalidity and unenforceability.[6]

Once that round of the patent dance is completed, the parties then "engage in good faith negotiations to agree on which, if any, patents" from the sponsor and applicant lists should be litigated.[7] If agreement is reached, then "not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement."[8] If agreement is not reached, 42 U.S.C. § 262(*l*)(5) calls for a further round of patent lists to be exchanged, but first the applicant "shall notify the … sponsor of the number of patents" that it will include on its list. [9] This gives the biosimilar applicant some control over the ensuing litigation, because "the number of patents listed by the … sponsor … may not exceed the number of patents listed by the … applicant," except that if the applicant does not list any patents, then the sponsor may list one patent.[10] Once that is settled, both parties "shall simultaneously exchange" their second lists of patents.[11] Then, the reference product sponsor has "not later than 30 days after the exchange of [the second] lists" to "bring an action for patent infringement with respect to each patent that is included on such lists."[12]

Even after that litigation, the dance may not be over because 42 U.S.C. § 262(*l*)(8) permits the reference product sponsor to seek a preliminary injunction before the biosimilar product is marketed. If there were any patents included in either of the first patent lists but not included on the agreed-upon list or the second lists:

> (8) Notice of commercial marketing and preliminary injunction.
>
> (A) Notice of commercial marketing. The 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).
>
> (B) Preliminary injunction. After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is [included in either of the first lists but not included on the agreed-upon list or the second lists].[13]

Complementing the procedures of 42 U.S.C. § 262(*l*), provisions in 35 U.S.C. § 271(e) make submitting a biosimilar application an act of infringement of a patent that is or that could be identified in a patent list under Section 262(*l*)(3), and impose consequences on the reference product sponsor/patent holder for failing to list a patent that "should have been included" in a patent list and/or for failing to bring suit within the 30-day time periods.

III. The Neupogen® Biosimilar Dispute

The Federal Circuit decision in *Amgen v. Sandoz*[14] involved a dispute between Amgen Inc. and Sandoz Inc. over Sandoz's biosimilar of Amgen's Neupogen® (filgrastim) product. In May 2014, Sandoz sought FDA approval of a biosimilar of Neupogen® (filgrastim), which is a recombinantly produced human granulocyte colony-stimulating factor protein (C-CSF) used to reduce the chance of infection in certain cancer patients receiving chemotherapy. Although Sandoz notified Amgen of its biosimilar application, it did not provide a copy of the application to Amgen and did not follow any of the other patent dance provisions of the BPCIA.[15]

Amgen sued Sandoz in the U.S. District Court for the Northern District of California, alleging, inter alia, that Sandoz violated California's unfair competition laws by failing to comply with the BPCIA.[16] The district court ruled in Sandoz's favor and found no violation of the BPCIA to support Amgen's state law claims.[17] The Federal Circuit held that Sandoz did not have to share its biosimilar application or follow the complicated patent dance provisions of the BPCIA, but that the statute did require Sandoz to give 180-day pre-marketing notice after its product was approved, so that it could not enter the market until September 2, 2015.[18] Sandoz announced the launch of its product, Zarxio® (filgrastim-sndz), on September 3, 2015.[19]

A. Biosimilar Applicants Do Not Have to Join in the Patent Dance

In a decision that surprised many stakeholders and attorneys who had spent countless hours parsing the complicated provisions of Section 262(*l*), the Federal Circuit held that biosimilar applicants do not have to engage in the patent dance at all. In particular, the court determined that even though Section 262(*l*)(2)(A) states that "the subsection (k) applicant ... (A) ***shall*** provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k)," the requirement is optional because other portions of the statute impose specific consequences for failing to following this first step of the patent dance.[20] In her decision dissenting-in-part from this aspect of the majority decision, Judge Newman criticized the majority for disrupting the "explicit balance of obligations and benefits" set forth in the BPCIA.[21]

Some biosimilar applicants may follow Sandoz's lead and decide not to engage in the patent dance. Others may prefer to take advantage of the statutory structure for resolving patent disputes and avoid being subject to an immediate declaratory judgment action by the reference product sponsor, which 42 U.S.C. § 262(*l*)(9)(C) permits if the biosimilar applicant "fails to provide the application and information required under [Section 262(*l*)](2)(A)]."

Amgen did not file a petition for certiorari to the Supreme Court on this issue.

B. Biosimilar Applicants Cannot Give Pre-Marketing Notice Prior to Approval

Even though the Federal Circuit essentially interpreted "shall" in Section 262(*l*)(2)(A) as meaning "may," it found less flexibility in the "shall" of Section 262(*l*)(8)(A). Instead, the court held that biosimilar applicants ***must*** provide the required 180-day pre-marketing notice to the reference product sponsor, and that they ***cannot*** do so until the FDA has approved the biosimilar product.[22] In his decision dissenting-in-part from this aspect of the majority decision, Judge Chen criticized the majority for giving reference product sponsors a "windfall" of six additional months of market exclusivity beyond the 12 years already provided by Section 262(k)(7)(A).[23]

On this issue, Sandoz filed a petition for certiorari to the Supreme Court on February 16, 2016 (response due March 21, 2016).

IV. The Neulasta® Biosimilar Dispute

Further clarification of Section 262(*l*)(8)(A) is being sought in the dispute between Amgen Inc. and Apotex Inc. over Apotex's proposed biosimilar of Amgen's Neulasta® (pegfilgrastim) product, which is currently pending at the Federal Circuit.[24] The pharmaceutical Neulasta® (pegfilgrastim) is approved for use to reduce the incidence of infection associated with certain chemotherapy treatments. After Apotex filed its biosimilar application, Apotex and Amgen engaged in the patent dance provisions of the BPCIA and agreed that two Amgen patents should be litigated. Before this process was completed, Apotex gave Amgen prior notice of commercial marketing, even though its biosimilar product had not (and still has not) been approved. Amgen sued Apotex in the U.S. District Court for the Southern District of Florida, asserting infringement of the agreed-upon patents and seeking a declaratory judgment and preliminary injunction on the pre-marketing notice issue.

A. Do Biosimilar Applicants Who Engage in the Patent Dance Have to Give Pre-Marketing Notice?

Amgen asserts that the notice given was ineffective under the Federal Circuit's interpretation of Section 262(*l*)(8)(A) in *Amgen v. Sandoz*,[25] while Apotex argues that Section 262(*l*)(8)(A) does not apply at all when the biosimilar applicant has participated in the patent dance and provided its biosimilar application under Section 262(*l*)(2)(A).[26] The district court ruled in favor of Amgen on the pre-marketing notice issue, and Apotex appealed to the Federal Circuit. That appeal is pending and is being reviewed on an expedited schedule.[27]

V. The Remicade® Biosimilar Dispute

Other issues of statutory construction have arisen in the dispute between Janssen Biotech, Inc. and Celltrion Healthcare Co., Ltd. over the pharmaceutical Remicade® (infliximab), which is pending before the U.S. District Court for the District of Massachusetts.[28]

cont. on page 4

cont. from page 3

The Remicade® product has been approved for the treatment of Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis. Celltrion's biosimilar application has not yet been approved, but it cleared a significant hurdle on February 9, 2016, when an FDA advisory panel voted in favor of approval.[29]

Janssen filed its complaint against Celltrion in March 2015, alleging violations of the BCPIA and infringement of six patents.[30] Janssen's BCPIA claims alleged that Celltrion failed to follow the requirements of the BCPIA by:

- failing to timely provide information regarding its manufacturing process as required by Section 262(*l*)(2)(A);
- consenting to Janssen's patent list and thereby circumventing the negotiation procedures of Section 262(*l*)(4) and (5) and accelerating the time in which Janssen must bring suit; and
- prematurely providing notice of commercial marketing before its product is approved.[31]

Janssen and Celltrion both moved for partial summary judgment on the premature pre-marketing notice issue, and Janssen also moved for preliminary and permanent injunctions enjoining Celltrion from commercially marketing its "proposed biosimilar until at least 180 days after they provide an effective notice of commercial marketing."[32] All motions were denied without prejudice "[a]s agreed by the parties" on February 10, 2016.[33]

A. Which Steps of the Patent Dance Are Mandatory?

The pending Federal Circuit decision in *Amgen v. Apotex* may resolve the premature pre-marketing notice issue since Celltrion, like Apotex, participated in the patent dance. Resolution of the other BPCIA issues raised in this case could shed light on which steps of the patent dance are mandatory and which sequences can be side-stepped.

Celltrion might believe that *Sandoz* resolves the Section 262(*l*)(2)(A) issue in its favor—if a biosimilar applicant need not provide ***any*** information under Section 262(*l*)(2)(A), how can it be a violation to provide a copy of the biosimilar application? On the other hand, the court may determine that, although a biosimilar applicant can choose ***whether*** to engage in the patent dance that commences with the sharing of information under Section 262(*l*)(2)(A), if it decides to do so, it must provide ***all*** of the information the provision calls for, including the "other information that describes the process or processes used to manufacture the biological product that is the subject of such application."[34] The majority in *Sandoz* noted that a biosimilar applicant who fails to engage in the patent dance may face an immediate declaratory judgment action under Section 262(*l*)(9).[35] In this regard, Section 262(*l*)(9)(C) states that the reference product sponsor may bring a declaratory judgment action on "any patent that claims the biological product or a use of the biological product" if the biosimilar applicant "fails to provide the application ***and*** information." In parallel, Section 262(*l*)(9)(A) states that the reference product sponsor may not bring a declaratory judgment action prior to receipt of the pre-marketing notice if the biosimilar applicant has provided "the application ***and*** information." In a case where the biosimilar applicant has provided the application but not the "other information," which provision applies? If this scheme of choices and consequences does not contemplate that the biosimilar applicant would provide some, but not all, of the information called for under Section 262(*l*)(2)(A), does that mean that the biosimilar applicant must provide all or none of the information? Or does *Sandoz* indicate that the biosimilar applicant always has the option to withhold information?

The issues raised under Section 262(*l*)(4) and (5) may be even more complex. After Celltrion commenced the patent dance by sharing its biosimilar application, Janssen provided a list of patents in accordance with Section 262(*l*)(3)(A), and Celltrion provided its statement of defenses in accordance with Section 262(*l*)(3)(B). Along with its statement of defenses, Celltrion stated that it "did not seek to limit the patents to be litigated," and, as a result, no further negotiations under Section 262(*l*)(3)-(5) were required. Janssen had to bring suit within 30 days,[36] since Section 262(*l*)(6) requires the reference product sponsor to bring suit "not later than 30 days" after the parties agree on the patents to be litigated.[37] In its Complaint, Janssen alleges that Celltrion's efforts to "circumvent" the negotiation procedures forced it to "assert patent infringement claims that might never have needed to be litigated," or that "would have been litigated in a different form."[38, 39] However, if Section 262(*l*)(3) and (4) are found to be provisions to be followed in order to reach agreement, it seems possible that a court could permit Section 262(*l*)(3)(C) and (4) to be side-stepped if the biosimilar applicant agrees to litigate all patents on the reference product sponsor's list of patents. The court may find that Section 262(*l*)(9)(B) sheds light on this issue, since it imposes consequences if the biosimilar applicant "fails to complete an action required … under paragraph 3(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A)," but does not impose consequences for failing

to engage in negotiations under paragraph (4) if the biosimilar applicant immediately agrees to litigate all patents on the reference product sponsor's first list.

B. When Does the Reference Product Sponsor Have to Dance at the Courthouse?

As noted above, Janssen brought suit within 30 days of receiving Celltrion's statement of defenses in case Celltrion's interpretation of Section 262(*l*)(6) is found to be correct. It is 35 U.S.C. § 271(e)(6) that imposes consequences on the reference product sponsor/patent holder for not bringing suit within the 30-day period specified in Section 262(*l*)(6). That portion of the Patent Act provides in relevant part:

> (6) (A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—
>
> (i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and
>
> (ii) for which an action for infringement of the patent with respect to the biological product—
>
> (I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or
>
> (II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.
>
> (B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.[40]

Thus, Janssen felt compelled to bring suit to avoid its sole remedy being a reasonable royalty.[41]

However, it is possible that a reference product sponsor subject to 35 U.S.C. § 271(e)(6)(B) still could seek an injunction and/or damages in a patent suit brought under 35 U.S.C. § 271(a) after the biosimilar product is on the market. This is because 35 U.S.C. § 271(e)(6) refers to "paragraph (4)," which applies to "an act of infringement described in paragraph (2)," which defines the artificial act of infringement that can arise from filing a biosimilar application. When and if a court is faced with this issue, it will have to decide whether Section 271(e)(6)(B) was intended to completely foreclose the ability to obtain an injunction or recover damages from a biosimilar applicant, or only limit the remedies available in an action brought under Section 271(e)(2).

VI. Dance Goes On

The majority in *Amgen v. Sandoz* referred to the BPCIA as "a riddle wrapped in a mystery inside an enigma," and noted the court's efforts "to unravel the riddle, solve the mystery, and comprehend the enigma."[42] The issues raised in *Amgen v. Sandoz*, *Amgen v. Apotex*, and *Janssen v. Celltrion* reveal the complexities and uncertainties surrounding the patent dance provisions, and suggest that it could be years before we have a complete understanding of which steps are mandatory, which steps are optional, and how the different steps are interrelated.

(Endnotes)

* Courtenay C. Brinckerhoff is a partner in the Chemical, Biotechnology and Pharmaceutical practice at Foley & Lardner LLP and editor of the firm's PharmaPatentsBlog.com. The views expressed in this article are personal to the author and do not necessarily reflect those of other members of Foley & Lardner LLP or its clients.

cont. on page 6

cont. from page 5

[1] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.).
[2] 42 U.S.C. § 262(*l*)(2).
[3] 42 U.S.C. § 262(*l*)(3)(A).
[4] 42 U.S.C. § 262(*l*)(3)(B).
[5] *Id*.
[6] 42 U.S.C. § 262(*l*)(3)(C).
[7] 42 U.S.C. § 262(*l*)(4)(A).
[8] 42 U.S.C. § 262(*l*)(6)(A).
[9] 42 U.S.C. § 262(*l*)(5)(A).
[10] 42 U.S.C. § 262(*l*)(5)(B)(ii).
[11] 42 U.S.C. § 262(*l*)(5)(B)(i).
[12] 42 U.S.C. § 262(*l*)(6)(B).
[13] 42 U.S.C. § 262(*l*)(8).
[14] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).
[15] *Id.* at 1352-53.
[16] *Id.* at 1353.
[17] *Id.*
[18] *Id.* at 1357, 1360.
[19] Press Release, *Sandoz launches ZarxioTM (filgrastim-sndz), the first biosimilar in the United States*, Novartis (Sept. 3, 2015), *available at* http://multimediacapsule.thomsonone.com/novartis/sandoz-launches-filgrastim-sndz.
[20] *Sandoz*, 794 F.3d at 1354-55 (emphasis added).
[21] *Id*. at 1366 (Newman, J., concurring in part and dissenting in part).
[22] *Id.* at 1357.
[23] *Id.* at 1367 (Chen, J., concurring in part and dissenting in part).
[24] Docket, *Amgen Inc. v. Apotex Inc*., No. 16-1308 (Fed. Cir. 2016) (on appeal from S.D. Fla., No. 0:15-cv-61631-JIC).
[25] *Id.*
[26] Brief for Plaintiffs-Appellees, *Apotex*, No. 16-1308, Dkt. No. 67, at 42-55 (Fed. Cir. Feb. 4, 2016).
[27] Opening Brief for Defendants-Appellants, *Apotex*, No. 16-1308, Dkt. No. 38, at 29-35 (Fed. Cir. Dec. 30, 2015).
[28] Docket, *Janssen Biotech, Inc. v. Celltrion Healthcare Co.,* No. 1:15-cv-10698-MLW (D. Mass. 2015).
[29] *FDA's Arthritis Advisory Committee Recommends Approval of Celltrion's CT-P13, a Proposed Biosimilar Infliximab, for All Indications*, BusinessWire (Feb. 9, 2016), http://www.businesswire.com/news/home/ 20160209006848/en/FDA%E2%80%99s-Arthritis-Advisory-Committee-Recommends-Approval-Celltrion%E2%80%99s.
[30] Complaint, *Janssen*, No. 1:15-cv-10698-MLW, Dkt. No. 1 (D. Mass. Mar. 3, 2015).
[31] *Id.* at 29-31.
[32] Plaintiffs' Partial Motion for Summary Judgment and a Preliminary and Permanent Injunction, *Janssen*, No. 1:15-cv-10698-MLW, Dkt. No. 34, at 2 (D. Mass. Apr. 8, 2015).
[33] Order, *Janssen*, No. 1:15-cv-10698-MLW, Dkt No. 103, at 1 (D. Mass. Feb. 10, 2016).
[34] Celltrion eventually did share manufacturing information, which led to the dismissal of Count 8, relating to infringement of U.S. Patent No. 6,773,600, directed to methods of purifying biological products.
[35] *Sandoz*, 794 F.3d at 1356.
[36] Plaintiffs' Rule 56.1 Statement of Material Facts Not in Dispute in Support of Plaintiffs' Motion for Partial Summary Judgment, *Janssen*, No. 1:15-cv-10698-MLW, Dkt. No. 34-2, at 4 (D. Mass. Apr. 8, 2015).
[37] Although Janssen disputes this interpretation of the BPCIA, it nevertheless brought suit within 30 days of this statement.
[38] Complaint, *supra* note 30, at 23-26.
[39] One of the asserted patents, U.S. Patent No. 6,284,471, is undergoing reexamination at the U.S. Patent and Trademark Office. A motion to stay the district court proceedings with regard to that patent is pending. Plaintiff's Motion To Stay, *Janssen*, No. 1:15-cv-10698-MLW, Dkt. No. 8 (D. Mass. Mar. 16, 2015).
[40] 35 U.S.C. § 271(e)(6).
[41] Complaint, *supra* note 30, at 24-25.
[42] *Sandoz,* 794 F.3d at 1351 n.1.

NYIPLA Calendar

www.nyipla.org

Annual Meeting

➤ TUESDAY, MAY 17, 2016 ◄

The Princeton Club, 15 West 43rd Street, New York, NY 10036

PRESIDENT'S CORNER

The NYIPLA is abuzz with excitement regarding the 94th Annual Dinner in Honor of the Federal Judiciary on April 1, 2016. Preparing for the event is a great thrill, particularly for me, as President of the Association. This Dinner brings together our members, their guests and the Federal Judiciary in a unique setting to allow for a lovely social event celebrating the practice of intellectual property law.

From the NYIPLA's perspective, the Judges Dinner provides a way for the organization to give back to the intellectual property law community. First and foremost, we honor the federal judges within our jurisdiction and the chief judges of the patent pilot programs throughout the country. Over 150 federal judges, magistrate judges, and honored guests attended the event last year, and we expect at least as many will attend this year. Our honored guest list also includes key leaders from the U.S. Patent and Trademark Office, the Court of Federal Claims, the International Trade Commission, the Court of International Trade, the bankruptcy courts in our jurisdiction, and the New York Court of Appeals. Every year, each honored guest is hosted by an NYIPLA member at their table. This gives the hosts an opportunity to spend an evening with an esteemed judge or official. What a wonderful way to expand your network and impress your clients.

Our keynote speakers this year will be a duo of National Public Radio (NPR) celebrities. One is Nina Totenberg, who is an award-winning, legal affairs correspondent known for her reporting on the happenings of the U.S. Supreme Court. Peter Sagal will present with Nina Totenberg. Peter is also an acclaimed NPR personality, well-known for hosting NPR's panel game show called "Wait, Wait, Don't Tell Me." On his show, Peter tests listeners' and show participants' knowledge of current events in an engaging and humorous format. Together, Peter and Nina will surely be entertaining. I am truly excited to *see* and hear their presentations. And, if you are an NPR listener, I'm sure you too share my enthusiasm. If you don't listen to public radio, trust me, you will be pleasantly surprised!

In addition, each year at the Judges Dinner, the NYIPLA honors someone in the IP community for his or her outstanding public service. This year, we will honor retired Chief Judge Leonard Davis (E.D. Tex.), who was influential in making IP a household phrase in Texas. At a time when opportunities under U.S. patent law to invalidate U.S. patents are ever growing and legislators continue to threaten patent owners with more, it is nice to honor a jurist whose court has a reputation for upholding patents. Judge Davis handled more than 1,700 individual IP cases as a judge and transformed his court in Tyler, Texas into one of the most prestigious patent courts in America. The NYIPLA congratulates Judge Davis on his outstanding public service in IP law.

Finally, the Judges Dinner is a way for us to celebrate the NYIPLA organization with our members, many of whom have worked tirelessly to make the NYIPLA the dynamic organization that it is today. I particularly wish to recognize the Judges Dinner planning committee, this year led by Anne Hassett, and our fantastic executive office, headed by Feikje Van Rein. Without their hard work and guidance, the Judges Dinner simply would not be possible.

Dorothy R. Auth

HISTORIAN'S CORNER

As Time Goes By — On the Shoulders of Giants

"We are like dwarfs sitting on the shoulders of giants. We see more, and things that are more distant, than they did, not because our sight is superior or because we are taller than they, but because they raise us up, and by their great stature add to ours." (Quoting from "Metalogicon" by John of Salisbury, published in 1159 A.D.)

Early in 2016, two giants of our Association passed away. Both of them, namely, Evelyn Sommer and David F. Ryan, were past members of our Association's Board of Directors.

Evelyn Sommer was a member of our Association's Board from 1988 to 1991. Back then, she was one of only a handful of women to serve in that capacity. She served well as an active, thoughtful, diplomatic and graceful member of the Board.

Prior to graduation from Brooklyn Law School, Evelyn worked as a research chemist. Later she was an in-house patent attorney at Union Carbide in Manhattan, and she eventually worked her way up to become Chief Patent Counsel for Champion International in Stamford, Connecticut.

Evelyn taught patent and trademark law courses for many years at Quinnipiac University School of Law and its predecessor, the University of Bridgeport Law School. She had a photographic memory for IP case law. Upon her retirement from teaching, she worked in private practice full-time up until ten days before she passed away at the age of 91.

Dave Ryan was a member of our Association's Board from 2007 to 2010. During his service on the Board, he brought a quick wit and easy sense of humor, as well as a deep sense of commitment to our Association's role as a guidepost for the IP profession.

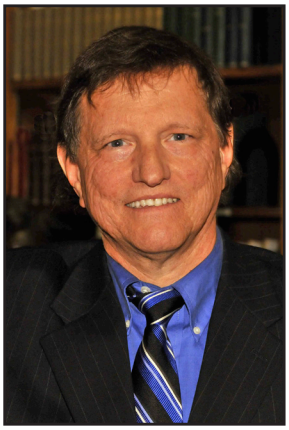
Prior to, and after, retiring from practice as an IP litigator for Fitzpatrick, Cella, Harper & Scinto, Dave served as a Co-Chair of the NYIPLA Amicus Brief Committee. In that capacity, he was author/co-author of a number of NYIPLA amicus briefs relating to antitrust and/or trade regulation issues at the IP interface. He passed away at the age of 73.

Dave and Evelyn shared at least two things in common. One was the intellectual capacity and electricity that they brought to our Association's table. The other was an avid support for the arts in the NY metropolitan region.

Those of us who had the pleasure of getting to know Dave and Evelyn, be it through our Association's activities, through school, through mentoring, or as colleagues in the practice of law, will not forget them. They offered us a special peek at what John of Salisbury might have envisioned when he coined the phrase "shoulders of giants." They also offered us a glimpse of what it is like to witness minds of steel in action. May many more similar minds of steel, tempered as they need be by kind consideration for others, grace our Association's ranks going forward!

With kind regards,

Dale Carlson



Dale Carlson, a retired partner at Wiggin and Dana, LLP is "distinguished practitioner-in-residence" at Quinnipiac University School of Law, NYIPLA historian, and a Past President. His email is dlcarlson007@gmail.com. The views expressed herein are those of the author and do not reflect the views of Quinnipiac University School of Law or the NYIPLA.

A Mixed Bag at the PTAB for Biosimilar Applicants

*By Paul A. Calvo, Ph.D.**

Some of the first institution decisions for inter partes review ("IPR") in a biosimilars context were recently handed down by the Patent Trial and Appeal Board ("PTAB" or "Board").[1] On July 13, 2015, the PTAB issued their institution decision on patents that Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim") had petitioned for IPR. Boehringer Ingelheim petitioned for IPR of two patents owned by Genentech, Inc. (U.S. Pat. Nos. 7,820,161 ("the '161 patent") and 7,976,838 ("the '838 patent"))[2] and one owned by Biogen Inc. (U.S. Pat. No. 8,329,172 ("the '172 patent")),[3] each of which dealt with the pharmaceutical Rituxan® (rituximab), an antibody that binds to the B-lymphocyte antigen CD20. The PTAB instituted trial on the two Genentech patents, but declined to do so for the Biogen patent. However, Boehringer Ingelheim requested an adverse judgment in all cases, likely due to negative clinical trial data for their BI 695500 biosimilar product.[4]

More recently, the PTAB denied institution on two petitions by Amgen challenging formulation patents owned by AbbVie, Inc. AbbVie's patents broadly cover its pharmaceutical Humira® (adalimumab), a human anti-tumor necrosis factor alpha antibody. In challenging U.S. Pat. Nos. 8,916,157 ("the '157 patent") and 8,916,158 ("the '158 patent"),[5] Amgen asserted that the generic formulations claimed were obvious in view of the prior art.

Amgen's and Boehringer Ingelheim's patent challenges are significant because the challenged patents significantly extend patent exclusivity for these blockbuster drugs beyond the original filings of the compounds themselves.

I. PTAB Continues Its Critical Treatment of Therapeutic Dosing Claims

For the Rituxan® product, the challenged patents generally claim (1) combination therapy using rituximab and methotrexate to treat rheumatoid arthritis (RA), (2) treating RA in certain patients that do not respond to other therapy according to a specific dosing regimen, and (3) treating low-grade B-cell non-Hodgkin's lymphoma using chemotherapy followed by administration of rituximab according to a specific regimen. Importantly, all of these indications are specifically recited on the Rituxan® product label and ostensibly would thus be infringed by a rituximab biosimilar developer copying the Rituxan® product label.

In deciding these Rituxan® product petitions, the PTAB remained consistent with its previous critical treatment of dosing regimen claims. For example, the PTAB recently held that dosing regimen claims associated with administration of the pharmaceutical Myozyme® were obvious in view of the prior art.[6] With respect to the Genentech '161 patent, the claims are directed to an RA combination therapy using rituximab and methotrexate. In petitioning for IPR, Boehringer Ingelheim asserted that the prior art suggested that treating RA with combination therapies, including methotrexate, was gaining recognition as an important approach for treating RA. The Board agreed with Boehringer Ingelheim and instituted review,[7] even though Genentech argued that the prior art's suggestion to treat RA with rituximab was inconsistent with the scientific literature at the time of the invention.

The claims of the '838 patent are directed to treating RA patients who experience an inadequate response to a TNFα-inhibitor, using an antibody that binds CD20, and specifies certain benchmarks for efficacy. With respect to the '838 patent, Boehringer Ingelheim asserted that the prior art disclosed treating RA using similar doses of rituximab alone and in conjunction with methotrexate and corticosteroids, as well as the therapeutic benchmarks. They also argued that treating RA patients who do not respond to TNFα-inhibitors was expressly disclosed in the prior art. The Board again sided with Boehringer Ingelheim despite Genentech's arguments that the cited art disclosed using contrary doses and that the dosing regimen displayed unexpected properties.[8]

II. The Risks of Using Clinical Trial Protocols as Printed Publications

Boehringer Ingelheim was unsuccessful, however, in convincing the Board to institute IPR for the Biogen '172 patent. The only claim of the '172 patent is directed to a method of treating low-grade B-cell non-Hodgkin's lymphoma by administering a specific chemotherapy followed by a specific dosing regimen of rituximab maintenance therapy. Here, Boehringer Ingelheim was not able to demonstrate that their cited art qualified as a publicly available printed publication.

cont. on page 10

cont. from page 9

In asserting invalidity, Boehringer Ingelheim first contended that the claim of the '172 patent was unpatentable over two references—the ECOG 1496 and ECOG 4494 clinical trial protocols. The ECOG is a cooperative group, funded primarily by the National Cancer Institute, composed of a large network of researchers, physicians, and health care professionals at public and private institutions around the world which performs multicenter cancer clinical trials. Boehringer Ingelheim contended that, because those trial protocols were designated as active prior to the effective filing date of the '172 patent, the ECOG could provide them to member institutions and physicians at ECOG institutions, and in turn, could discuss the protocols freely, distribute them to other physicians and patients, obtain informed consent from patients, and enroll patients in the clinical trials. They also contended that ECOG 1496 and ECOG 4494 were distributed to all members of the cooperative shortly after activation of the trial and before the '172 patent's effective filing date with no confidentiality restrictions.[9]

The Board concluded, however, that Boehringer Ingelheim presented no *direct evidence* from the ECOG, or from anyone directly associated with the ECOG, explaining specifically whether or how ECOG 1496 and ECOG 4494 were distributed, or whether the protocols were under confidentiality restrictions. Nor did Boehringer Ingelheim advance such firsthand evidence to support their contention that the ECOG protocols were actually disseminated to all members of the cooperative without confidentiality restrictions. Particularly problematic for Boehringer Ingelheim was that they did not explain how or where *they* obtained the ECOG protocols. Instead, they relied extensively on their expert's declaration for an explanation. However, the Board found that Boehringer Ingelheim's expert did not assert any firsthand knowledge of how the ECOG protocols at issue were distributed. The Board then declined to recognize ECOG 1496 and ECOG 4494 as printed publications based merely on expert testimony, even given the expert's "substantial credentials."[10]

Boehringer Ingelheim also asserted unpatentability based on another single reference, which did not explicitly disclose all of the claimed limitations, and relied on the general teaching in the art to assert claim 1 of the '172 patent was obvious. However, the Board was not persuaded, stating that although Boehringer Ingelheim represented the challenge based on a single reference, they relied on at least eight additional references to explain why claim 1 would have been obvious.[11]

The Board's treatment of the clinical trial protocols as prior art publications is reminiscent of the difficulty of using white papers or manuals in the electronics industry for the same purpose. Since it may be difficult to establish that clinical trial protocols were indexed or somehow cataloged, proving public accessibility may remain a challenge. In this case, since all of the unpatentability contentions were based in part on the ECOG protocols or did not adequately explain why a skilled artisan would have modified the cited references to arrive at the subject matter of the challenged claim, the Board denied institution.

III. Biologic Versus Small Molecule Formulations

Biologics are inherently more complex molecules than small molecules and are more susceptible to damage during formulation and long-term storage. The most common causes of protein degradation are protein aggregation, deamidation, and oxidation.[12] The claims of the AbbVie formulation patents are generally directed to high-concentration liquid formulations of human anti-TNF alpha antibodies at a concentration of 20 to 150 mg/ml. In challenging the validity of AbbVie's formulation patents, Amgen asserted that the formulation of antibodies was generally known at the time of AbbVie's filings, and that the ordinary skilled artisan would have been motivated to optimize different parameters such as pH, and components such as surfactants and polyols. Since the pharmaceutical Remicade® (infliximab) was also available at the time, and was of the same antibody class (IgG) as other known antibody formulations, Amgen argued that the skilled artisan would have understood that the formulation components of an antibody formulation could be applied to a new formulation of a structurally similar antibody.[13]

For its part, AbbVie argued that development of stable liquid antibody formulations, especially those at a concentration high enough to be suitable for subcutaneous administration, was far from routine. AbbVie argued that the commercial antibody formulations on which Amgen relied were either (1) low-concentration (10 mg/ml or less) liquid formulations or (2) lyophilized (i.e., freeze-dried) formulations, and thus irrelevant to the claimed formulations. AbbVie also argued that the prior art demonstrates unpredictability, not predictability, in the art of formulating proteins and that very often, proteins have to be evaluated individually and stabilized on a trial-and-error basis. And unfortunately for Amgen, AbbVie pointed to Amgen's prior reliance on particular pieces of prior art as evidence of unpredictability in the art during prosecution of Amgen's own protein formulation patent applications, as well as their expert's prior published statements regarding the complexities of protein folding and instability.[14]

In denying Amgen's petition, the PTAB was not persuaded that the prior art provided sufficient guidance such that a skilled artisan would have had a reasonable expectation of success in arriving at the formulation of stable, liquid pharmaceutical compositions comprising antibodies at a concentration of 20 to 150 mg/ml for several reasons. First, the PTAB felt that Amgen did not identify a commercially available antibody product that was available in liquid form, within the claimed antibody concentration range. The PTAB also maintained that while the prior art relied on by Amgen did indeed provide general guidance for making antibody formulations, it also underscored its unpredictability.[15]

IV. Key Takeaways from the Institution Decisions

Even though Boehringer Ingelheim failed to have trial instituted on one of the challenged patents, dosing regimen claims appear to be particularly vulnerable to IPR challenge. However, the use of clinical trial protocols as prior art may be difficult because the PTAB will closely scrutinize whether they qualify as publicly available printed publications. While early-filed biologic formulation patents appear to be stronger than their small molecule counterparts, later-filed formulation patents will likely come under fire as the world of prior art has increased.

Since biosimilar applicants can forgo the BPCIA's patent-exchange process[16] – at least for now – biosimilar applicants will increasingly use post-grant challenges at the USPTO to obtain patent certainty. Also, because there is a possibility to carve out patented indications from a product label, biosimilar applicants may not need to challenge all patented indications. No doubt these lessons are being learned by reference product sponsors as well in hopes of identifying ways to shore up patent estates covering their blockbuster biologics from future challenges.

(Endnotes)

* Paul A. Calvo, Ph.D. is a director in the Biotechnology/Chemical Group at Sterne, Kessler, Goldstein & Fox P.L.L.C., in Washington, D.C. He represents a diverse group of U.S. and international companies in the biotechnology and pharmaceuticals industries. Dr. Calvo provides counsel with regard to patents, and is experienced in U.S. and international patent procurement and enforcement matters, FDA/ANDA practice, technology transfer, invalidity, noninfringement, freedom-to-operate and patentability opinions, and due diligence investigations.

[1] In IPR 2013-00365, Hospira challenged Janssen's U.S. Pat. No. 6,747,002 related to dosing regimens for erythropoietin. Janssen disclaimed the challenged claims thereby rendering the petition for IPR moot.

[2] *Boehringer Ingelheim Int'l GmbH v. Genentech, Inc*., IPR2015-00415, Paper 13 (Jul. 17, 2015) and *Boehringer Ingelheim Int'l GmbH v. Genentech, Inc*., IPR2015-00417, Paper 11 (Jul. 14, 2015), respectively.

[3] *Boehringer Ingelheim Int'l GmbH v. Biogen Inc*., IPR2015-00418, Paper 14 (Jul. 13, 2015).

[4] *Boehringer Ingelheim stops biosimilar rituximab development*, Generic & Biosimilars Initiative (Oct. 30, 2015), http://www.gabionline.net/Biosimilars/News/Boehringer-Ingelheim-stops-biosimilar-rituximab-development.

[5] *Amgen, Inc. v. AbbVie Biotech. Ltd*., IPR2015-01514, Paper 9 (Jan. 14, 2015) and *Amgen, Inc. v. AbbVie Biotech. Ltd*., IPR2015-01517, Paper 9 (Jan. 14, 2016), respectively.

[6] *Biomarin Pharm. Inc. v. Genzyme Therapeutic Prods. Ltd. P'ship*, IPR2013-00537, Paper 79, at 17-21 (Feb. 23, 2015).

[7] *Genentech* , IPR2015-00415, Paper 13, at 12-23.

[8] *Genentech* , IPR2015-00417, Paper 11, at 16-23.

[9] *Biogen*, IPR2015-00418, Paper 14, at 9.

[10] *Id.* at 10-11.

[11] *Id*. at 14-21.

[12] Cleland, J.L., M.F. Powell and S.J. Shire, *The development of stable protein formulations: a close look at protein aggregation, deamidation, and oxidation,* 10 Crit. Rev. Ther. Drug Carrier Syst. 307-77 (1993).

[13] *Amgen*, IPR2015-01514, Paper 9, at 12.

[14] *Id*. at 12-14.

[15] *Id*. at 14-15.

[16] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

Don't Wait to Be Asked to the Patent Dance in Canada: Biosimilars Litigation in the United States and Canada

*By Melissa M. Dimilta and Emily P. Kettel**

A biologic drug, commonly referred to as a "biologic," is a protein-based therapy that is derived from, or produced using, a living organism. A biosimilar, or a "subsequent entry biologic" ("SEB"), as it is referred to in Canada, is a biologic that enters the market with a demonstrated similarity to a reference biologic. Interest in biologic drugs and biosimilars in the United States and Canada has increased in recent years, resulting in a corresponding increase in biologics litigation in both jurisdictions. The United States and Canada both have abbreviated pathways for biosimilar manufacturers to receive marketing authorization, as well as specialized procedures for resolving drug patent disputes. However, the manner in which biosimilar manufacturers interact with innovator manufacturers in these disputes differs significantly between the jurisdictions.

I. Biosimilars in the United States—The Patent Dance

In the United States, the Biologics Price Competition and Innovation Act ("BPCIA")[1] establishes and encourages parties to participate in the "patent dance," a complex patent dispute resolution process in which innovators, referred to as reference product sponsors ("RPS"), and biosimilar manufacturers exchange information and engage in litigation in three phases.

In the first phase, the biosimilar manufacturer provides the RPS with a copy of the biosimilar application and other information within 20 days of the acceptance of the biosimilar application by the Food and Drug Administration ("FDA").[2] The biosimilar manufacturer may provide the RPS with additional information requested by or on behalf of the RPS.

In the second phase, the RPS provides the biosimilar manufacturer with a list of patents that the RPS reasonably believes will support a claim of patent infringement against the biosimilar manufacturer, and identifies which patents on this list the RPS would be prepared to license to the biosimilar manufacturer.[3] In response, the biosimilar applicant may provide its own list of patents believed to be infringed by the RPS, and it is required to provide a detailed statement describing the factual and legal bases for its opinion that the patents on the RPS's list are invalid, or unenforceable or would not be infringed.[4]

In the third phase, the RPS must provide the biosimilar manufacturer with a detailed statement describing the factual and legal bases for its opinion that any patents on its list and any patents listed by the biosimilar applicant will be infringed, as well as respond to any statements made by the biosimilar applicant about the patents' unenforceability or invalidity.[5]

The parties then enter a period of negotiations, following which the RPS may commence litigation on any of those patents, seeking an injunction to prevent the biosimilar manufacturer from selling its product in the United States.

Biosimilar innovators such as Amgen and Janssen have taken the position in litigation that the patent dance is mandatory, and biosimilar manufacturers cannot opt out of the process. In the Federal Circuit's 2015 *Amgen v. Sandoz* decision, however, the court held that the patent dance is optional, and that a biosimilar manufacturer does not have to share its biosimilar application with the RPS or follow the patent dispute resolution procedures set out in the BPCIA.[6] The court also held that the biosimilar manufacturer must give 180-days' pre-marketing notice to the RPS once the FDA has approved the biosimilar product.[7]

II. Biosimilars in Canada—The Traditional Approach

Canada has taken a different approach to the approval and litigation of biologics and biosimilars than the United States. In Canada, there is no corresponding patent dance or specific legislation for biologic drug products. Manufacturers of biosimilar products in Canada must participate in the procedure set out in the Patented Medicines (Notice of Compliance) Regulations ("PMNOC Regulations"), which is the same legislation that governs traditional, small-molecule generic drugs.[8]

A. PMNOC Procedure in Canada

The PMNOC Regulations are essentially the Canadian equivalent of the Hatch-Waxman Act. Under the PMNOC Regulations, a manufacturer that has filed a New Drug Submission ("NDS"), or a supplement to an NDS, seeking marketing approval (in Canada, referred to as a Notice of Compliance ("NOC")) is called a "first person." A first

person may submit a "patent list" to the Minister of Health in relation to an NDS or NDS supplement for addition to the Patent Register.[9] The Patent Register is similar to the Orange Book. Patents for both traditional, small-molecule drugs and biologics can be listed on the Patent Register, whereas patents cannot be listed in the Orange Book for biologics.

A manufacturer seeking an NOC through a submission that "directly or indirectly" compares its drug with, or makes reference to, another drug marketed in Canada under an NOC is called a "second person."[10] Manufacturers of biosimilar products are considered second persons and are required to address the patents listed on the Patent Register.[11] A second person seeking an NOC must either await patent expiry or must address the patents listed on the Patent Register by serving a Notice of Allegation and Detailed Statement ("NOA") on the first person. If a patent is not listed on the Patent Register at the time the biosimilar NDS was filed, the biosimilar manufacturer need not address that patent.

A first person who receives an NOA has 45 days within which to initiate a proceeding in the Federal Court requesting an order prohibiting the Minister of Health from issuing an NOC to the second person until after the expiration of a patent addressed in the NOA.

The PMNOC Regulations proceedings are intended to be summary procedures and generally litigation concludes within 24 months. Evidence is filed by way of affidavit and the hearing is based on a paper record without the benefit of live evidence.

B. Patent Infringement and Impeachment Actions

Patent infringement and impeachment actions (actions invalidating the patent in question) are also available to RPS and biosimilar manufacturers in Canada.

Biosimilar manufacturers seeking market entry in Canada can attempt to invalidate or render unenforceable claims of a listed patent through an impeachment action. If the impeachment action is successful, the invalidated patent is removed from the Patent Register, no longer poses a barrier to market entry, and does not need to be addressed by any party by way of an NOA. An impeachment action involving a biosimilar follows the normal procedures for patent impeachment actions in Canada. A plaintiff commences an impeachment action by way of a statement of claim (equivalent to a complaint in the United States), stating the bases establishing standing and the reasons the patent is unenforceable or its claims are invalid. Unlike PMNOC Regulations proceedings, a patent impeachment action features full documentary and oral discovery and a trial with *viva voce* evidence. To date, no biosimilar manufacturer has impeached a patent before receiving an NOC for its biosimilar.

An RPS can initiate an infringement action against a biosimilar manufacturer following the biosimilar manufacturer's market entry.

These procedures are illustrated by the pending case of *Hospira Healthcare Corp. v. The Kennedy Trust for Rheumatology Research*,[12] where the biosimilar manufacturer Hospira is seeking a declaration of invalidity and non-infringement of Canadian Patent No. 2,261,630 ("the '630 Patent"). By counterclaim, the Kennedy Trust for Rheumatology Research and others seek a declaration that the claims of the '630 Patent are valid and that Hospira and others infringe and induce infringement of the '630 Patent. The trial, which will address the validity and infringement of the '630 Patent, is scheduled to commence in July 2016.[13]

III Biosimilars in Canada and the United States: Key Differences

The patent dance in the United States differs from the Canadian dual process of PMNOC Regulations and infringement/impeachment actions in the following ways:

Mandatory versus non-mandatory nature: In contrast to the BPCIA, the PMNOC Regulations are mandatory, assuming that a biosimilar manufacturer wishes to receive an NOC prior to expiry of a listed patent. For example, Amgen markets and sells filgrastim in Canada under the brand name NEUPOGEN®, and listed Canadian Patent No. 1,341,537 ("the '537 Patent") on the Patent Register against NEUPOGEN. To seek an NOC to market a filgrastim biosimilar product, Apotex was obligated by the PMNOC Regulations to address the '537 Patent by way of an NOA.

Notice to RPS: The PMNOC Regulations require a biosimilar manufacturer to provide notice to an RPS prior to market authorization by way of an NOA only for patents listed on the Patent Register against the reference product. The RPS has no opportunity to assert unlisted patents through the PMNOC Regulations process. However, the RPS can commence an infringement action post-NOC issuance for any patent, whether listed on the Register or not. Once the biosimilar NOC issues, the biosimilar manufacturer is free to market the biosimilar without delay or providing further notice to the RPS.

For example, Celltrion Healthcare Co. Ltd. filed NDSs for two infliximab biosimilars of Janssen's REMICADE® product. At the time Celltrion filed its NDSs, no patents were listed on the Patent Register for REMICADE. One month later, in December 2012,

cont. on page 14

cont. from page 13

Janssen listed the '630 Patent on the Patent Register. As no patents had been listed on the Patent Register when Celltrion filed its submissions, Celltrion did not have to provide notice to Janssen or address any patents in an NOA. Celltrion received two NOCs for its biosimilar products in January 2014.

In contrast, the Federal Circuit in *Amgen v. Sandoz*[14] and the U.S. District Court in *Amgen, Inc. v. Apotex Inc.*[15] both held that a biosimilar manufacturer must provide notice to the RPS after FDA approval.

Finality of litigation: Should an RPS choose to litigate patents based on information obtained through the patent dance, the RPS initiates litigation in Federal Court that ultimately will lead to a final judgment on the issues of infringement and invalidity. PMNOC Regulation proceedings, in contrast, do not result in final decisions on infringement or invalidity, and, accordingly, their outcome does not determine either person's rights to bring patent infringement or impeachment actions under the Patent Act.

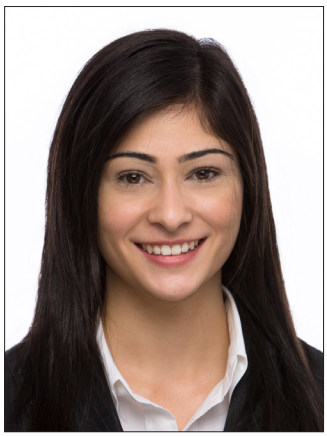
For example, as discussed above, Apotex addressed by way of an NOA Amgen's '537 Patent, which was listed on the Patent Register for NEUPOGEN. In *Amgen Canada v. Apotex Inc.*,[16] the Federal Court found that the only claim at issue was obvious and dismissed Amgen's prohibition application. Amgen appealed the decision. Shortly thereafter, Apotex's NOC issued, allowing Apotex to market and sell its biosimilar in Canada. Despite a decision of invalidity in the PMNOC Regulation litigation, Amgen was permitted under Canadian law to commence a patent infringement action against Apotex on the same '537 Patent.

IV. Conclusion

Biosimilars appear to present a significant and growing wave of pharmaceutical patent litigation in the United States and Canada. While the United States has enacted legislation establishing the patent dance, Canada has chosen to proceed via its already established, traditional route used for small-molecule generic drugs. It remains to be seen which process will be better equipped to handle the complex nature of biologic drug products.

(Endnotes)

* Melissa M. Dimilta is an associate in Bennett Jones LLP's Toronto office. She practices in all areas of intellectual property law, and assists clients with resolving and litigating intellectual property disputes with an emphasis on patent litigation and trademark litigation. In particular, she has significant experience litigating under the Patented Medicines (NOC) Regulations. She is also a registered trademark agent in Canada and is involved in trademark prosecution and opposition proceedings. Emily P. Kettel is also an associate in Bennett Jones LLP's Toronto office. She specializes in intellectual property litigation matters and assists clients with intellectual property disputes, with emphasis on the pharmaceutical, technology and consumer products industries. She has litigated matters in the Federal Court and Ontario Superior Court and has appeared before a number of administrative tribunals. She is also a registered Canadian trademark agent.



[1] 42 U.S.C. § 262(k).
[2] 42 U.S.C. § 262(*l*)(2).
[3] 42 U.S.C. § 262(*l*)(3)(A).
[4] 42 U.S.C. § 262(*l*)(3)(B.)
[5] 42 U.S.C. § 262(*l*)(3)(C).
[6] *Amgen Inc.v. Sandoz Inc.,*794 F.3d 1347, 1355-57 (Fed. Cir. 2015).
[7] *Id.* at 1357-58.
[8] SOR/93-133; the mandatory participation in the PMNOC Regulations procedure has not yet been challenged for biosimilars in Canada.
[9] PMNOC Regulations, s. 4(1).
[10] PMNOC Regulations, s. 2, 5(1).
[11] *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*, Section 2.1.2, Health Canada (March 2010), http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php.
[12] Case No. T-396-13.
[13] Hospira did not address the '630 Patent through the PMNOC Regulations as the '630 Patent did not issue until December 2012, and was not listed on the Patent Register when the Hospira filed its NDS. The Minister of Health's decision to grant Hospira's NOC was set aside on March 9, 2015, and is the subject of an appeal by both the Minister of Health and Hospira.
[14] 794 F.3d at 1355-57.
[15] Order on Motion for Preliminary Injunction, *Amgen, Inc. v. Apotex Inc.,* No. 15-61631-CIV, Dkt. No 71 (S.D. Fla. Dec. 9, 2015).
[16] 2015 FC 1261.

Biosimilars and the *Mensing* Product Liability Shield: A Primer for Patent Litigators

*By Alexandra D. Valenti, Joshua A. Whitehill, Elaine Herrmann Blais and Robert V. Cerwinski**

As any patent litigator who tries Hatch-Waxman cases knows, a generic drug has to have the same label as the branded reference listed drug ("RLD"), with very limited exceptions.[1] This essentially bright-line rule has clarified Hatch-Waxman disputes, where a generic manufacturer's product label, together with the rest of its Abbreviated New Drug Application, limits what the generic manufacturer can market. Thus, the label itself can be dispositive of the issue of infringement.[2] Unbeknownst to many patent litigators though, the "same labeling" requirement for generic drugs has also significantly impacted products liability litigation by shielding generic drug manufacturers from a variety of state law tort claims. This shield, based on federal preemption, was established by the United States Supreme Court in its landmark case *PLIVA, Inc. v. Mensing*,[3] and *Mensing*'s progeny in federal and state courts.

With the passage of the Biologics Price Competition and Innovation Act ("BPCIA") in 2009 and the FDA's approval in March 2015 of Sandoz's Zarxio® product, the first licensed biosimilar product in the United States, the pharmaceutical industry and its patent attorneys have been primarily focused on how to maneuver through the complexities of the new regulatory framework, and how (if at all) to engage in the "patent dance."[4] However, the impending flood of new biosimilar products[5] may also bring a flurry of products liability cases. Products liability litigators may need to consider important differences between generic drugs and biosimilars to determine whether *Mensing* applies to biosimilars.

Although the BPCIA was enacted for many of the same purposes as the Hatch-Waxman Act, such as to streamline the regulatory approval process and to facilitate competition with lower cost alternatives, the statutory schemes differ in ways that affect how generic drugs and biosimilars reach the market and how they are sold. For instance, unlike the Hatch-Waxman Act, the BPCIA does not contain a corresponding "same labeling" requirement, which means that a biosimilar product's label could be substantively different than the label of the reference listed product ("RLP"). Based on the "same labeling" requirement for generic drugs, generic drug manufacturers have successfully relied on *Mensing* preemption to defeat various state law claims. Biosimilar manufacturers, however, may need to consider if and how the BPCIA's lack of a "same labeling" requirement (and any FDA regulation or guidance on biosimilar labeling, which the FDA has yet to release) may impact the availability of *Mensing* preemption. In addition, while pharmacists can automatically substitute a generic drug for the RLD, biosimilars will not qualify for automatic substitution unless they are deemed "interchangeable" by the FDA.[6] Manufacturers of non-interchangeable biosimilars may therefore choose to actively market their products, which can potentially lead to failure-to-warn or false advertising claims. Thus far, generic drug manufacturers have generally been able to ward off these claims based on established defenses, such as federal preemption or lack of proximate causation.

While the focuses of Hatch-Waxman and products liability cases are distinct, patent litigators and products liability litigators may counsel the very same pharmaceutical company clients and may have to decipher some of the same statutory and regulatory schemes that apply to product labels, interchangeability, and the content of pharmaceutical products. To service their clients most effectively, these lawyers should work collaboratively and keep apprised of the legal and regulatory issues that they each may face. The aim of this article is to help pharmaceutical patent litigators appreciate some of the issues surrounding products liability that may arise in the unfamiliar and somewhat uncertain legal landscape of biosimilars.

I. Biosimilar Labeling: *Mensing* Preemption of Failure-to-Warn Claims

State law tort claims based on insufficient warnings in generic pharmaceutical product labels, i.e., "failure-to-warn" claims, are preempted under the United States Supreme Court's decision in *PLIVA, Inc. v. Mensing*.[7]

As noted above, the Hatch-Waxman Act requires a generic pharmaceutical manufacturer to provide a label that is the same as the branded reference drug label. Based on this federal "sameness" requirement, the Supreme Court in *Mensing* held that a generic company

cont. on page 16

cont. from page 15

would violate federal law if it changed its version of the FDA-approved brand label to satisfy a state law duty to properly warn.[8] In other words, it is "impossible for [generic drug manufacturers] to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."[9] In this way, there is a conflict between state and federal law, and the state law duty is preempted by federal law.[10]

The Supreme Court also rejected any claim that a generic drug manufacturer can unilaterally change its labeling under various federal procedures. For instance, the Court held that generic drug companies cannot use the "changes-being-effected" process to unilaterally change their labeling, nor can they send "Dear Doctor" letters to provide additional information to physicians above and beyond what is already stated in the brand label.[11] Moreover, the only mechanism by which generic drug companies purportedly could achieve a change in the package insert—to propose or ask the FDA for assistance in effecting a change—would not in itself have satisfied any state law duty to provide adequate labeling.[12] Thus, the federal requirement that generic labels must have the same label as the reference listed branded product generally[13] preempts failure-to-warn claims.

But, will similar preemption principles bar failure-to-warn claims against biosimilars? Because the BPCIA does not require the same labels for a biosimilar and the RLP, and since the FDA has yet to promulgate any regulations or release final guidance on biosimilar labeling, the answer is unclear.

Take the Zarxio® product as an example. The Zarxio product is Sandoz's biosimilar of Amgen's Neupogen® (filgrastim) product. The FDA and Sandoz agreed that the Zarxio product's label should be "essentially the same" as the Neupogen product label, the FDA gave the Neupogen product label to Sandoz to use as template for its Zarxio product, and the FDA instructed Sandoz to highlight and justify any changes it made to the Neupogen product label, much in the same way justification would be required if the Zarxio product were a generic drug approved under the Hatch-Waxman Act.[14] Although the FDA and Sandoz agreed about the labeling for the Zarxio product, the pharmaceutical industry has raised questions about whether the "same labeling" approach is appropriate for biologics, and the FDA still has not issued any formal guidance on biosimilar labeling.[15]

Under *Mensing*, the key question is whether "essentially the same" is comparable to the "same as" requirement under Hatch-Waxman, such that preemption would apply. *Mensing*'s reasoning leaves open an argument that only a federal requirement of identical labels can have preemptive effect on state law failure-to-warn claims. Without a requirement that the labels be the same, the generic manufacturer could arguably comply with both federal law and a state law duty to provide adequate warnings. In particular, *Mensing* notes that a generic manufacturer cannot even strengthen a warning without the brand moving first, which may not be the case with biosimilars, even where the FDA requires a label that is "essentially the same as" the brand label. In other words, it might not be impossible for biosimilar manufacturers to comply with both federal and state law, as biosimilar manufacturers might be able to amend their product labels unilaterally to strengthen warnings if necessary to satisfy state tort law standards.

Because federal law arguably does not require the Zarxio product's label to be the same as that of the Neupogen product, hypothetical tort plaintiffs could argue that *Mensing* preemption would not apply to failure-to-warn claims based on its label. Looking ahead, if the FDA were to require a particular biosimilar to copy the RLP's label, it might be that *Mensing* preemption applies in that case even though the overall regulatory framework allows for unilateral changes.

II. Biosimilarity vs. Bioequivalence: *Bartlett* Preemption of Design Defect Claims

Since *Mensing*, courts have further strengthened the applicability of federal preemption to state tort law claims against generic pharmaceutical manufacturers. In *Mutual Pharm. Co. v. Bartlett*, the United States Supreme Court expressly reaffirmed *Mensing*, and additionally held that design defect allegations against a generic drug manufacturer, like allegations that directly challenge a generic drug's labeling, are preempted by federal law.[16] The Supreme Court reached this conclusion because, to avoid state law design defect liability, a generic drug manufacturer would either have to change a pharmaceutical product's design or its labeling from that approved by the FDA for the brand-name medication, neither of which is permissible under federal law.[17] As the Supreme Court explained, "redesign [is] not possible . . . [because] the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based."[18] Thus, such state law requirements that conflict with federal law are preempted and "without effect."[19] Subsequently, numerous federal and state courts have applied *Bartlett* in rejecting plaintiffs' design defect claims against generic drug manufacturers as preempted.[20]

To obtain approval, a biosimilar applicant must provide data showing, among other things, that the product "is highly similar to the reference product notwithstanding minor differences in clinically inactive components," that "the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling," and that "the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product."[21] Due to the complexity of their structure, manufacture, and characterization, however, biosimilars are not required to be chemically or clinically identical to the RLP. Since there is no federal "sameness" requirement that the active substance in the biosimilar be identical to that in the RLP, unlike the Hatch-Waxman framework for generic drugs, tort plaintiffs may argue that *Bartlett* preemption should not apply to design defect claims based on biosimilar products. Again, because the federal regulatory framework under the BPCIA allows for differences between an RLP and its biosimilars, biosimilar manufacturers will need to consider whether *Bartlett* preemption is available to bar state law tort claims for design defects.

III. No Automatic Substitution: Failure-to-Warn and False Advertising Claims

As discussed above, pharmacists cannot automatically substitute biosimilars to the same extent that they can automatically substitute generic drugs. This means that to provide a patient with a biosimilar that the FDA has not deemed interchangeable, a physician will normally need to explicitly prescribe the biosimilar for the patient, or else the patient will receive the RLP. In contrast, if a physician prescribes a small molecule drug, a pharmacist typically can unilaterally substitute the RLD with the generic version of the drug. As a result, biosimilar manufacturers may choose to actively market their biosimilar products, whereas generic drugs are generally not marketed. These realities may have two consequences in terms of product liability claims against biosimilar manufacturers.

First, in many cases, generic drug manufacturers have been able to defend themselves from failure-to-warn claims by successfully challenging proximate causation, an essential element of a tort claim. In the generic drug context, a typical fact pattern is as follows: A physician prescribes the patient a branded drug product. The patient goes to the pharmacy to fill that prescription, and the pharmacist substitutes a generic product due to insurance plan requirements and/or to save the patient money on co-pays. The patient, therefore, is only ever exposed to the generic product even though the physician had originally prescribed the branded product. The patient is injured and later files a product liability suit against the generic manufacturer on a failure-to-warn theory. In these cases, at least to the extent the failure-to-warn claim is not already barred under a preemption theory, a proximate cause defense may further shield the generic manufacturer from liability. Because the physician only prescribed the brand drug, the physician likely relied only on the brand label in making his or her prescribing decision. The physician breaks the chain of causation between the generic product and the alleged injury. The patient-plaintiff, therefore, cannot establish proximate causation between the generic's product label and the injury.[22] In order to establish proximate causation, the patient-plaintiff would have to demonstrate that the physician reviewed the generic's product label and relied upon that label in making the prescribing decision.

On the other hand, because only interchangeable biosimilars can be automatically substituted for the RLP, in order for the patient to be exposed to a non-interchangeable biosimilar product the physician must have prescribed the biosimilar and not the RLP. In these circumstances, tort plaintiffs may argue that the proximate cause defense seen in generic drug cases should not be available to biosimilar manufacturers.

Second, because biosimilar manufacturers cannot rely on automatic substitution for increased prescriptions of their products, these companies may find it necessary to actively market their products to physicians and patients, in much the same way that branded pharmaceutical products are marketed. As a result, if a biosimilar manufacturer were to actively market its product, that product may be subject to false advertising claims. These claims are often challenged by generic manufacturers because generic products generally are not marketed or advertised.

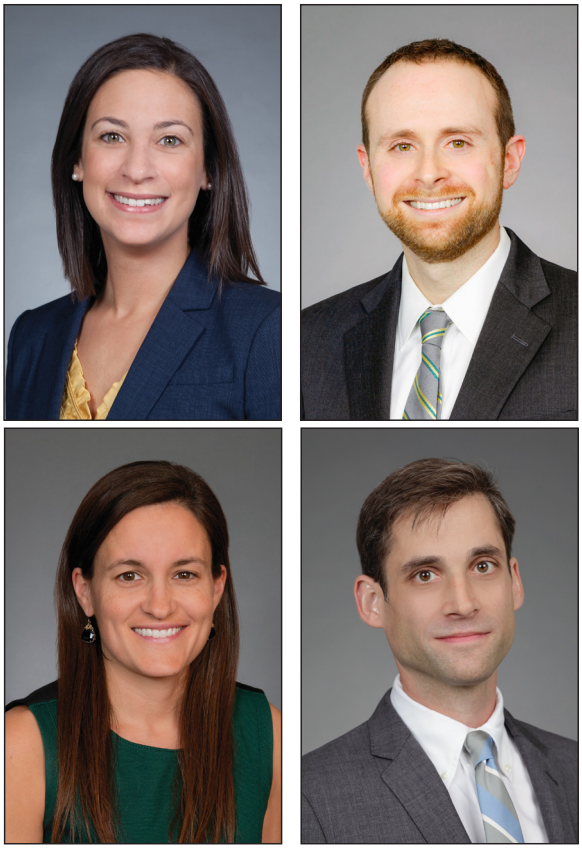
IV. Conclusion

Biosimilars present a complex, new obstacle for regulators, courts, pharmaceutical companies, and litigators to tackle. The pharmaceutical industry and patent litigators are awaiting FDA guidance and regulations on biosimilar labeling, naming, and interchangeability because those issues will impact how new biosimilars will be prescribed, sold, and litigated under the BPCIA. Those issues may also have implications down the road for biosimilar manufacturers' potential liability for failure-to-warn, design defect, and false advertising claims. Because of some key differences between the

cont. on page 18

cont. from page 17

BPCIA and the Hatch-Waxman Act, litigators defending biosimilar manufacturers may need to get creative and think outside of the *Mensing* box. Still, the overriding similarity of both Acts' objectives to streamline the drug approval process and allow for smoother market entry of bioequivalent pharmaceutical products may prompt courts to modify established products liability doctrines, or create new ones, that extend to biosimilar manufacturers the same kind of protections that are available to generic drug manufacturers.



(Endnotes)

* Alexandra D. Valenti is an associate in the Intellectual Property Group of Goodwin Procter LLP's New York office. She focuses her practice on patent matters, with an emphasis on biotechnology and pharmaceuticals, as well as on products liability litigation. Joshua A. Whitehill is a senior litigation associate in the Intellectual Property Group of Goodwin Procter LLP's New York office, and focuses his practice on patent matters, with a concentration in the areas of biotechnology and pharmaceuticals. Mr. Whitehill is a member of the NYIPLA's Publications Committee. Elaine Herrmann Blais is a partner in the Intellectual Property Group at Goodwin Procter LLP and the head of the Litigation Department in the firm's Boston office. She focuses her practice on intellectual property litigation, particularly with respect to patent litigation. Robert V. Cerwinski is a partner in Goodwin Procter's IP Litigation Group in New York. His primary focus is on patent and trade secret litigation involving pharmaceutical and biological products. Ms. Blais and Mr. Cerwinski are co-founders and editors of Goodwin Procter's biosimilars blog, www.bigmoleculewatch.com, and editors of the firm's annual Biosimilars Reference Guide. The opinions expressed are those of the authors and do not necessarily reflect the views of Goodwin Procter LLP or its clients.

[1] *See* 21 U.S.C. § 355(j)(2)(A)(v) ("An abbreviated application for a new drug shall contain … information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers[.]"). In limited situations, a generic manufacturer, can revise or remove information that is in the reference product's label, provided that such removal has no impact on the safety or efficacy of the drug. *See id.*; 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.127(a)(7).

[2] *See*, *e.g.*, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1326 (Fed. Cir. 2012) (holding that a generic drug could not infringe a method of treatment claim where the reference product's label did not suggest that the drug was safe and effective for the claimed use).

[3] 131 S. Ct. 2567 (2011).

[4] *See generally Amgen Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

[5] On February 9, 2016, the FDA's Advisory Committee overwhelmingly supported approval of Celltrion's infliximab product, a biosimilar of Janssen's Remicade® product, which makes it seem likely that the FDA will soon approve a second biosimilar in the United States. *See* Celltrion Press Release, *FDA's Arthritis Advisory Committee Recommends Approval of Celltrion's CT-P13, a Proposed Biosimilar Infliximab, for All Eligible Indications* (Feb. 10, 2016), http://celltrion.com/en/company/notice_view.asp?idx=481&code=ennews.

[6] *See* 42 U.S.C. § 262(i)(3) ("The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."); *see also* 42 U.S.C. § 262(k)(4).

[7] 131 S. Ct. 2567 (2011).

[8] *Id.* at 2578.

[9] *Id.*

[10] *Id.*

[11] *Id.* at 2575-76.

[12] *Id.* at 2578.

[13] Some courts have allowed plaintiffs to proceed on narrow failure-to-warn theories that the generic pharmaceutical manufacturer allegedly failed to update its label to match a strengthened branded product label. In these circumstances, courts have held that *Mensing* does not require dismissal of the so-called "failure-to-update" claim because it was not impossible for the generic pharmaceutical manufacturer to have changed its label to match the branded label. *See*, *e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013).

[14] *See* Administrative and Correspondence Documents for BLA # 125553, Memorandum of Meeting Minutes (Nov. 19, 2013), at 16-17, and General Advice Letter (Feb. 6, 2015), at 6, *available at* http://www.accessdata.fda.gov/drugsatfda_ docs /nda/2015/125553Orig1s000AdminCorres.pdf.

[15] In June 2015, AbbVie filed a Citizen Petition challenging the FDA's use of the "same labeling" approach for the Zarxio product, which was supported by comments from Amgen Inc. and Genentech Inc. and opposed by comments from Momenta Pharmaceuticals, Inc. and Sandoz. *See* FDA Citizen Petition Docket ID: FDA-2015-P-2000, *available at* http://www.regulations.gov/#!docketDetail;D=FDA-2015-P-2000. In December 2015, other industry groups filed an additional Citizen Petition asking the FDA to adopt a "same labeling" approach for biosimilars (*see* FDA Citizen Petition Docket ID: FDA-2015-P-4529, *available at* http://www.regulations.gov/#!docketDetail;D=FDA-2015-P-4529); while in January 2016, other industry groups asked the FDA to adopt a dissimilar approach (*see* FDA Citizen Petition Docket ID: FDA-2015-P-5022, *available at* http://www.regulations.gov/#!docketDetail;D=FDA-2015-P-5022).

[16] 133 S. Ct. 2466, 2470 (2013).

[17] *Id.* at 2474-76.

[18] *Id.* at 2475.

[19] *Id.* at 2476-77.

[20] *See*, *e.g.*, *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 165 (3d Cir. 2014); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014); *In re Isotretinoin Litig.*, No. ATL-L-1321-09, 2013 WL 3483813, at *5-6 (N.J. Super. Ct. June 28, 2013).

[21] 42 U.S.C. § 262(k)(2); *see also* 42 U.S.C. § 262(k)(4) (describing additional requirements for an interchangeability determination).

[22] *See*, *e.g.*, *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013) (no causation on failure-to-update claim where plaintiff's physician "wrote a prescription for the reference listed drug, Reglan, which a pharmacist then filled with metoclopramide" and plaintiff's "prescribing physician relied on information provided by the manufacturer of the reference listed drug, which included the updated warning"); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1097-98 (8th Cir. 2013) (where "[Plaintiff's] physician prescribed Reglan—not generic metoclopramide," finding no causation on failure-to-update claim because "the causal link between [plaintiff's] injury and [generic manufacturer's] admitted failure to incorporate the 2004 label change, if any, was broken"); *Huck v. Physicians Grp.*, No. LACV018947, Order, at 8-9 (Iowa Dist. Ct. Sept. 24, 2015) ("[B]ased on the undisputed facts that neither Huck nor either of her physicians ever read or relied on PLIVA's package insert, any other material provided by PLIVA or any communication from PLIVA[,] . . . PLIVA is entitled to summary judgment on the ground that PLIVA's failure to adopt the 2004 sentences was not a cause of Huck's injuries.").

Trends in State Laws on Pharmacy Substitution of Interchangeable Biosimilars

*By Thomas Meloro and Tara Thieme**

Since 2013, at least 31 states have considered or passed legislation regulating the substitution of a biosimilar drug product for the "reference product" upon which FDA approval was based.[1] Requirements of these laws differ substantially from state to state. However, industry players have reached consensus on some legislative language, which may harmonize future legislation. This article provides a brief summary of the currently enacted state laws on biosimilar substitution and discusses current trends for specific provisions.

I. A Little Background – Pharmacy Substitution of Generic Drug Products

To provide context for a discussion of biosimilars substitution laws, a little background on generic drug substitution law is useful. Although the FDA regulates the approval of generic drug products, individual states regulate when and how that generic product may be substituted for the reference product. In general, state laws either require or permit a pharmacist to substitute a generic drug that is therapeutically equivalent to the branded drug. In 14 states, generic substitution is mandatory; in the remaining 36 states, generic substitution is permissive.[2] When the prescriber indicates that the drug is not to be substituted, e.g., by writing "dispense as written," "may not substitute," or similar language, the pharmacist must provide the branded drug.[3] In addition, depending on the state, generic substitution laws may also require patient notification or consent, or that the price of the generic is less than or equal to the branded version for substitution to be required.[4]

Unlike generic drug products, biosimilars are not evaluated as "therapeutically equivalent" to the reference drug. Instead, the FDA deems a biosimilar product to be "highly similar" to the reference product.[5] Should the biosimilar applicant choose to pursue it, a biosimilar may also be deemed "interchangeable" with the reference drug.[6] To prove interchangeability, the biosimilar applicant must demonstrate that the product produces the "same clinical result as the reference product in any given patient" and, for products with multiple doses, that the risk of switching between the reference product and the biosimilar is not greater than the risk of administering only the reference product.[7] Due to these differences in the regulatory process, states have begun to adopt laws regulating the substitution of biosimilars that diverge from the laws governing generic substitution.

II. Currently Enacted and Pending State Legislation on Biosimilar Substitution

A. Enacted Laws

As of the writing of this article, 18 states have enacted laws regulating the substitution of biosimilars by pharmacists. The enacted biosimilar substitution laws address three main issues: (1) interchangeability and substitution; (2) additional duties for pharmacists; and (3) regulation of the biosimilar product and associated product liability.

1. Regulations on Substitution

All 18 states that have enacted laws governing biosimilar substitution expressly require the substituted biosimilar to be approved as an interchangeable biosimilar by the FDA.[8] In Indiana and Washington, a practitioner must affirmatively indicate that substitution is permitted.[9] All remaining states except Indiana and Washington disallow substitution when the prescribing practitioner expressly prohibits substitution in writing or in a verbal or electronic instruction.[10] Many states also have prerequisites to substitution, such as requiring patient notification before substituting the reference drug with an interchangeable biosimilar.[11] Some states require counseling patients on topics such as the price difference between the products and/or require that the biosimilar product costs less than the reference product in order to be substituted.[12]

2. Additional Requirements for Pharmacists When Making Biosimilar Substitutions

Pharmacists may have additional responsibilities when substituting an interchangeable biosimilar for a reference product, such as a requirement to provide notice to the prescriber. Seventeen states require the pharmacist to notify the practitioner after substitution, although the length of time to complete this task varies from 24 hours in North Dakota to ten days in Delaware and Indiana.[13] Most other states give the pharmacist three to five days to notify the prescribing practitioner of the substitution.[14] More recently, states have been adopting a general period of "reasonable time."[15]

Twelve states require pharmacists to keep records of substitutions for a specified period of time, varying anywhere from one to ten years.[16] Statutes in Utah, North Carolina, Texas, California, and Georgia require record keeping but do not provide a specific retention period.[17] The Louisiana statute does not contain record-keeping requirements specific to biosimilar product substitution.[18]

3. Regulation of the Biosimilar Product and Associated Liability for Pharmacists

Nine states have elected to include a provision directed towards pharmacists' liability concerns, mandating that a pharmacist who substitutes incurs no greater liability by dispensing the biosimilar product than if he/she had dispensed the prescribed reference product.[19] Utah requires that the interchangeable product must be "permitted to move in interstate commerce."[20]

B. Trends and Currently Pending Legislation

In December 2014, the Generic Pharmaceutical Association ("GPhA") and the Biotechnology Innovation Organization ("BIO") announced that they had reached an agreement regarding recommended language for the notification requirements of biosimilar substitution.[21] The compromise language states:

> Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. If no such system is available between the pharmacist and prescriber, the pharmacist shall communicate the biologic product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:
> • There is no FDA-approved interchangeable biologic for the product prescribed; or
> • a refill prescription is not changed from the product dispensed on the prior filling of the prescription.[22]

Statutes enacted in 2014 in Delaware and Indiana contain provisions similar to the compromise language.[23] Moreover, eight of the ten state laws enacted in 2015 reflect this compromise and include some reference to automatic notification of prescribers through electronic health records, with Louisiana being the exception.[24] Two of these eight states include the "reasonable time" language, while the remaining six states specify a specific time to provide notice.[25] In addition, the statute in Utah amended in 2015 now reflects the compromise language.[26]

As of the writing of this article, bills are pending in Arizona, Connecticut, Hawaii, Idaho, Kentucky, Michigan, Missouri, Nebraska, New York, Oklahoma, Pennsylvania, and Vermont.[27] The bills in Arizona, Connecticut, Hawaii, Idaho, Kentucky, Missouri, Nebraska, and Pennsylvania reflect the compromise language from BIO and GPhA.

Table 1. Enacted Biosimilar Substitution State Laws in Chronological Order

	Date Enacted	Patient Notification Required?	Practitioner Notification Required?	Record Period?	Other	Citation
VA	03/16/2013	Yes, prior to dispensing and on the label	Yes, 5 business days (sunset July 1, 2015)	2 years	Patient has the right to refuse substitution; must inform patient of retail costs (sunset July 1, 2015)	Va. Code § 54.1-3408.04 (2013)
UT	04/26/2013	Yes, patient may request or consent to substitution	Yes, 5 business days Amended statue reflects compromise language	Record keeping required, but no period given	Pharmacist incurs no greater liability; product must be able to move in interstate commerce	Utah Code § 58-17b-605.5 (2013), as amended by H.B. 279 (2015)
FL	06/03/2013	Yes	No	2 years	Patient has the right to refuse substitution; must inform patient of retail costs	Fla. Stat. § 465.0252 (2013); § 465.025(3)(a) (Record retention)
OR	06/06/2013	Yes, prior to dispensing	Yes, within 3 business days	3 years		Or. Rev. Stat. § 689.522 (2013), as amended by S.B. 460 (2016)
ND	06/26/2013	Yes	Yes, within 24 hours	5 years	Patient has the right to refuse substitution	N.D. Cent. Code § 19-02.1-14.3 (2013)
IN	03/31/2014	Yes	Yes, 10 calendar days	2 years for pharmacist, 7 years prescriber	Contains provisions similar to compromise language	Ind. Code § 16-42-25-1 to -8 (2014); §§ 25-26-13-25(a), 16-39-7-1 (Record retention)
DE	05/28/2014	Yes, prior to dispensing and on the label	Yes, 10 days	3 years	Contains provisions similar to compromise language	Del. Code tit. 24, §§ 2549A, 2532 (2014)
MA	06/23/2014	Yes	Yes, reasonable time	1 year for both pharmacist and prescriber	Reflects compromise language	Mass. Gen. Laws ch. 112, § 12EE (2014)
CO	04/03/2015	Yes, in writing and orally, and on the label	Yes, reasonable time	2 years	Reflects compromise language; substitution only allowed where biosimilar costs less than reference product; no greater liability for pharmacist in substituting	Colo. Rev. Stat. § 12-42.5-122 (2015)
TN	05/04/2015	Yes, on label	Yes, within 5 days	2 years	Reflects compromise language; no greater liability for pharmacist in substituting	Tenn. Code Ann. § 53-10, Part 2 (2015); § 53-14-110 (Record retention)
GA	05/06/2015	Yes, on label	Yes, 2 business days	Record keeping required, but no period given	Reflects compromise language; to be substituted, prescriber must use non-proprietary name; patient may refuse substitution	Ga. Code § 26-4-81 (2015)
WA	05/11/2015	Yes	Yes, 5 business days	2 years	Reflects compromise language; no greater liability for pharmacist in substituting; must substitute where cheaper than reference product and otherwise allowed	Wash. Rev. Code § 69.41 (2015); § 18.64.245 (2013) (Record retention)
NC	05/21/2015	Yes	Yes, reasonable time	Record keeping required, but no period given	Reflects compromise language; no substitution unless cost of substitute is less than the reference product; no greater liability for pharmacist in substituting; drug quality provisions	N.C. Gen. Stat. § 90-85.27-31 (2015)
LA	07/01/2015	Does not address	Yes, 5 days	No specific regulations for biosimilars	No cause of action against pharmacist for a communication as required by this section	H.B. No. 319, La. Reg. Sess., Act. No. 391 (2015) (amending R.S.37: 1164(16), enacting R.S. 37:1164(58) and 1226.1))
IL	07/30/2015	Yes	Yes, 5 days	5 years	Reflects compromise language	S.B. 455, Ill. Pub. Act. 99-200 (2015)
TX	09/01/2015	Yes, on label	Yes, 3 business days	Record keeping required, but no period given	Reflects compromise language (sunset September 1, 2019); patient may refuse substitution; no greater liability for pharmacist in substituting	Tex. Code §§ 562.005-011 (2015)
CA	10/06/2015	Yes	Yes, 5 days	Record keeping required, but no period given	Reflects compromise language; no greater liability for pharmacist in substituting	S.B. 671, adding § 4073.5 to Ca. BPC (2015)
NJ	11/09/2015	Yes, in writing and on the label	Yes, 5 business days	5 years	No greater liability for pharmacist in substituting	A-2477 (2015), adding new section to N.J. Rev. Stat., ch. 6, tit. 24

cont. on page 22

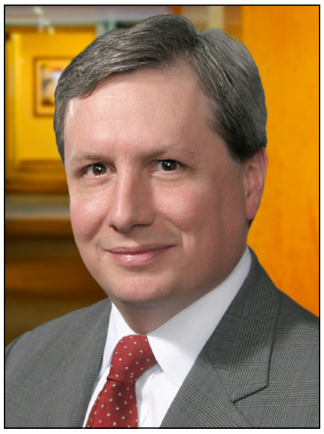
cont. from page 21

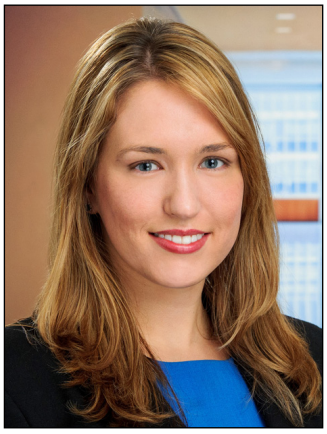
III. Conclusion

Despite potential hurdles in biosimilar substitution, all states which have established standards for biosimilar substitution, except Indiana and Washington, allow interchangeable biosimilars to replace brand-name biologics unless instructions from the prescribing practitioner dictate otherwise. State legislation on biosimilar substitution generally includes provisions addressing (1) interchangeability and substitution; (2) additional duties for pharmacists; and (3) regulation of the biosimilar product and associated product liability, and vary by state. However, industry players have reached consensus on some legislative language, which may help harmonize future legislation.

(Endnotes)

* Thomas Meloro is a Partner and Chair of the Intellectual Property Department at Willkie Farr & Gallagher LLP. Tara Thieme is an associate in Willkie Farr & Gallagher LLP's Intellectual Property group, where her practice focuses on intellectual property litigation. The opinions expressed are those of the authors and do not necessarily reflect the views of Willkie Farr & Gallagher LLP or its clients.





[1] Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NCSL Health Highlights (Jan. 4, 2016), http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx.

[2] HHS, Office of the Assistant Sec'y for Planning & Evaluation, ASPE Issue Brief: Expanding the Use of Generic Drugs, Appendix A: List of State Laws Governing Generic Substitution by Pharmacists (2010), *available at* http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf.

[3] *Id*.

[4] *See* Jordan Paradise, *The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System*, 41 Am. J. L. & Med. 75 (2015).

[5] 42 U.S.C. § 262(i)(2).

[6] 42 U.S.C. § 262(k)(4).

[7] 42 U.S.C. § 262(k)(4)(A)(ii) & (B).

[8] For state law citations, *see* Table 1.

[9] *See* Ind. Code § 16-42-25-4 (2014) (explaining that a pharmacist may substitute a biosimilar product if the prescribing practitioner has "for a written prescription, signed on the line under which the words 'May substitute' appear; or . . . electronically transmitted the instruction 'May substitute.'"); Wash. Rev. Code § 69.41.120 (2015) (explaining that every drug prescription needs to contain an explicit instruction on whether or not substitution is permitted, "unless substitution is permitted under a prior-consent authorization.").

[10] *See* Table 1.

[11] *See, e.g.*, Va. Code § 54.1-3408.04(B) (2013) (pharmacist must inform the patient prior to dispensing the interchangeable biosimilar).

[12] *See, e.g.,* Fla. Stat. §§ 465.0252(2)(c), 465.025(3)(a) (2014) (requiring pharmacist to notify purchaser of cost difference between reference product and biosimilar). For additional states, *see* Table 1.

[13] *Compare* N.D. Cent. Code § 19-02-.1-14.3(2)(d) (2013) *with* Ind. Code § 16-42-25-5(a) (2014) *and* Del. Cod. tit. 24, § 2549A(b) (2014).

[14] *See, e.g.,* Va. Code § 54.1-3408.04(C) (2013) ("When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designees shall provide . . . notification . . . within five business days[.]"). For additional states, *see* Table 1.

[15] *See, e.g.,* Colo. Rev. Stat. § 12-42.5-122(1)(b)(II) (2015) ("Within a reasonable time after dispensing a biological product, the dispensing pharmacist or his or her designee shall communicate to the prescribing practitioner the specific product dispensed to the patient[.]"). For additional states, *see* Table 1.

[16] *Compare* Fla. Stat. § 465.0252(d) (2014) (requiring records be maintained for at least two years) *with* Miss. Code Ann. § 73-21-118(2)(e) (2013) (requiring records be maintained for at least ten years).

[17] Ga. Code Ann. § 26-4-81(d)(1) (2015); N.C. Gen. Stat. § 90-85.30 (2015); Tex. Oc. Code Ann. § 562.005 (2015); Utah Code § 58-176-605.5(7) (2013); S.B. 671, adding § 4073.5 to Ca. BPC (2015).

[18] H.B. No. 319, La. Reg. Sess., Act. No. 391 (2015) (amending R.S.37:1164(1226.1)).

[19] *See e.g.*, Colo. Rev. Stat. § 12-42.5-122(1)(a) (2015) ("A pharmacist making a substitution shall assume the same responsibility for selecting the dispensed drug product as he or she would incur in filling a prescription for a drug product prescribed by a generic name…").

[20] Utah Code § 58-176-605.5(2)(b) (2013), as amended by H.B. 279 (2015).

[21] Randi Hernandez, *Industry Players Reach Compromise on Biosimilar Substitution*, BioPharm Int'l (Dec. 12, 2014), http://www.biopharminternational.com/industry-players-reach-compromise-biosimilar-substitution.

[22] Generic Pharmaceutical Association Press Release, *Statement by Ralph G. Neas, GPhA President and CEO Regarding State Biosimilar Legislation*, GPhA (Dec. 9, 2014), http://www.gphaonline.org/gpha-media/press/statement-by-ralph-g-neas-gpha-president-and-ceo-regarding-state-biosimilar-legislation.

[23] Del. Code tit. 24, § 2549A(b) (2014); Ind. Code, § 16-42-25-5 (2014).

[24] *See* Table 1.

[25] *Id*.

[26] Utah Code § 58-17b-605.5(8) (2013) as amended by H.B. 279, Utah 2015 Gen. Sess., Prescription Notification Amendments (2015).

[27] *See* Cauchi, *supra*, note 1.

Notable Trademark Decisions

(Unless noted, all decisions are precedential)

*By Pina Campagna and Michael Cannata**

Board Rejects Request for Reconsideration

By Order dated July 13, 2015, the Board denied Knowluxe LLC's ("Knowluxe") motion to dismiss a petition for cancellation on the grounds that the claims were implausible and that the rights asserted by Guess? IP Holder L.P. ("Guess") conflicted with (1) the doctrine of aesthetic functionality and (2) the prohibition against claims of trademark rights in gross.

Knowluxe requested that the Board reconsider its denial of Knowluxe's motion to dismiss, claiming that there was "an incomplete legal basis for the Board's decision on the Motion." Specifically, Knowluxe argued that the decision did not address its arguments regarding the doctrine of aesthetic functionality or the prohibition against trademark rights in gross.

After articulating the applicable rules regarding reconsideration, the Board observed that a motion to dismiss involves only one discrete issue—the sufficiency of the pleading. In that regard, the Board concluded that its previous decision correctly analyzed and concluded that Guess properly pled both its likelihood of confusion and dilution claims. The Board also concluded that Knowluxe's other arguments addressed issues apart from the legal sufficiency of Guess' claims and, thus, were superfluous. The Board concluded that these arguments "are in the nature of defenses, i.e., matters which are alleged to bar the relief requested by [Guess]…[and that Knowluxe]…will have an opportunity to assert any appropriate defense, develop the record, and argue the merits of its case.…"

Finally, the Board rejected Knowluxe's attempt to analogize this matter to the Board's decision in *Selva & Sons, Inc. v. Nina Footwear, Inc.,* 705 F.2d 1316 (Fed. Cir. 1983). In *Selva*, the Federal Circuit determined that the Board had not properly articulated the grounds for dismissing a petition. But here, unlike in *Selva*, the Board concluded that it had addressed the substantive issue before it, that is, the sufficiency of the petition. According to the Board, what it did not address were issues that were unrelated to the substantive issue presented.

Guess? IP Holder L.P. v. Knowluxe LLC, 116 USPQ2d 2018 (TTAB Dec. 9, 2015).

Motion for Protective Order Deemed Improper

The Board rejected a motion for a protective order, finding that the litigant was only trying to avoid responding to discovery requests. The opposer served the applicant with a comprehensive set of initial written discovery demands, including interrogatories, document demands, and requests for admission. After failing to secure an extension of time to respond to the demands, the applicant, on the date that responses were due, filed a motion for a protective order.

The Board, however, held that the applicant's motion was improper. The Board observed that the applicant's motion was in contravention of "the Board's policy that filing for such relief is not an appropriate manner in which a party may object to discovery with which it has been served."

With respect to the applicant's contention that the number of interrogatories was excessive, the Board, citing Rule 2.120(d)(1), concluded that the appropriate response was to serve a general objection to the number of interrogatories instead of responses and specific objections. According to the Board, this approach is consistent with the parties' duty to cooperate in discovery.

In addition, the Board observed that it is improper to request a protective order simply to delay the service of discovery responses. The Board explained that the applicant had the burden to demonstrate why, specifically, the opposer's discovery requests warranted a protective order. The Board analyzed the discovery requests at issue and concluded that "[t]he information and documents requested are standard and typical for a proceeding involving the asserted grounds, are tailored to the claims and are framed to seek information that is clearly relevant."

The Board criticized not only the applicant's failure to cite any supporting legal authority in its motion, but also the timing of the motion, which was filed on the date that the applicant's discovery responses were due. In sum, the Board held that conduct of this nature "amounts to a unilaterally manufactured delay."

Finally, citing its inherent authority to impose sanctions, the Board ordered the applicant to show good cause why the Board should not sanction her by finding

cont. on page 24

cont. from page 23

(1) that the applicant forfeited her ability to object to the discovery requests on the merits and (2) that the opposer's requests for admission are deemed admitted.

Emilio Pucci Int'l BV v. Rani Sachdev, 2016 WL 462870 (TTAB Jan. 20, 2016).

U.S. Court of Appeals for the Federal Circuit Decides the "Slants" Case

On December 22, 2015, the U.S. Court of Appeals for the Federal Circuit held en banc in a 9-3 decision that excluding "disparaging marks" from protection under the Lanham Act is a violation of the First Amendment.

In November 2011, Simon Tam, an Asian-American band member, filed an application to register the band's name THE SLANTS for "entertainment in the nature of live performances by a musical band." The Examining Attorney refused to register the mark under Section 2(a) of the Lanham Act on the ground that the mark is disparaging to "people of Asian descent." Section 2(a) excludes the registration of "scandalous, immoral, or disparaging marks." Among others, Section 2(a) covers marks that a "substantial composite of the referenced group" perceives as disparaging a religion, nation, ethnic group, belief system, and the like.[1] Both the TTAB and the Federal Circuit upheld the refusal to register the mark. In April 2015, the Federal Circuit sua sponte ordered rehearing en banc to consider whether Section 2(a)'s bar on registering disparaging marks violates the First Amendment. The Court concluded that it did, citing these major points:

1. The exclusion of disparaging marks denies important legal rights to trademark owners.
2. The disparagement provision at issue is viewpoint discriminatory on its face.
3. The government's argument that Section 2(a) regulates only commercial speech, which is subject to a lower standard of scrutiny, did not stand.[2]
4. Trademark registration is not "government speech"—use of a mark by its owner is clearly private speech because the marks are a source identifier.
5. The government-controlled copyright registration system does not make copyrighted works into government speech so the same should apply to trademarks.
6. Trademark registration (derived from the Commerce Clause, not the Spending Clause) is not a program through which the government is seeking to get its message out through recipients of funding.
7. Disapproval of a mark is not a legitimate government interest and the theory that it does not want to be associated with a disparaging mark is not a valid theory to refuse its registration.

Because the Federal Circuit has struck down a federal statute, the Supreme Court will likely review this case. In addition, the decision may influence what happens in the REDSKINS case. Therefore, the final say on this matter remains to be seen.

In re Tam, 808 F.3d 1321 (Fed. Cir. 2015).

Petitioner's Motion to Amend Petition to Cancel and Respondent's Motion for Summary Judgment Granted

In one of the first precedential TTAB cases this year, the Board clarified the timing for statement of use requirements.

Petitioner Embarcadero sought cancellation of a registration for the mark DELPHIX

for database management software in Class 9 (Serial No. 77/649689) on the pleaded claim that the Respondent committed fraud regarding its statement of use (SOU) in commerce of the mark. Respondent Delphix moved for summary judgment to dismiss Embarcadero's claim that the registration was obtained by fraud. Embarcadero filed a cross-motion to add Section 2(a) false association, "false representation," and nonuse claims to its petition. The Board granted the summary judgment motion and part of the motion to amend.

On August 12, 2009, Respondent filed its SOU with a use in commerce date of March 1, 2009. On October 1, 2009, the USPTO issued an office action rejecting the specimen. On January 25, 2010, Respondent filed an extension of time to submit the SOU (an "insurance extension of time" until July 28, 2010). On February 3, 2010, Respondent filed its response with a substitute specimen and declaration with a changed date of use in commerce of December 3, 2009. The USPTO accepted the statement and the registration issued (Reg. No. 3768914).

On the issue of fraud, an applicant must knowingly make false, material representations of fact in connection with its application with the intent to deceive the USPTO. The Respondent indicated that even though there was an inaccuracy in the SOU, there was no ev-

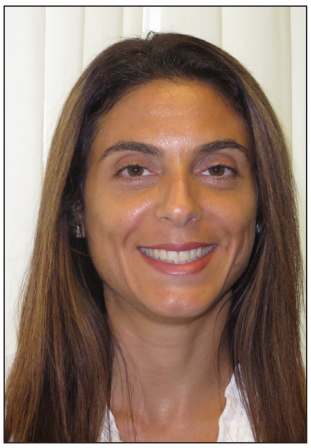
idence that the inaccuracy resulted from an intent to deceive. Since Petitioner had not produced any documents supporting its fraud claim, Embarcadero failed to raise a genuine issue as to Delphix's intent to deceive the USPTO[3] and the motion to dismiss the fraud claim was granted.

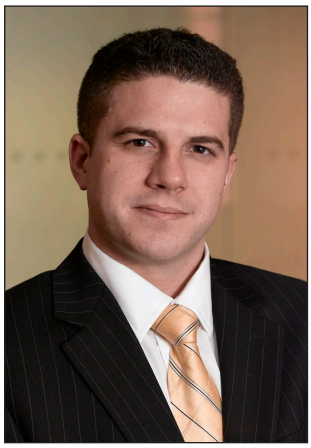
Regarding Petitioner's motion to amend, the first two claims for false association under Section 2(a) and for "false representation" were completely dismissed as being both untimely and fruitless. Petitioner maintained that after Delphix filed a first, flawed SOU on August 12, 2009, Delphix could not later file another SOU claiming a first use date after August 12, 2009. The Board held that it will "consider evidence of use which occurred after the filing of the [SOU] but within the original or extended period for filing the [SOU]." Thus, an applicant may amend its SOU to state dates of use that fall after the statement of use filing date, but before the expiration of the deadline for filing the statement of use. Here, the "insurance extension of time" saved the day for Respondent. The Board did, however, grant Petitioner's motion to add the nonuse claim, giving it 15 days to amend.[4]

Embarcadero Technologies, Inc. v. Delphix Corp., 117 USPQ2d 1518 (TTAB 2016).

(Endnotes)

* Pina Campagna is a partner at Carter, DeLuca, Farrell & Schmidt, LLP. Ms. Campagna's practice includes representing regional, national and international businesses, with a particular concentration in trademark and design patent matters. She is Co-Chair of the Trademark Law & Practice Committee. Michael Cannata is an associate in the intellectual property group at Rivkin Radler LLP and has experience litigating complex intellectual property, commercial, and other business disputes in state and federal courts across the country. He is a member of the Trademark Law & Practice Committee.





[1] Under Section 2(a), the USPTO has canceled the registration of REDSKINS and refused many others, such as STOP THE ISLAMISATION OF AMERICA, THE CHRISTIAN PROSTITUTE, AMISHHOMO, MORMON WHISKEY, KHORAN for wine, HAVE YOU HEARD THAT SATAN IS A REPUBLICAN?, RIDE HARD RETARD, ABORT THE REPUBLICANS, HEEB, SEX ROD (apparently some sort of reference to the Red Sox), MARRIAGE IS FOR FAGS, DEMOCRATS SHOULDN'T BREED, REPUBLICANS SHOULDN'T BREED, 2 DYKE MINIMUM, WET BAC/WET B.A.C., URBAN INJUN, SQUAW VALLEY (in part), N.I.G.G.A. NATURALLY INTELLIGENT GOD GIFTED AFRICANS, "a mark depicting a defecating dog … (found to disparage Greyhound's trademarked running dog logo)," "an image consisting of the national symbol of the Soviet Union with an 'X' over it," and more. *In re Tam,* 808 F.3d at 1330.

[2] The Court stated: "*every time* the PTO refuses to register a mark under § 2(a), it does so because it believes the mark conveys an expressive message—a message that is disparaging to certain groups." *Id.* at 1338 (italics in original).

[3] The Board observed that, although it must view the claim of fraud in a light most favorable to the non-movant, Embarcadero "was required to set forth specific facts, by declarations or as otherwise provided in [Fed. R. Civ. P. 56(e)], evidence supporting an inference of Respondent's fraudulent intent...." *Embarcadero Technologies, Inc. v. Delphix Corp.,* 117 USPQ2d 1518, 1522 (TTAB 2016).

[4] Embarcadero "must plead that Respondent did not use [its mark] with the software listed in the registration within the time for filing its statement of use as extended, *i.e.*, no later than July 28, 2010." *Id.* at 1526 (TTAB 2016).

Patent Litigation from the Law Clerks' Perspective – Strategies for Success and Pitfalls to Avoid

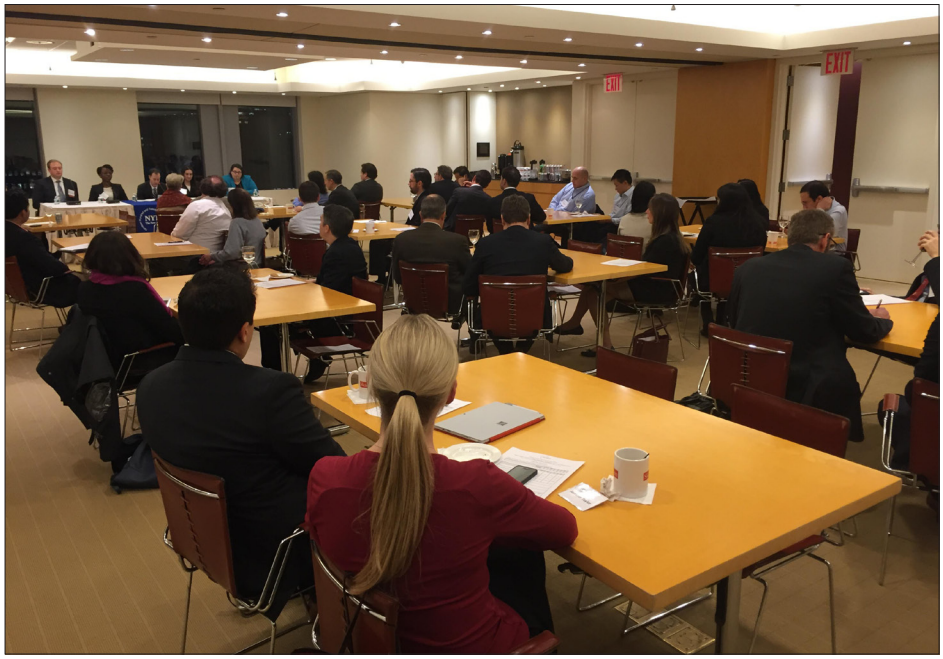
By Edward L. Tulin

On January 13, 2016, the Patent Litigation Committee, in conjunction with Skadden, Arps, Slate, Meagher & Flom, LLP, hosted a panel entitled, "Patent Litigation from the Law Clerks' Perspective—Strategies for Success and Pitfalls to Avoid." Gianna Cricco-Lizza, a former clerk for Judge Mary L. Cooper of the U.S. District Court for the District of New Jersey; Christina F. Emerson, a former clerk for Judge Peter G. Sheridan of the U.S. District Court for the District of New Jersey; Deborah Kemi Marin, a former clerk for Judge Gregory M. Sleet of the U.S. District Court for the District of Delaware; and Stephen O'Donohue, a former clerk for Judge Claire C. Cecchi of the U.S. District Court for the District of New Jersey, served as panelists. The panel was moderated by Edward L. Tulin, a former clerk for Magistrate Judge Christopher J. Burke of the U.S. District Court for the District of Delaware. This diverse panel was able to offer a broad range of perspectives on key jurisdictions for patent practice—for both 2014 and 2015, the District Courts of Delaware and New Jersey were the second and third most common venues, respectively, for patent cases, surpassed only by the Eastern District of Texas.

This well-attended presentation covered a number of topics of great interest to patent litigators, including the judicial treatment of 35 U.S.C. § 101 motions and initial challenges to patent infringement complaints, the role of PTAB proceedings in district court litigation, best practices for dispositive motions, and strategies for surviving and thriving at a patent trial.

For instance, the panelists discussed the prevailing conventional wisdom among patent defendants from 2-3 years ago, which was that initial motions to dismiss were a waste of time in infringement cases, and that patent plaintiffs had little to fear from such motions. The panelists all agreed that this conventional wisdom has changed dramatically, with Section 101 dismissals becoming more common in the District Courts of both Delaware and New Jersey, as well as in other jurisdictions.

The panelists also offered a lively discussion of pre-trial, trial, and post-trial proceedings in the District Courts of Delaware and New Jersey. The panelists particularly emphasized the importance of providing copies of documents and presentations to the clerks, explained how local counsel can be a critical part of trial presentations, and taught how to best situate post-trial motions within the record.



Young Lawyers Roundtable: The ABCs of ADR

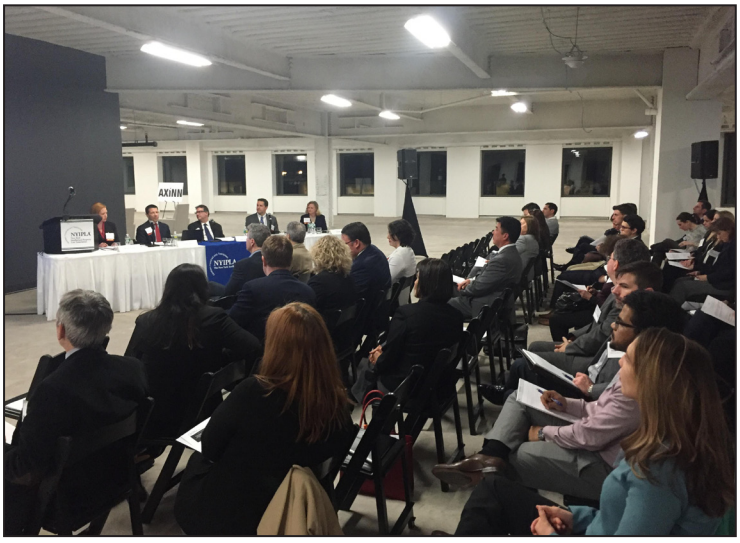
By Michael Sebba

On February 23, 2016, The Young Lawyers Committee continued its Roundtable series with a discussion entitled, "The ABCs of ADR." Hosted at Crowell and Moring LLP, the discussion featured Dan Ebenstein (Amster, Rothstein & Ebenstein LLP) and Theo Cheng (Fox, Horan & Camerini LLP) and moderator Michael Sebba (Amster, Rothstein & Ebenstein, LLP), leading a conversation about the roles of arbitration and mediation in IP law. The participants at the Roundtable discussed topics including what to look for in an arbitration clause, when either arbitration or mediation can be superior to litigation for a client, and how ADR differs from traditional litigation and dispute resolution. The Young Lawyers Committee encourages all young lawyers to attend the next Roundtable event.

Biosimilars Panel: Hot Topics and Issues in the Biosimilars Space

By Abigail Langsam

On February 29, 2016, the Women in IP Law Committee presented a panel discussion entitled, "Hot Topics and Issues in the Biosimilars Space." Hosted at Axinn, Veltrop & Harkrider LLP, the discussion provided an overview of the current legal and regulatory landscape surrounding biosimilar drug products—from the perspectives of both reference drug holders and biosimilar applicants. Robert Isackson (Orrick, Herrington & Sutcliffe LLP) and David Leichtman (Robins Kaplan LLP) addressed patent litigation and strategy under the Biologics Price Competition and Innovation Act, and provided an update on recent case law in the biosimilars space. Chad Landmon (Axinn, Veltrop & Harkrider LLP) addressed FDA issues for biosimilars, including agency guidances and the status of pending applications. Terry Rea (Crowell & Moring LLP) addressed the use of inter partes review proceedings to obtain resolution of patent issues in the biologics space, as well as strategic considerations when choosing between the Patent Trial and Appeal Board and district court with regard to commencing proceedings. Abigail Langsam (Kaye Scholer LLP) moderated the panel.



The presentation drew a large and diverse audience of practitioners from both sides of the biologics/biosimilars aisle. The Women in IP Law Committee wishes to thank the panelists, Axinn, Veltrop & Harkrider LLP, and Lisa Lu for making the evening such a success.

Moving UP ▲ & Moving ON ➤➤➤

➤ Z. Ying Li, formerly of Ropes & Gray LLP, has joined Steptoe & Johnson LLP as a partner in its intellectual property practice.

➤ William McCabe and Gene Lee, formerly of Ropes & Gray LLP, and Martin Gilmore, formerly of WilmerHale, have joined Perkins Coie LLP in its intellectual property practice. Messrs. McCabe and Lee join as partners and Mr. Gilmore joins as senior counsel.

➤ Pablo Hendler, formerly of Ropes & Gray LLP, has joined Jones Day as a partner in its intellectual property group.

➤ Peter Thurlow, formerly of Jones Day, has joined Polsinelli PC as a shareholder in its Intellectual Property practice.

➤ Justin Daniels, formerly of Proskauer Rose LLP, has joined Burford Capital LLC as a managing director in its New York office.

➤ Lisa A. Chiarini, formerly of Fish & Richardson P.C., has joined Reed Smith LLP as a partner in its Intellectual Property, Information & Innovation Group.

➤ Scott Howard, formerly of Patterson Belknap Webb & Tyler LLP, has become an Administrative Patent Judge at the PTO's Patent Trial and Appeal Board.

➤ Steven Edwards, formerly of Hogan Lovells, has joined Quinn Emanuel Urquhart & Sullivan LLP as of counsel in its litigation group.

➤ Michael Dougherty and Tony Pezzano, formerly of King & Spalding, have joined Hogan Lovells as partners in the Intellectual Property Media and Technology Practice Group.

➤ Jeffrey Snow, formerly of Cooper & Dunham LLP, has joined Pryor Cashman LLP as a partner in its Intellectual Property, Litigation, and Digital Media Groups.

➤ Elizabeth Gardner, A. Antony Pfeffer, Richard DeLucia, and K. Patrick Herman, formerly of Kenyon & Kenyon LLP, have joined Orrick, Herrington & Sutcliffe LLP in its intellectual property practice. Ms. Gardner and Messrs. Pfeffer and DeLucia join as partners and Mr. Herman joins as of counsel.

➤ Merri Moken, formerly of Kenyon & Kenyon LLP, has joined Holland & Knight LLP as a partner in its Intellectual Property Group.

➤ Gerard Haddad and Jennifer BianRosa, formerly of Dickstein Shapiro LLP, have joined Blank Rome LLP in its intellectual property practice as partner and of counsel, respectively.

■

The Report's Moving Up and Moving On feature is for the Association's members. If you have changed your firm or company, made partner, received professional recognition, or have some other significant event to share with the Association, please send it to The Report editors: William Dippert (wdippert@patentusa.com) or Mary Richardson (mary.e.w.richardson@gmail.com).

Minutes of January 15, 2016

Meeting of The Board of Directors of The New York Intellectual Property Law Association

The Board meeting was held at the Midtown offices of Cadwalader, Wickersham & Taft LLP. President Dorothy Auth called the meeting to order at 12:30 p.m. In attendance were:

Frank DeLucia	Matthew McFarlane
Walter Hanley	Colman Ragan
Anthony LoCicero	Robert Rando
Kathleen McCarthy	Peter Thurlow

Raymond Farrell and Robert Isackson participated by phone. Annemarie Hassett, Garrett Brown, Jessica Copeland, Denise Loring, and Jeanna Wacker were absent and excused from the meeting. Feikje van Rein was in attendance from the Association's executive office.

The Board voted unanimously to approve the Minutes of the December 9, 2015 Board meeting, incorporating a minor change.

Treasurer Rob Rando reported that the Association's finances continue to be sound. He noted that program revenues are up. At this time, no deposits have been paid to the Waldorf Astoria New York Hotel for the annual Judges Dinner.

Rob Rando reported that the Association added 27 new members, including 20 new members from Fitzpatrick, Cella, Harper & Scinto. The Board approved admission of the new members.

Rob Isackson reported on the activities of the Amicus Brief Committee. Rob mentioned that the most recent ABC meeting held a moment of silence in honor of Dave Ryan's recent passing. The ABC then went on to give the Board updates and advance notice of upcoming actions: *Amgen Inc. v. Sandoz Inc.* (not proceeding with a brief, and Amgen apparently is not filing a petition for certiorari review in the Supreme Court); *Achates Reference Publishing, Inc. v. Apple Inc.* (potential action in a case involving jurisdiction over IPR review); *Cooper v. Lee* and *MCM Portfolio LLC v. Hewlett-Packard Co.* (some interest in ABC members in weighing in on administrative exhaustion cases); *Regeneron Pharmaceuticals, Inc. v. Merus B.V.* (upcoming request for amicus support likely to be proposed).

With respect to Dave Ryan, the Board considered naming a scholarship in Dave Ryan's name and connecting that scholarship to Dave's longtime interest in the intersection between antitrust and patent law. President Auth noted Dave's tireless efforts on behalf of the organization, and noted that he will be sorely missed. The Board held a moment of silence in Dave's honor.

President Auth reported on the status of the Judges Dinner. She informed the Board that Nina Totenberg and Peter Sagal would be the main speakers, that plans for the Dinner are on pace, and that the panel for the Day of the Dinner CLE Luncheon Program is in process of being set, with marketing materials for the CLE to be sent out shortly.

Matt McFarlane and Colman Ragan reported on the activities of the Special Projects Committee. Matt and Colman reported that the two professors from Benjamin N. Cardozo School of Law, Felix Wu and Aaron Wright, were overwhelmingly positive on the ability of the NYIPLA to participate in activities underway. The professors mentioned NYIPLA assistance with seminars on diverse careers in IP law, and possibly a seminar series. The SPC will continue its investigation of local schools to gauge interest at those other institutions. Several Board members expressed interest in assisting with the effort.

Rob Rando reported on activities of the Legislative Action Committee. LAC working groups are in the process of preparing white papers, to be followed by meetings in Washington, D.C., relating to: (1) IPR provisions of pending patent reform bills, (2) changes to U.S. IP law that may be required if the Trans-Pacific Partnership treaty is implemented, and (3) in conjunction with an ad hoc committee of the Association, pending trade secret legislation. The LAC understands that little legislative activity will take place this year, so does not anticipate much activity in the near future.

Board members reported on upcoming and recent programs of the Association.

Committee liaisons reported on the activities of various Association Committees.

The meeting adjourned at 2:00 p.m.

The next Board meeting will take place on February 9, 2016, and will include Committee Chairs.

Minutes of February 9, 2016

Meeting of The Board of Directors of The New York Intellectual Property Law Association

The Board meeting was held at The Union League Club, 38 East 37th Street. President Dorothy Auth called the meeting to order at 5:15 p.m. In attendance were:

Frank DeLucia	Kathleen McCarthy
Walter Hanley	Matthew McFarlane
Annemarie Hassett	Colman Ragan
Robert Isackson	Peter Thurlow
Denise Loring	Jeanna Wacker

Jessica Copeland, and Robert Rando participated by telephone. Garrett Brown, Raymond Farrell, and Anthony Lo Cicero were absent and excused from the meeting. Feikje van Rein and Lisa Lu were in attendance from the Association's executive office.

The Board approved the Minutes of the January 15, 2016 Board meeting.

Treasurer Rob Rando reported that the Association's finances continue to be sound. Overall, expenses were about the same as, and revenue was slightly down from, last year.

Rob Rando reported that the Association added 19 new members, including seven new student members and one new corporate member. The Board approved admission of the new members to the Association.

Rob Isackson reported on the activities of the Amicus Brief Committee. The Board discussed the Committee's revised proposal for filing an amicus brief before the Federal Circuit in support of the petitioner in *Regeneron Pharmaceuticals, Inc. v. Merus B.V.,* relating to the standard for a finding of unenforceability for inequitable conduct. The brief would be due February 23. Jeanna Wacker recused herself from any discussion of the matter.

With Rob Isackson recusing himself, the Board also discussed the Committee's proposal for filing a brief before the Supreme Court in *Kirtsaeng v. John Wiley & Sons, Inc*. The Board approved preparation of the brief.

The Committee is monitoring a number of other cases and will make proposals for filing amicus briefs, as appropriate.

Anne Hassett and Denise Loring reported on activities of the Legislative Action Committee. The trade secret working group, along with the ad hoc Trade Secret Committee, prepared a white paper on pending trade secret legislation. Based on information received from ACG, it appears that the legislation has strong support in Congress and is on a relatively fast track for approval. Therefore, the sense is that it will not be useful for the Association to weigh in on that legislation at this time. Denise Loring acknowledged the efforts of the trade secret working group and ad hoc committee in preparing the white paper. It was suggested that the white paper be modified and published on the Association's website or in some other medium.

ACG also reported that the U.S. Trade Representative has begun the process of identifying changes in U.S. law necessitated by the Trans-Pacific Partnership (TPP) treaty, if it is implemented. The TPP working group is preparing white papers addressing these issues so that the Association's views on the required changes may be heard.

Matt McFarlaine reported on the Strategic Planning Committee's ongoing discussions with faculty members at Cardozo Law School to conduct one or more programs for students in the IP arena. They are targeting the beginning of the 2016 academic year for commencement of the programs.

Rob Rando reported on upcoming programs. The Board discussed speakers for the Day of the Dinner program on April 1. Rob Rando also reported on the progress of an educational program for local federal judges.

Denise Loring reported on the activities of the Media Committee. The Committee is considering a new communication for members reporting on activities in the NYIPLA, which would be either a stand-alone communication, or incorporated into the current weekly report to members.

David Leichtman and Jonathan Auerbach joined the meeting to discuss the Inventor of the Year Committee's recommendations for this year's award. The Committee received seven submissions. The Board approved the Committee's recommendations for the winner and for second place. The Board discussed ways to get the word out to inventors for next year's award.

President Auth adjourned the meeting at 6:35 p.m.

The next Board meeting will take place on March 9, 2016.

WALDORF ASTORIA
NEW YORK HOTEL

APRIL 1, 2016

THE
NEW YORK INTELLECTUAL PROPERTY
LAW ASSOCIATION

In conjunction with
THE NYIPLA 94TH ANNUAL DINNER IN HONOR OF THE FEDERAL JUDICIARY
present

DAY OF THE DINNER CLE LUNCHEON

Changing the Rules of the Road

Recent Amendments to the Fed. R. Civ. P., the Continued Push for Patent Law Reform, and the Impact on Intellectual Property Litigation

REGISTRATION
11:00 A.M. – 11:30 A.M.

LUNCH
11:30 A.M. – 12:20 P.M.

PRESENTATION
12:20 P.M. – 2:15 P.M.

2.0 NY/NJ CLE PROFESSIONAL CREDITS FOR BOTH NEWLY ADMITTED AND EXPERIENCED ATTORNEYS

PRESENTER

MICHELLE K. LEE
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

PANELISTS

HONORABLE LEONARD P. STARK
CHIEF JUDGE OF THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HONORABLE SHIRA A. SCHEINDLIN
DISTRICT JUDGE OF THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

HONORABLE JOSEPH A. DICKSON
MAGISTRATE JUDGE OF THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHRIS ISRAEL
PARTNER OF THE AMERICAN CONTINENTAL GROUP

MODERATOR

ANTHONY LO CICERO
NYIPLA IMMEDIATE PAST PRESIDENT

Hosted by the
NYIPLA Programs Committee

Nineteen Hundred and Twenty-two NYIPLA®

Last Name	First Name	Company/ Firm /School	State	Membership Type
Albulesu	Emily	Benjamin N. Cardozo School of Law	New York	Student
Bakaya	Shaheen		New York	Active 3-
Cefo	Damir	Cohen & Gresser LLP	New York	Active 3+
Chappell	Daniel	Suffolk University Law School	Massachusetts	Student
Chaudhry	Sana	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3-
Cieluch	Jennifer	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3-
Cokleski	Katrina	L'Oreal USA Products, Inc.	New Jersey	Corporate
Cox	Wayne	Maurice A. Deane School of Law at Hofstra University	New York	Student
DiCocco	Vincent	Albany Law School	New York	Student
Dukarm	Amisha	Western State College of Law at Argosy University	California	Student
Edwards	Devon	Willkie Farr & Gallagher LLP	New York	Active 3-
Flanz	Scott	Skadden, Arps, Slate, Meagher & Flom LLP	New York	Active 3-
Forte	Steven	Michigan State University College of Law	Michigan	Student
Gaudette	Bonnie	Frommer Lawrence & Haug LLP	New York	Active 3+
Horton	Amanda	Quinnipiac University School of Law	Connecticut	Student
Hsu	Nathan	George Washington University Law School	New York	Student
Joyner	Kaela	University of Washington School of Law	Washington	Student
Kim	Edward	Fordham University School of Law	New York	Student
Klein	Daniel	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3+
Macmull	Joel	Archer & Greiner P.C.	New Jersey	Active 3+
Maniscalco	Stephen	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3-
Marotta	Robert	Benjamin N. Cardozo School of Law	New York	Student
Massaro	Brandon	Quinnipiac University School of Law	Connecticut	Student
McDonough	Connor	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3+
Milea	Michael	Paul, Weiss, Rifkind, Wharton & Garrison LLP	New York	Active 3-
Misra	Anup	Winston & Strawn LLP	New York	Active 3+
Ogurchak	Audrey	Syracuse University College of Law	New York	Student
Oliver	Jason	Baker & Hostetler LLP	New York	Active 3+
Patel	Ankit	Gibbons P.C.	New York	Active 3+
Pino III	Dominic	William & Mary Law School	Virginia	Student
Pyatt	April	New York Law School	New York	Student
Rotberg	Tuvia	Amster Rothstein and Ebenstein LLP	New York	Active 3+
Sprigman	Christopher	Simpson Thacher & Bartlett LLP	New York	Active 3+
Szumarska	Maja	Gibney, Anthony & Flaherty, LLP	New York	Active 3+
Weiss	Matthew	Columbia University Law School	New York	Student
Whitcher	Emily	Harvard Law School	New York	Student
Wright	Briggs	Orrick, Herrington & Sutcliffe LLP	New York	Active 3-

The New York Intellectual Property Law Association, Inc.

Telephone (201) 461-6603 www.NYIPLA.org

The Report is published bi-monthly for the members of The New York Intellectual Property Law Association.
Correspondence may be directed to *The Report* Editors,
William Dippert, wdippert@patentusa.com, and Mary Richardson, mary.e.w.richardson@gmail.com