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In This Issue

Recent Developments in Biosimilars Case Law

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In an effort to ameliorate concerns regarding the high costs of "biologic" pharmaceuticals, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) of 2009, which was incorporated as Title VII of the Patient Protection and Affordable Care Act. P.L. 111-148, 124 Stat. 119.[1] Although the BPCIA created an abbreviated approval pathway for generic versions of approved biologics, or "biosimilars," as well as specific litigation procedures, the BPCIA has seen little application by pharmaceutical companies to date. Recently, however, multiple lawsuits have tested the BPCIA's boundaries, where biosimilars developers have challenged patents outside the BPCIA litigation procedures in hopes of gaining clarity more quickly than the BPCIA might otherwise permit.

This article provides a brief summary of the BPCIA patent information exchange provisions and describes recent attempts by applicants to litigate outside of the statutory framework presented by the BPCIA.

I. Patent Dispute Resolution Procedures Under the BPCIA

The BPCIA established an abbreviated approval pathway for "generic" versions of approved biologics, or "biosimilars," and created a patent dispute resolution process that is, in some ways, analogous to the provisions of the Hatch-Waxman Act, but which fundamentally differs in many details. To seek approval of a biosimilar, an applicant files a "section 351(k) application" with the Food and Drug Administration (FDA) based on a reference Biologics License Application (BLA) for the biologic.[2]

A 351(k) application must demonstrate that: (1) the proposed product is "biosimilar" to the reference product (through analytical, animal and human studies); (2) the proposed product uses the same mechanism of action as the reference product, but only to the extent the mechanism of action is known for the reference product; (3) the proposed product has the same conditions of use as the reference product; (4) the proposed product has the same route of administration, dosage form, and strength as the reference product; and (5) the facility in which the proposed product is manufactured meets standards ensuring the product is safe, pure, and potent.[3] After the 351(k) application is accepted by the FDA, a series of patent-related information exchanges begins between the applicant and the reference product sponsor.

A. Paragraph 3 Exchanges

The first group of patent information exchanges under the BPCIA procedure involves the identification of relevant information and patents by the reference product sponsor and

cont. on page 3

PRESIDENT'S CORNER

Having entered the second half of my term as President, I have been thoroughly pleased with the breadth, scope, and diverse nature of the programs that the Association has organized and sponsored.

A program that particularly captured the wide range of interests of our members was the one that took place at The Union League Club on December 11. This program featured Lead Administrative Patent Judge Michael Tierney of the Patent Trial and Appeal Board ("PTAB"), who provided an informative presentation on post-grant review proceedings as seen from the eyes of an administrative patent judge. Judge Tierney's presentation followed one of the most unique presentations in my experience with the Association, namely, a talk by Senior Judge Leonard Wexler of the United States District Court for the Eastern District of New York. Not only did Judge Wexler comment on his decades-long experience as a federal judge—including a discussion of how he managed his first patent case many years ago—but he also showed and commented on a video highlighting the five members of the Eastern District bench who served in the United States military during the Second World War. These five judges, who discussed their experiences both during the war and on the bench, are among 60 senior federal judges who served in the armed forces during that war. Without the continued participation of these senior jurists, all of whom are approaching or are over 90 years old, the federal judicial system would be hard-pressed to keep up with its increasing workload. Judge Wexler's presentation will long be remembered by all who attended.

An annual highlight of the Association year is the One-Day Patent CLE Seminar which was held on November 20, 2014 at the Princeton Club. This event is always one of the best-attended events of its kind. This year the program featured a keynote presentation by Chief Judge Jerome Simandle of the United States District Court for the District of New Jersey.

Our Women in IP Law Committee hosted a unique "Storytelling for Lawyers" presentation, and our newly formed Law Firm Practice Committee sponsored a program on starting and running an IP law practice. Both of these programs were well received by our membership.

In addition to programs like these, which are coordinated by the Programs Committee with the assistance of other committees, the Association continues to move forward on the judicial and legislative fronts. Our Amicus Brief Committee continues to monitor cases of importance to Association members and expects to file additional briefs during this term. Our Legislative Action Committee has been closely monitoring events in Washington, D.C., as we head into a new congressional year. It is expected that Association representatives will be traveling to Washington, D.C., in the near future to express our views on prospective patent reform legislation to Congressional staffers.

Of course, the highlight of any Association year is the Annual Dinner in Honor of the Federal Judiciary, which this year will take place on March 27 at The Waldorf Astoria New York Hotel. I am very pleased to advise that the Association will be presenting its Outstanding Public Service award to Chief Administrative Patent Judge James Smith of the PTAB, in recognition of his seminal work in the administration of the post-grant review proceedings authorized by the America Invents Act. Our Keynote speaker will be the Honorable Madeleine Albright, who was Secretary of State during the Clinton administration and was the first woman to hold that position. These two speakers promise to make this year's Dinner particularly exceptional.

Anthony Lo Cicero

cont. from page 1

applicant. First, within 20 days after the FDA publishes a notice of acceptance for a 351(k) application, the applicant "shall" provide a copy of the application to the reference product sponsor.[4] Then, within 60 days of receipt of the application, the reference product sponsor must provide to the applicant a list of patents for which it believes a claim of patent infringement could reasonably be asserted against a person making, using, offering to sell, selling or importing the biological product that is the subject of the 351(k) application ("Paragraph 3(A) List").[5] The reference product sponsor must also identify any patents on such list that the reference product sponsor would be willing to license to the applicant.[6] Next, within 60 days following receipt of the reference product sponsor's patent list, the 351(k) applicant may optionally provide its own list of relevant patents for which it believes a claim of patent infringement could reasonably be asserted by the reference product sponsor ("Paragraph 3(B) List").[7] The 351(k) applicant must also provide for each patent identified on both the Paragraph 3(A) List and the Paragraph 3(B) List (1) a statement that it will not market its product until the relevant patents have expired or (2) contentions that the patents are invalid, unenforceable, or would not be infringed by the proposed product.[8] In addition, the 351(k) applicant must provide a response to each patent identified by the reference product sponsor as available for license.[9] The reference product sponsor then has 60 days to respond with its own contentions of validity and infringement.[10]

After completing the initial exchanges, the parties have 15 days to negotiate in good faith which patents will be subject to litigation.[11] If the parties reach an agreement, the reference product sponsor must bring an action within 30 days of such agreement.[12] However, if the parties fail to agree within the 15 days, another round of exchanges follows.[13]

B. Paragraph 5 Exchanges

This second round of exchanges begins with the 351(k) applicant providing to the reference product sponsor the number of patents that it wishes to litigate.[14] Within five days, the parties are then required to simultaneously exchange lists of the patents each party believes should be the subject of the patent infringement action ("Paragraph 5 Lists").[15] The reference product sponsor must bring an action for patent infringement for all patents listed on the Paragraph 5 Lists, and litigation must commence within 30 days of the Paragraph 5 List exchange.[16]

The 351(k) applicant also has an obligation to notify the reference product sponsor of "the first commercial marketing of the biological product *licensed under subsection (k)*" at least 180 days prior to launch ("Paragraph 8(A) Notice").[17] After receiving the Paragraph 8(A) Notice, but prior to the expiration of the 180-day period, the reference product sponsor may seek a preliminary injunction based on any patent that was included in the Paragraph 3 Lists but excluded from either the Paragraph 5(B) List ("Excluded Paragraph 3 Patents") or, if the parties reached agreement, the list of patents the parties agreed to litigate.[18]

Notably, where the applicant has provided its application under Paragraph 2(A), neither party may seek declaratory judgment on an Excluded Paragraph 3 Patent before the Paragraph 8(A) Notice is provided.[19] However, if the applicant fails to provide its application to the reference product sponsor, the reference product sponsor, but not the applicant, may bring a declaratory judgment action.[20] How and under what circumstances these provisions apply has become the subject of litigation, discussed in detail below.

II. Recent Attempts to Litigate Outside the BPCIA Patent Exchange Procedures

To date, there apparently have been no instances of actions filed after the parties completed the BPCIA patent exchange procedures. However, several biosimilar developers have sought to test the scope and applicability of the patent exchange procedures through declaratory judgment actions.

A. *Sandoz Inc. v. Amgen Inc.*

Sandoz brought a declaratory judgment action against Amgen and Hoffmann-La Roche, requesting a judgment of invalidity and non-infringement of two patents allegedly covering a biologic protein known as etanercept, which Amgen markets as Enbrel®.[21] Enbrel® is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with moderate to severe rheumatoid arthritis.

At the time the complaint was filed, Sandoz alleged that it had "devoted substantial effort and tens of millions of dollars developing its etanercept product." Sandoz further alleged that it had begun Phase III clinical trials, but had not yet submitted its 351(k) application.[22] Sandoz further contended that it had provided its Paragraph 8(A) Notice to Amgen and Hoffmann-La Roche.[23] Amgen and Hoffmann-La Roche responded in September 2013 by filing a motion to dismiss for lack of subject matter jurisdiction, arguing that because Sandoz had not begun Phase III clinical trials and no 351(k) application had

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been submitted to the FDA at the time of the complaint, the dispute was not sufficiently current, immediate, and real to constitute an actual case or controversy.[24]

The district court granted the motion and dismissed the case.[25] The court ruled that (1) because Paragraph 8(A) Notice requires the product be "licensed under subsection (k)," the court lacked statutory authority to consider the dispute until *after* the FDA approved the biosimilar product; and (2) as a factual matter, a case or controversy did not exist.[26] The court explained that although the BPCIA permits declaratory judgment actions after an applicant gives notice of commercial marketing, Sandoz's notice in this case was not proper because its product was not "licensed under subsection (k)" as required by the statute at the time of notice.[27] In addition, the court found that because Amgen had made no explicit threats to sue and Amgen's general statements regarding patent enforcement did not "suffice to show an 'imminent threat,'" Sandoz had not established a real and immediate injury or threat of future harm sufficient for declaratory judgment jurisdiction.[28] Addressing the exchange procedures of the BPCIA, the court also noted that "neither a reference product sponsor, such as Amgen, nor an applicant, such as Sandoz, may file a lawsuit unless and until they have engaged in a series of statutorily-mandated exchanges of information."[29]

Sandoz appealed the judgment to the U.S. Court of Appeals for the Federal Circuit, filing its opening brief in March 2014.[30] Sandoz's brief focused on statutory construction, arguing that (1) the BPCIA, by its plain text, does not require patent exchanges to be completed prior to commencing a declaratory judgment action and (2) the district court's interpretation of notice under Paragraph 8(A) creates an additional 180-day period of exclusivity that was not contemplated by Congress.[31] Sandoz also argued that under the standard set forth in *MedImmune, Inc. v. Genentech, Inc.* the district court erred in finding no case or controversy.[32]

In May 2014, Amgen and Hoffmann-La Roche filed their opposition brief, arguing that (1) the BPCIA precludes Sandoz's declaratory judgment action until the BPCIA prerequisites of commercial marketing notice and patent exchanges are met; (2) Sandoz's construction "eviscerates the statutory framework, is inconsistent with the BPCIA's cross-referencing within the PHSA [Public Health Service Act] and between it and the [Declaratory Judgment Act], furthers no logical public policy, undermines orderly access to the courts and invites gamesmanship"; and (3) even if, as Sandoz argues, the BPCIA provisions do not apply, the district court did not err in dismissing the suit because Sandoz failed to establish an actual case or controversy, even under the *MedImmune* standard.[33]

On December 5, 2014, the Federal Circuit affirmed the district court decision, finding that Sandoz did not allege an injury of sufficient immediacy and reality to create subject matter jurisdiction for declaratory judgment.[34] Specifically, the court focused on what it deemed the contingent nature of the controversy between the parties, finding that any dispute about patent infringement was subject to significant uncertainties and thus not sufficiently immediate and real under the totality of the circumstances standard of *MedImmune*.[35] Notably, the Federal Circuit expressly limited its ruling to general subject matter jurisdiction principles only. The court declined to reach the lower court's interpretation of the BPCIA, stating:

> Our resolution of this case makes it unnecessary for us to address the district court's BPCIA rationale. We also do not decide whether, once an application is filed under the BPCIA, that statute forecloses a declaratory judgment action concerning whether the ultimate marketing of the application-defined product would infringe under 35 U.S.C. § 271(a).[36]

Because the Federal Circuit declined to address the interpretation of the BPCIA, it left open the question of whether the court will permit a biosimilar applicant to file a declaratory judgment action outside of the patent exchange requirements of the BPCIA after filing its biosimilar application. In addition to the district court's dismissal in *Sandoz v. Amgen*, two other cases have been dismissed relying in part on a failure to proceed with BPCIA exchange procedures prior to suit.

B. *Celltrion Healthcare Co. v. The Kennedy Trust for Rheumatology Research*

Celltrion filed a complaint for declaratory judgment against the Kennedy Trust for Rheumatology Research, the owner of a number of patents related to Remicade®.[37] Celltrion argued that a definite and immediate controversy existed between the parties because Celltrion's product was in its final form and the Kennedy Trust had made a number of statements regarding its assertion of patent rights against biosimilar developers.[38]

On August 28, 2014, the Kennedy Trust filed a motion to dismiss for lack of jurisdiction arguing that (1) Celltrion has not established a real and immediate injury or threat of injury; (2) there is no subject matter jurisdiction because Celltrion has bypassed the BPCIA framework; and (3) the court should stay

this later-filed action until the USPTO's earlier-filed reexamination/reissue proceedings are concluded.[39] Celltrion filed its opposition on September 29, 2014, arguing that (1) the case is ripe because the dispute between Celltrion and the Kennedy Trust is "definite and concrete," and "real and substantial"; (2) the BPCIA prohibitions on declaratory judgment actions do not apply to this case and are not jurisdictional; and (3) the court should not stay the case because a stay would not simplify the issues and Celltrion faces "severe prejudice" if a stay is granted.[40]

On December 1, 2014, the court granted the Kennedy Trust's motion and dismissed the case for lack of subject matter jurisdiction. The court ruled that "Celltrion is simply too far from receiving FDA approval of Remsima for the exercise of declaratory judgment jurisdiction to be proper" and "Kennedy has not expressed a clear intent to pursue infringement claims against Celltrion."[41] In dicta, the court noted that "[e]ven if the Court were to find that Celltrion had engaged in sufficient meaningful preparation to market Remsima and that the threat of injury was sufficiently demonstrable, the Court would still exercise its discretion to decline to hear this case in light of the existence of the BPCIA statutory framework for the resolution of patent disputes in the licensing of biosimilars."[42]

Although the Federal Circuit declined to address the BPCIA's impact on jurisdiction in *Sandoz v. Amgen*, the district court here addressed the issue. However, this aspect of the court's order was in the context of the court's discretion to decline to hear the case and did not directly address whether the BPCIA exchange provisions are mandatory.

C. *Hospira, Inc. v. Janssen Biotech, Inc.*

Another suit was filed in the Southern District of New York involving the same patents as the *Celltrion* cases discussed above. In this case, Hospira filed a complaint for declaratory judgment against Janssen Biotech, NYU Langone Medical Center, New York University, and the Kennedy Trust for Rheumatology Research.[43] The complaint alleges that Hospira has an agreement with Celltrion such that Hospira is an authorized user of Celltrion's abbreviated biologic license application ("ABLA") and plans to market its own biosimilar of Remicade® after Celltrion's ABLA is approved.[44] Like *Celltrion*, the *Hospira v. Janssen Biotech* case was assigned to District Judge Paul A. Crotty.

The defendants filed two motions: (1) a motion to sever the claims against Janssen/NYU (who have jointly-owned patents) and the Kennedy Trust and transfer the claims against Janssen/NYU to the District of Massachusetts where the related *Celltrion v. Janssen* suit was brought and (2) a motion to dismiss for lack of subject matter jurisdiction.[45] The motion to dismiss focused on the alleged uncertainty of Celltrion's FDA approval, the alleged uncertainty of a dispute under the Janssen/NYU patents (one expires in June 2016 and the other is currently in reexamination), and the alleged lack of any apprehension of suit by Hospira.[46] Janssen/NYU also argued that the court should decline jurisdiction because the BPCIA patent exchange provisions should apply to Hospira and because the ABLA has been filed but Hospira has not provided a Paragraph 8(A) Notice.[47] Hospira opposed these motions, arguing that there was a case or controversy and that the BPCIA was not a bar to the suit.[48]

As in the *Celltrion* case, Judge Crotty granted Janssen's motion to dismiss for lack of subject matter jurisdiction. The court noted that Hospira relied on Celltrion activities to show meaningful preparation but then "minimize[d] its coextensive relationship with Celltrion" when arguing that it is not subject to BPCIA procedures.[49] Again, in dicta the court noted that even if jurisdiction were present, the court would exercise its discretion to decline to hear the case due to the applicability of the BPCIA.[50]

It appears that the dismissals in *Celltrion* and *Hospira* were not appealed. Thus, the Federal Circuit will not likely weigh in on the propriety of the rulings, and the BPCIA uncertainty will continue.

D. *Amgen Inc. v. Sandoz Inc.*

A second case between Amgen and Sandoz has arisen based on Sandoz's filing of a section 351(k) application related to a different Amgen product. In July 2014, Sandoz announced that the FDA accepted its section 351(k) application for a biosimilar of Amgen's biologic filgrastim, marketed as Neupogen®.[51] Neupogen® is indicated for decreasing incidence of infection, as manifested by neutropenia, in patients receiving cancer treatment.

In late October 2014, Amgen filed a complaint for patent infringement, conversion, and unfair competition (Cal. Bus. & Prof. Code § 17200) against Sandoz, alleging that Sandoz had refused to follow the patent information exchange procedures set forth in the BPCIA.[52] Specifically, the complaint alleged that Sandoz sent a letter to Amgen stating that Sandoz "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and a later letter stating that Sandoz had chosen not to exercise its "right to use the patent information exchange process of the BPCIA."[53] Amgen

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argued that Sandoz's failure to provide its application was an impermissible attempt to avoid the patent information exchange procedures of the BPCIA.[54]

Sandoz filed an answer on November 20, 2014, claiming that it had complied with the BPCIA "in all respects" because the "BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor immediately after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation would render superfluous BPCIA subsection (l)(9)(C)[.]"[55] Sandoz further argued that "[t]he BPCIA clearly and cleanly separates the FDA review and approval process described in 42 U.S.C. § 262(k) from the patent exchange process described in 42 U.S.C. § 262(l). Amgen wrongly seeks to create a link between the patent information exchange provisions and the regulatory review where one does not exist in the BPCIA."[56]

In its counterclaims, Sandoz seeks a declaratory judgment that:

> (1) subsection (k) applicants may elect not to provide the subsection (k) application to the reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C);
>
> (2) Amgen cannot obtain damages, restitution, or injunctive relief, including enjoining Sandoz from continuing to seek FDA review of its subsection (k) application for filgrastim, for Sandoz's electing not to provide the reference product sponsor with the subsection (k) application;
>
> (3) the exclusive consequence of the BPCIA for a biosimilar applicant that does not choose to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process is for the applicant to lose its right to file a declaratory judgment action regarding patents for the biological product while authorizing the reference product sponsor to bring such an action immediately, or for use of the biological product as set forth in 42 U.S.C. § 262(*l*)(9)(C);
>
> (4) Amgen's claims for violation of California's Unfair Competition Law and conversion cannot state a claim for relief as they seek remedies that are improper, unlawful, and/or preempted—including injunction, restitution, and damages—for a biosimilar applicant's decision not to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process;
>
> (5) Amgen's cause of action for conversion fails to state a claim due to the non-exclusive property right Amgen possesses in its license for Neupogen®;
>
> (6) the manufacture, use, offer for sale, and sale of biosimilar filgrastim do not and will not infringe any valid claim of U.S. Patent No. 6,162,427 ("the '427 patent") under 35 U.S.C. § 271(a), (b), (c), or (e)(2)(C)(ii); and
>
> (7) the claims of the '427 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially created bases for invalidation.[57]

On January 6, 2015, Amgen filed a motion for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) or in the alternative a motion for summary judgment under Federal Rule of Civil Procedure 56.[58] Amgen sought an order that Sandoz is required to provide its ABLA to Amgen (the BPCIA provision is not optional) and that Sandoz's notice of commercial marketing under Paragraph 8(A) "must be preceded by FDA's licensure" of Sandoz's product.[59] In addition, Amgen requested that the court dismiss Sandoz's declaratory judgment counterclaims because under subsection 262(*l*)(9)(C) only Amgen can bring an action for declaratory judgment when Sandoz has not timely provided its ABLA.[60] As of the writing of this article, a hearing on the motion had been set for February 12, 2015.

III. Conclusion

As reflected in several recent cases, although it has been almost five years since the introduction of the BPCIA, much uncertainty still exists for reference product sponsors and 351(k) applicants alike. Rulings thus far have favored reference product sponsors. The Federal Circuit likely will continue to weigh in during the coming years to further shed light on the application of this complex statutory framework.

(Endnotes)

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[1] A "biologic" is a class of pharmaceutical derived or extracted from a biological source. "Biological Product" is also defined in 42 U.S.C. § 262(i) as "a virus, therapeutic serum, toxin, antitoxin,


vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."

[2] 42 U.S.C. § 262(k)(2)(A). Notably, Sandoz Inc. announced July 24, 2014 that the FDA is reviewing its request to market a biosimilar version of Amgen Inc.'s Neupogen®, marking the first publicly disclosed application filed under the BPCIA. *See* the press release at http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml (last visited Dec. 22, 2014).

[3] 42 U.S.C. § 262(k)(2)(A).

[4] 42 U.S.C. § 262(*l*)(2)(A-B).

[5] 42 U.S.C. § 262(*l*)(3)(A).

[6] *Id.*

[7] 42 U.S.C. § 262(*l*)(3)(B)(i).

[8] 42 U.S.C. § 262(*l*)(3)(B)(ii).

[9] 42 U.S.C. § 262(*l*)(3)(B)(iii).

[10] 42 U.S.C. § 262(*l*)(3)(C).

[11] 42 U.S.C. § 262(*l*)(4)(A).

[12] 42 U.S.C. § 262(*l*)(6)(A).

[13] 42 U.S.C. § 262(*l*)(4)(B).

[14] 42 U.S.C. § 262(*l*)(5)(A).

[15] 42 U.S.C. § 262(*l*)(5)(B).

[16] 42 U.S.C. § 262(*l*)(6)(B).

[17] 42 U.S.C. § 262(*l*)(8)(A) (emphasis added).

[18] 42 U.S.C. § 262(*l*)(8)(B).

[19] 42 U.S.C. § 262(*l*)(9)(A).

[20] 42 U.S.C. § 262(*l*)(9)(C).

[21] Complaint at 8-9, *Sandoz Inc. v. Amgen Inc.*, No. 3:13-cv-02904-MMC, Dkt. 1 (N.D. Cal. June 24, 2013).

[22] *Id.*

[23] Opp. to Motion to Dismiss for Lack of Jurisdiction, *Sandoz Inc. v. Amgen Inc.*, No. 3:13-cv-02904-MMC, Dkt. 55 (N.D. Cal. Sept. 13, 2013).

[24] Motion to Dismiss for Lack of Jurisdiction at 1-2, *Sandoz Inc. v. Amgen Inc.*, No. 3:13-cv-02904-MMC, Dkt. 40 (N.D. Cal. Aug. 16, 2013).

[25] *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904-MMC, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), *aff'd,* 773 F.3d1274 (Fed. Cir., 2014) ("*Sandoz I*") (Order Granting Motion to Dismiss for Lack of Jurisdiction).

[26] *Id.* at 2-3.

[27] *Id.* at 3.

[28] *Id.* at 3-4.

[29] *Id.* at 3.

[30] Corrected Non-Confidential Brief of Plaintiff-Appellant, *Sandoz Inc. v. Amgen Inc.*, No. 2014-1693, Dkt. 28 (Fed. Cir. Mar. 14, 2014).

[31] *Id.* at 21-24.

[32] *Id.* at 24-26.

[33] Non-Confidential Opposition Brief of Defendants-Appellees at 28, 50, *Sandoz Inc. v. Amgen Inc.*, No. 2014-1693, Dkt. 38 (Fed. Cir. May 27, 2014).

[34] *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1275 (Fed. Cir. 2014) ("*Sandoz II*").

[35] *Id.* at 1280-81.

[36] *Id.* at 1282.

[37] Complaint, *Celltrion Healthcare Co. v. The Kennedy Trust for Rheumatology Research*, No. 1:14-cv-02256-PAC, Dkt. 2 (S.D.N.Y. Mar. 31, 2014). In March 2014, Celltrion Healthcare Co., Ltd. and Celltrion, Inc. also brought a declaratory judgment action in the District of Massachusetts against Janssen Biotech, Inc., requesting a judgment of patent invalidity and non-infringement of three Janssen patents allegedly covering Remicade®. This suit was voluntarily dismissed by Celltrion on October 23, 2014 after a motion to dismiss for lack of jurisdiction had been fully briefed by the parties but before the motion had been decided.

[38] *Id.*

[39] Motion to Dismiss for Lack of Jurisdiction, *Celltrion Healthcare Co. v. The Kennedy Trust for Rheumatology Research*, No. 1:14-cv-02256-PAC, Dkt. 20 (S.D.N.Y. Aug. 28, 2014).

[40] Opp. to Motion to Dismiss for Lack of Jurisdiction, *Celltrion Healthcare Co. v. The Kennedy Trust for Rheumatology Research*, No. 1:14-cv-02256-PAC, Dkt. 23 (S.D.N.Y. Sept. 29, 2014).

[41] *Celltrion Healthcare Co. v. The Kennedy Trust for Rheumatology Research*, No. 1:14-cv-02256-PAC, Dkt. 32 at 7 (S.D.N.Y. Dec. 1, 2014) (Order Granting Motion to Dismiss for Lack of Jurisdiction).

[42] *Id.* at 8.

[43] Complaint, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 1 (S.D.N.Y. Aug. 29, 2014).

[44] *Id.* at 2.

[45] Motion to Sever and Transfer, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 35 (S.D.N.Y. Oct. 9, 2014); Motion to Dismiss for Lack of Subject Matter Jurisdiction, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 37 (S.D.N.Y. Oct. 9, 2014).

[46] Motion to Dismiss for Lack of Subject Matter Jurisdiction at 7-18, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 37 (S.D.N.Y. Oct. 9, 2014).

[47] *Id.* at 19.

[48] Opp. to Motion to Dismiss for Lack of Subject Matter Jurisdiction, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 42 (S.D.N.Y. Oct. 16, 2014).

[49] *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 1:14-cv-07049, Dkt. 60 (S.D.N.Y. Dec. 1, 2014) (Order Granting Motion to Dismiss at 2-3).

[50] *Id.* at 3.

[51] The announcement can be viewed at: http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml (last visited Dec. 22, 2014).

[52] Complaint at 2-3, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741, Dkt. 1 (N.D. Cal. Oct. 24, 2014). Also in late October 2014, Amgen filed a Citizen Petition with the FDA requesting that the FDA require a 351(k) applicant certify that it will comply with the BPCIA prior to the FDA accepting the ABLA. Amgen again argued that the patent dispute resolution process of the BPCIA is not optional. Momenta Pharmaceuticals, Inc. has commented on Amgen's petition, arguing that the BPCIA "is crystal clear in establishing a regulatory pathway that is separate and distinct from the patent exchange and any private patent enforcement activities." The docket can be viewed at http://www.regulations.gov/#/docketDetail;D=FDA-2014-P-1771.

[53] *Id.* at 24, 26.

[54] *Id.* at 26.

[55] Answer and Counterclaims at 3, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741, Dkt. 22 (N.D. Cal. Nov. 20, 2014).

[56] *Id.* at 24.

[57] *Id.* at 32-33.

[58] Motion for Judgment on the Pleadings or Partial Summary Judgment, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741, Dkt. 35 (N.D. Cal. Jan. 6, 2015).

[59] *Id.* at 9.

[60] *Id.* at 24.

A Tale of Two Claim Constructions– When the Patent Expires During an AIA Review

*By Kenneth R. Adamo, David W. Higer, and Eugene Goryunov**

Practitioners have spoken extensively about the broadest reasonable interpretation ("BRI") standard the Patent Trial and Appeal Board ("PTAB") applies in Leahy-Smith American Invents Act ("AIA") reviews. There is one major nuance: the BRI standard applies only to claims of an unexpired patent. Like the district courts, the PTAB applies the *Phillips v. AWH Corp.* standard to claims of an expired patent.[1]

The legal distinction between the two standards—BRI and *Phillips*—is outside the scope of this article. Instead, this article discusses PTAB cases addressing which standard should apply when a patent in an AIA review expires—naturally or by other means—before the review is concluded. This article concludes by noting questions arising out of the PTAB current cases.

I. Claim Construction at the PTAB

The claims of an *unexpired* patent in an AIA review are given their "broadest reasonable construction in light of the specification." Use of the BRI standard is premised on the patent owner's ability to amend claims.[2] When a patent *expires*, however, its claims cannot be amended and the PTAB applies the *Phillips* standard.[3] Under the *Phillips* standard, claim terms are given their "ordinary and customary meaning."[4]

II. Switching Claim Construction Standards

The appropriate claim construction standard, based on PTAB cases to date, for a patent that expires during a review depends on (1) when the patent expires and (2) whether the patent expires by artificial means.[5] Below we discuss the two bookend cases.

Toyota Motor Corp. v. Hagenbuch: The PTAB instituted an AIA review of a then-unexpired patent, construing terms using the BRI standard. Before the patent owner filed its Response, the patent naturally expired. During a conference call, the parties agreed that the PTAB should construe terms using the *Phillips* standard because the patent had expired.[6]

Amkor Tech., Inc. v. Tessera, Inc.: The PTAB instituted an AIA review of a then-unexpired patent. The parties and the PTAB applied the BRI standard throughout the review.[7] After the evidentiary record had closed, however, the patent owner filed a terminal disclaimer of the patent.[8] The PTAB authorized the parties to brief the impact, if any, of the terminal disclaimer on the applicable claim construction standard.

The patent owner argued that the terminal disclaimer had an immediate impact; the BRI standard no longer applied because the claims could no longer be amended and *Phillips* was the correct standard. The petitioner responded that the BRI standard continued to apply because the patent owner "participated fully" in the review based on the BRI standard and improperly delayed filing its terminal disclaimer. The petitioner also argued that permitting the patent owner's terminal disclaimer to change the course of the review would have a "significant and drastic impact on post-grant review proceedings and encourage abuse by patent owners."[9]

The PTAB first noted that changing the claim construction standard at a late stage in the review would require the review to start over. The patent owner had many opportunities to challenge the BRI standard and, indeed, could have filed its terminal disclaimer earlier. The PTAB agreed with the petitioner that approving the patent owner's conduct would encourage "gamesmanship" and defeat the purpose of inter partes review ("IPR"). It could also create "a tool to alter claim construction at late stages in post-grant proceedings, to render prior discovery meaningless, and to disrupt trial dates and statutory deadlines." In view of the specific facts of the case, the PTAB chose to exercise its "exclusive jurisdiction" over the patent and "hold in abeyance" the terminal disclaimer until the termination or completion of the review.[10]

III. Questions Remain

A number of questions arise out of these two cases:

- ***What claim construction standard applies if the patent expires naturally, but after the initial phase?***

In *Square, Inc. v. Cooper*, the PTAB observed the patent would expire prior to the final written decision and

requested the parties to brief what claim construction standard should be applied.[11] The parties agreed the BRI standard should not apply since the "patent will have expired at the time of the final written decision."[12] It is unclear, however, how the PTAB would proceed if the parties were unable to agree.

- ***What claim construction standard should be applied if the patent expires naturally, but after a substantial amount of work has already been completed?***

To date, it is unclear how the PTAB would proceed if the patent expired under such circumstances. To avoid surprises, however, practitioners may want to consider the expiration date of the challenged patent early in the review.

- ***What claim construction standard should be applied if the patent owner files a terminal disclaimer, but early in the case?***

In *Amkor Tech., Inc. v. Tessera, Inc.*, the PTAB suggested the patent owner's post-institution Response may be the proper time to file a terminal disclaimer, but expressed no opinion if a later disclaimer would always be "held in abeyance."[13] Only time will tell if an earlier-filed terminal disclaimer will change the applicable claim construction standard.

IV. Conclusion

The PTAB's decisions in *Toyota* and *Amkor* demonstrate the PTAB's willingness to change the applicable claim construction standard after instituting review. What's more, the PTAB appears much more likely to apply a different claim construction standard if the review is in an early phase and there are no concerns of gamesmanship. Practitioners should monitor PTAB precedents as they address the various postures in which this issue can arise.

(Endnotes)

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This article reflects only the present considerations and views of the authors, which should not be attributed to Kirkland & Ellis LLP, or to any of its or their former or present clients.

1 *Intel Corp. v. FuzzySharp Techs., Inc.*, IPR2014-00002, Paper 9 at 8 (P.T.A.B. Jan. 31, 2014); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

2 Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

3 *Intel*, IPR2014-00002, Paper 9 at 8.

4 *Universal Remote Control Inc. v. Universal Elecs., Inc.*, IPR2013-00127, Paper 13 at 5–6 (P.T.A.B. July 16, 2013).

5 IPR2013-00242, Paper 129 at 11 (P.T.A.B. May 22, 2014).

6 IPR2013-00483, Paper 21 at 2 (P.T.A.B. Apr. 16, 2014).

7 IPR2013-00242, Paper 129 at 2–4.

8 IPR2013-00242, Paper 121 at 1 (P.T.A.B. Apr. 21, 2014).

9 IPR2013-00242, Paper 129 at 5–6.

10 *Id.* at 6–10.

11 IPR2014-00157, Paper 12 at 2–4 (P.T.A.B. Jun. 4, 2014).

12 IPR2014-00157, Paper 15 at 2 (P.T.A.B. Jun. 13, 2014).

13 IPR2013-00242, Paper 129 at 10.

NYIPLA Files Amicus Brief Arguing Against Granting Preclusive Effect to Trademark Trial and Appeal Board Decisions

*By Dyan Finguerra-DuCharme**

The question of whether to afford preclusive effect to Trademark Trial and Appeal Board ("TTAB") decisions on the issue of likelihood of confusion has been addressed inconsistently among the circuits. Following a divided opinion from the U.S. Court of Appeals for the Eighth Circuit, which refused to grant preclusive effect to the TTAB's finding, the United States Supreme Court granted certiorari on the issue in *B&B Hardware, Inc. v. Hargis Industries, Inc*., No. 13-352. The case also presents the question of whether, as an alternative to preclusion, the TTAB's finding should be given some deference by a district court.

In *B&B Hardware*, the Eighth Circuit held that a prior TTAB determination on confusion, which denied registration, carried no preclusive effect in the subsequent infringement case. In an earlier proceeding, the TTAB had concluded that Hargis's SEALTITE mark, for self-drilling and self-tapping screws used in metal buildings, could not be registered because the mark was likely to be confused with B&B's SEALTIGHT mark for aerospace fasteners. The district court refused to apply collateral estoppel on the issue of likelihood of confusion and gave no deference to the TTAB decision. In the end, the jury determined that there was no likelihood of confusion. *B&B Hardware, Inc. v. Hargis Indus., Inc*., 736 F. Supp. 2d 1212 (E.D. Ark. 2010).

The Eighth Circuit affirmed the district court's decision to not accord collateral estoppel to the TTAB's finding. *B&B Hardware, Inc. v. Hargis Indus., Inc.*, 716 F.3d 1020, 1025 (8th Cir. 2013). The court assessed whether the TTAB addressed the same matter as that which was sought to be precluded and concluded that because the TTAB focused mainly on the registration and the application and not on the "marketplace context," its analysis was not entitled to either a preclusive effect or deference.

In support of the Respondents, the New York Intellectual Property Law Association ("NYIPLA") has filed an amicus brief arguing that TTAB decisions should not be given preclusive effect as a matter of course in a subsequent litigation between the parties concerning the same marks at issue before the TTAB. The NYIPLA further argues that on the rare occasion that the TTAB considered marketplace evidence so that the parties have had a full and fair opportunity to be heard, the court should give minimal evidentiary weight to the TTAB decision on the narrow issue of registrability.

The TTAB adjudicates disputes concerning the registration of marks. In most oppositions, the issue presented is whether the applied-for mark so resembles the senior user's mark "as to be likely…to cause confusion." 15 U.S.C. § 1052(d). Section 1052(d) of the Lanham Act concerns only whether a mark is entitled to registration, not whether a party may use the mark in commerce. Thus, even if the TTAB denies registration on the grounds that it is likely to cause confusion with a prior mark, the junior user is not precluded from marketing, promoting, and selling goods or services under that mark.

On the other hand, whether use of a mark should be enjoined falls within the purview of a federal court. In a trademark infringement litigation, the question presented is whether the use of one mark in the marketplace is "likely to cause confusion" with another mark in use in the marketplace. 15 U.S.C. § 1114(1)(a). The district court can enjoin the junior user, award damages, and cancel a registration (if one had issued).

Although it appears that the district court and the TTAB decided the identical issue—whether the marks are likely to cause confusion—the two governing bodies usually consider different evidence to answer that question.[1] In the NYIPLA's view, because critical information is not assessed by the TTAB, its decision should not be given automatic preclusive effect in a subsequent litigation.

Additionally, TTAB proceedings are also more discrete and limited than federal litigations. Electronic discovery is frowned upon by the TTAB, and parties often choose to not take depositions because of the presumptions imposed by the TTAB concerning the goods, channels of trade, and targeted consumer. Likewise, consumer surveys are designed differently depending on whether it is a TTAB proceeding or litigation.

Because of these differences, among others, the NYIPLA took the position that the issues decided between the two forums are not identical and that the TTAB rarely considers the "context of the marketplace" thoroughly enough to allow a court to conclude that the parties have had a full and fair opportunity to litigate the issue of likelihood of confusion in an infringement context.

There are, however, some proceedings in which it appears that the TTAB has indeed fully considered marketplace realities when determining whether confusion is likely. To that end, the NYIPLA took the further position that on the rare occasion that a district court determines that the TTAB has fairly considered the context of the marketplace, the TTAB decision should be afforded minimal evidentiary weight on the narrow issue of entitlement to registration and not to the issue of whether there is a likelihood of confusion if the owner uses the mark.

(Endnotes)

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[1] Some examples of how the evidence presented in each forum differs are as follows: (1) if the drawing for at least one of the marks is in standard character form, the TTAB will compare the marks visually and phonetically without regard to the intended stylization, whereas a court will compare the marks as they appear in commerce including the visual similarities as well as the marks' actual pronunciation, stylization, and appearance; (2) the TTAB compares the goods as they are identified in the application and registration, which is often very broad and appear to overlap, whereas a court will look to the actual services rendered or goods sold bearing the mark; and (3) if the channels of trade and targeted consumers are not limited in either the registration or application, the TTAB will presume that the goods/services travel through the normal channels and are targeted to the ordinary purchasers of the identified goods/services, whereas a court will consider the actual channels of trade and targeted consumers including retail price points, packaging, advertising, and merchandising markets.

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Determining Standing in Light of the Federal Circuit's *Azure Networks, LLC v. CSR PLC* Opinion

*By Jonathan Short and Matthew Sklar**

When it comes time to enforce a patent, it is imperative to determine who has standing to sue. Certainly, defendants may have an interest in seeking to exclude a plaintiff from a case based on standing for a variety of reasons (e.g., damages or venue). It is well settled that ordinarily, those who hold legal title to the patent have standing to bring a patent infringement suit. *See* 35 U.S.C. §§ 100(d), 281; *Azure Networks, LLC v. CSR PLC,* 771 F.3d 1336, 1342 (Fed. Cir. 2014); *Prima Tek II, L.L.C. v. A-Roo Co*., 222 F.3d 1372, 1376-77 (Fed. Cir. 2000); *Enzo APA & Son, Inc. v. Geapag A.G*., 134 F.3d 1090, 1093 (Fed. Cir. 1998). However, it is common for a patent owner to grant patent rights to another by way of an exclusive license. The nature of an exclusive license has a significant impact on the standing question and, more particularly, whether the licensee and the licensor (i.e., the patent owner) have standing in a litigation proceeding. In many instances, an exclusive licensee and the licensor will bring a patent suit together as co-plaintiffs to ensure that standing requirements are satisfied. *Cf. Prima Tek II*, 222 F.3d at 1377 (recognizing that as a "general rule," a patentee should be joined in a patent infringement suit that is brought by an exclusive licensee). However, a recent opinion from the Federal Circuit—*Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336 (Fed. Cir. 2014)—suggests that exclusive licensees and patent owners must carefully examine the license agreement before bringing suit and cannot assume that both the exclusive licensee and the patent owner can always bring suit together.

The Transfer of All Substantial Rights

The Federal Circuit has stressed that, with regard to patent infringement suits involving a licensor or an exclusive licensee, the standing analysis should focus on whether there has been a transfer of "all substantial rights" in the patent-in-suit. *See Alfred E. Mann Foundation For Scientific Research v. Cochlear Corp*., 604 F.3d 1354, 1358-59 (Fed. Cir. 2010). If the licensor does not transfer all substantial rights to the exclusive licensee, the licensor remains the owner of the patent and retains the right to sue for infringement. *Id*. at 1359. On the other hand, if the licensor transfers all substantial rights to the exclusive licensee, the licensee is deemed equivalent to a patent owner for standing purposes and gains the right to sue on its own. *Id*. at 1359-60. Finally, with regard to exclusive license agreements in which the licensee does not obtain enough rights to be deemed an owner for standing purposes, "either the licensee or the licensor may sue, but both of them generally must be joined as parties to the litigation." *Id*. at 1360.

The Federal Circuit has explained that "a patentee should be joined, either voluntarily or involuntarily, in any infringement suit brought by an exclusive licensee." *Prima Tek II*, 222 F.3d at 1377. Although an exclusive licensee may bring suit on its own if it has been granted all substantial rights under the patent, a suit brought by an exclusive licensee—without the licensor—is an "exception." *Id*.

Accordingly, when an exclusive license agreement exists, the most prudent course of action may be for the licensor and the exclusive licensee to file suit jointly.

Azure Networks — The Licensor Loses Its Ability to Bring Suit

Despite the Federal Circuit's implication in *Prima Tek II* that a suit brought only by the exclusive licensee is unusual, the court affirmed in *Azure Networks* that the exclusive licensee may be the only party that has standing in some instances.

In *Azure Networks*, one of the named plaintiffs—Azure Networks, LLC ("Azure")—owned various patents and patent applications. *See Azure Networks*, 771 F.3d at 1341. Azure donated a patent application that would issue as the patent-in-suit—the '129 patent—to Tri-County, a Texas nonprofit corporation. *Id*. at 1340-41. Following this donation, Tri-County and Azure entered into an "Exclusive Patent License Agreement" (the "Agreement"). *Id*. at 1341.

Pursuant to the Agreement, Azure obtained "the exclusive, worldwide, transferable right to (i) make, have made, use, sell, offer to sell, import, and lease any products, (ii) use and perform any method, process, and/or services, and (iii) otherwise practice any invention in any manner under the '129 patent." *Id*. Azure also obtained the exclusive right to enforce the '129 patent, the right to sublicense the '129 patent, and authority to reach settlements without Tri-County's consent. Additionally, Azure received the ability to assign its

rights under the Agreement to any of its affiliates in connection with the sale of a "material portion of any Azure business unit" without Tri-County's consent. *Id*. Finally, Azure received the exclusive right, but not the obligation, "to control future prosecution or pay maintenance fees related to the '129 patent family." *Id*. In exchange for this license, Tri-County retained the right to receive proceeds from Azure's licensing or litigation activities. *Id*. Tri-County also reserved a royalty-free non-exclusive right to practice the '129 patent and make Tri-County branded products and had the right to terminate the Agreement in the event Azure breached the Agreement or if Tri-County's tax-exempt status was placed at risk due to its obligations. *Id*. In addition, although the Agreement expired with two years remaining on the '129 patent term, Tri-County had the option to renew the Agreement in one-year increments. *See id*. Finally, Tri-County could not encumber the '129 patent and was obligated to participate in litigation at Azure's request and in Azure's sole discretion. *See id*.

At the district court level, Tri-County and Azure together filed a patent infringement suit, and the named defendants sought to dismiss Tri-County from the case. *Id*. The named defendants claimed that "the significant rights transferred to Azure under the Agreement constituted an effective assignment for purposes of standing, leaving Tri-County with no rights to sue as co-plaintiff." *Id*. The district court agreed with this argument and dismissed Tri-County from the case because it found that "Tri-County's title in the patent and financial and reversionary interests therein were not sufficient to confer standing upon Tri-County." *Id*. at 1341-42.

On appeal, the Federal Circuit directed its attention to the Agreement itself to determine whether Tri-County transferred all substantial rights in the '129 patent and, if so, whether it had standing to bring suit with its licensee. *See id* at 1342. To determine whether the Agreement was "tantamount to an assignment," the Federal Circuit indicated that it "must ascertain the intention of the parties" to the Agreement and "examine the substance of what was granted." *Id*. (citation and quotation marks omitted). However, the court indicated that the intent of the parties alone is not dispositive. *Id*. Also, in determining whether all substantial rights were transferred, the Federal Circuit explained that it would consider the following "non-exhaustive" list of factors:

> (1) the nature and scope of the right to bring suit;
>
> (2) the exclusive right to make, use, and sell products or services under the patent;
>
> (3) the scope of the licensee's right to sublicense;
>
> (4) the reversionary rights to the licensor following termination or expiration of the license;
>
> (5) the right of the licensor to receive a portion of the proceeds from litigating or licensing the patent;
>
> (6) the duration of the license rights;
>
> (7) the ability of the licensor to supervise and control the licensee's activities;
>
> (8) the obligation of the licensor to continue paying maintenance fees; and
>
> (9) any limits on the licensee's right to assign its interests in the patent.

Id. at 1343.

The Federal Circuit recognized that the Agreement granted Azure the right to practice, enforce, and defend the '129 patent. *Id*. However, Tri-County did not retain control over Azure's litigation or licensing activities concerning the '129 patent. *See id*. Instead, Tri-County had a duty to join and cooperate in a suit if necessary while control over the suit remained with Azure. *See id*. at 1343-44. Furthermore, the Federal Circuit disregarded other factors that Tri-County argued indicated that it did transfer all substantial rights in the '129 patent. *See id*. at 1344-47.

Specifically, the Federal Circuit explained that Tri-County's right to receive a portion of the proceeds from enforcement of the '129 patent "does not defeat a transfer of substantial rights in the face of the factors . . . that strongly indicate Azure's ownership." *Id*. at 1344. Additionally, Tri-County's right to practice the patent, which was not exclusive, had "little force." *Id*. Tri-County did not make or sell any products, and it did not appear that it would do so in the future. *See id*. In addition, although Tri-County retained termination rights under the Agreement that could be exercised if Azure failed to perform or breached any terms of the Agreement, the Federal Circuit stated that "Tri-County's right to monitor whether Azure breaches any of its obligations does not amount to the type of control that [the Circuit has] found indicative of ownership in prior cases." *See id*. at 1344-45. In short, the termination rights were not equivalent to rights to control Azure's actions. *See id*. at 1345. Similarly, Tri-County's right to terminate the Agreement if it incurred tax liabilities did not undermine Azure's control of the '129 patent as Azure could re-acquire the patent if Tri-County terminated for that reason. *Id*. Finally, the Federal Circuit noted that although the Agreement

cont. on page 14

cont. from page 13

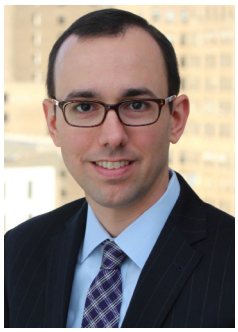
automatically terminated prior to the expiration of the '129 patent, the short patent life remaining after the automatic termination date and the rolling renewal cycle that could extend the Agreement until the patent's expiration did not suggest that Tri-County retained ownership of the patent. *See id.* at 1345-47.

The Federal Circuit explained that only Azure had standing to bring suit because Azure acquired significant rights under the '129 patent and Tri-County did not retain ownership in the patent. *Id.* at 1347. Furthermore, Tri-County could not join in the suit despite the fact that it had some interest in the '129 patent. *Id.* According to the Federal Circuit, a party that holds less than all substantial rights and lacks exclusionary rights does not have standing to bring suit. *Id.* Therefore, Tri-County could not have standing because it did not retain exclusionary rights under the licensed patent. *Id.*

Lessons Learned — The Relationship Between Standing and an Exclusive License

The Federal Circuit's *Azure Networks* opinion illustrates the importance of considering how the rights granted by an "exclusive" patent license agreement may impact infringement litigation. Indeed, a party to the agreement may be precluded from participating as a named party asserting patent infringement due to lack of standing. Moreover, as the opinion illustrates, even when the licensor and licensee bring a patent infringement suit together while assuming that they both have standing, the licensor—i.e., the patent holder—can be dismissed from the suit if it has given away certain rights.

Accordingly, when entering into an exclusive license agreement, both the licensor and the licensee should take care to ensure that the agreement is drafted so that it provides standing for those whom the parties expect to participate in patent infringement actions.



(Endnotes)

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Moving UP ▲ & Moving ON ➤➤➤

➤ Sean Grygiel, formerly of Fish & Richardson LLP, has joined Perkins Coie LLP as a partner in its Intellectual Property practice.

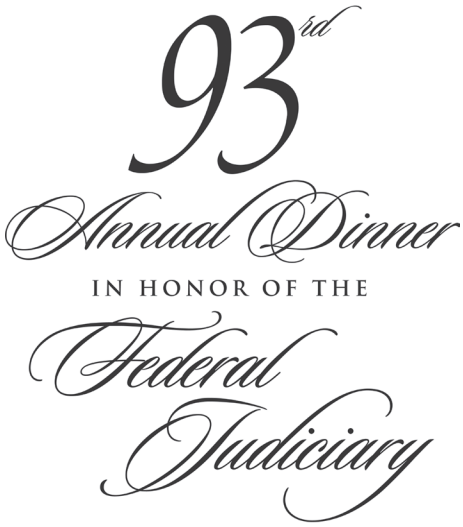
➤ Allison Levine Stillman of Mayer Brown LLP has been promoted to partner in its Intellectual Property practice.

➤ Manny Caixeiro of Perkins Coie LLP has been promoted to partner in its Intellectual Property practice.

➤ Christopher R. Chase, Jeremy S. Goldman, and Alan Sacks of Frankfurt Kurnit Klein & Selz, PC, have been promoted to partner in its Advertising, Marketing & Public Relations Group, Litigation Group, and Entertainment Group, respectively.

The Bulletin'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 Bulletin editors: Mary Richardson (mary.e.w.richardson@gmail.com) or Robert Greenfeld (rgreenfeld@steptoe.com).

The New York Intellectual Property Law Association will host its



Friday, March 27, 2015

THE WALDORF ASTORIA NEW YORK HOTEL

The New York Intellectual Property Law Association will host its 93rd Annual Dinner in Honor of the Federal Judiciary (Judges Dinner) on Friday, March 27, 2015. The Judges Dinner will take place at The Waldorf Astoria New York Hotel. This is the largest black-tie gathering of federal judges, government officials, corporate counsels, legal professionals, and representatives from other intellectual property associations.

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Profit Apportionment in Intellectual Property Damages: The Unique Case of Design Patents

*By John G. Plumpe and Kimberly J. Schenk**

It is well established in most areas of intellectual property ("IP") law that an award of monetary relief based on the profits earned from the sale of an infringing product should be apportioned to reflect the value of the property at issue in generating those profits. In practice, this apportionment presents one of the most challenging tasks a litigant faces in proving its damages case.[1] Courts are cognizant of this difficulty, but have nonetheless required apportionment as a predicate for an award based on the infringer's profits.[2]

Design patents provide an exception to this general principle. Unlike a utility patent, which protects the way an article is used and works (35 U.S.C. § 101), a design patent protects the way an article looks (35 U.S.C. § 171).[3] In 2013, the United States Patent and Trademark Office ("USPTO") issued fewer than 24,000 design patents[4] – less than one-tenth the number of utility patents. Notably, as design patents are fewer in number, they are also less frequently litigated.

In this article we will describe profit apportionment in three common types of IP litigation cases – those involving (1) trademarks and trade dress; (2) copyrights; and (3) utility patents. We then will discuss the availability of infringer's profits as a form of recovery in design patent litigation.

1. Apportionment in Trademark and Trade Dress Infringement Litigation

The Lanham Act allows for the recovery of the profits earned by a defendant related to the infringement of a trademark or trade dress or for other related violations. In a Lanham Act case, a prevailing plaintiff may, "subject to the principles of equity, . . . recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action."[5] Further, the statute provides that the award must be "compensation" and not a "penalty."[6]

While the statute does not specifically mention apportionment, many Lanham Act decisions suggest that an apportionment of defendant's profits should be considered in trademark and trade dress matters. For example, courts have found "an accounting is intended to award profits only on sales that are attributable to the infringing conduct."[7] Methods of apportioning profits in Lanham Act matters are case-specific and may entail consideration of the contribution made by the other functions and assets embodied in the infringing product, geographical limitations, IP valuation techniques, and other issues.

2. Apportionment in Copyright Infringement Litigation

Similarly, in copyright infringement litigation, the owner of an infringed work may pursue monetary remedies including actual damages and infringer's profits. Statutory damages are also available. Specifically, the Copyright Act of 1976 permits recovery of "any profits of the infringer that are attributable to the infringement that are not taken into account in computing actual damages," and also states that "the infringer is required to prove his or her deductible expenses and the elements of profit attributable to factors *other than* the copyrighted work."[8] Apportionment is also supported by copyright case law, including the often-cited *Sheldon v. Metro-Goldwyn Pictures Corp.* case, in which the United States Supreme Court affirmed a lower court's decision that principles governing apportionment of profits in utility patent infringement cases apply to cases of copyright infringement.[9]

3. Apportionment in Utility Patent Infringement Litigation

Unlike its counterparts in copyright and trademark law, the utility patent damages statute, 35 U.S.C. § 284, contains no provision for an award of infringer's profits *per se*. However, reasonable royalty damages are oftentimes, as a practical matter, an exercise in apportioning the total profits of the infringing product to those that are specifically derived from the elements of the product that infringe the patent's claims.[10]

For example, the fifteen *Georgia-Pacific* factors require, among other things, consideration of the established profitability of the product made under the patent; the utility and advantages of the patented property over old modes and devices; the portion of the realizable profit attributable to the invention as distinguished from non-patented elements; and the amount that a prudent licensee would have been willing to pay as a royalty and yet be able to make a reasonable profit.[11] Thus, a major difference between reasonable royalty damages derived based on the *Georgia-Pacific* factors and an award of infringer's profits is that a reasonable royalty award represents a split of the profits between a licensor and licensee in a hypothetical license negotiation, whereas an award of an infringer's total profit would grant all of those profits to the owner of the IP.

Further, recent utility patent decisions have focused attention on apportionment principles when determining not only the reasonable royalty rate, but also the royalty base.[12] The entire market value rule ("EMVR") requires that, when practicable, the royalty base be limited to the smallest saleable patent practicing unit with close relation to the patented technology, unless the patent holder can show that the patented element is a primary basis, if not the sole basis, of demand for the entire product.[13]

Until recently, plaintiffs have used this smallest saleable patent practicing unit exception as a means for claiming

reasonable royalty damages based on the entire value of a multicomponent product, even when the patent related to only a small component of the overall product.[14] However, the Federal Circuit's recent ruling in *VirnetX, Inc. v. Cisco Systems, Inc.*[15] clarified that the smallest saleable patent practicing unit theory cannot be invoked as an exception to the EMVR if that unit does not have close relation to the patented technology. The Federal Circuit recognized the difficulty this can create by requiring that the royalty be based on the value of a component that was never individually sold; however, it noted that "it is well understood that this process may involve some degree of approximation and uncertainty."[16]

4. Design Patent Infringement

The availability of the infringer's profits as a form of monetary relief in design patent cases is covered by 35 U.S.C. § 289, which states:

> Whoever during the term of a patent for a design, without license of the owner, (1) applies the patented design or any colorable imitation thereof, to any article of manufacture for the purpose of sale, or (2) sells or exposes for sale any article of manufacture to which such design or colorable imitation has been applied shall be liable to the owner to the extent of his total profit, but not less than $250, recoverable in any United States district court having jurisdiction of the parties.[17]

Courts have interpreted this to mean that the holder of an infringed design patent is entitled to recover all of the profits generated from the infringing product, without any requirement to apportion those profits to the incremental value of the design patent-in-suit as compared to other product elements, functional or otherwise.[18] The application of apportionment principles in design patent cases has been specifically rejected by courts on a number of occasions.[19]

5. Conclusion

Among the various forms of IP, design patents are unique in that infringement may result in disgorgement of the entire profit the infringer earns on the product incorporating the patented design, without any requirement to apportion those profits to account for other product features not covered by the patent. By contrast, in the areas of copyright, trademark/trade dress, and utility patent infringement, statutes and/or case law typically treat apportionment as a predicate to an award based on infringer's profits (or reasonable royalty damages).

(Endnotes)

* John G. Plumpe and Kimberly J. Schenk are Principals in the Intellectual Property Practice of Charles River Associates (www.crai.com). They act as experts in the analysis of damages in intellectual property and complex commercial disputes. The conclusions set forth herein are based on independent research and publicly available material. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any of the organizations with which the authors are affiliated. Any opinion expressed herein shall not amount to any form of guarantee that the authors or Charles River Associates has determined or predicted future events or circumstances, and no such reliance may be inferred or implied. The authors and Charles River Associates accept no duty of care or liability of any kind whatsoever to any party, and no responsibility for damages, if any, suffered by any party as a result of decisions made, or not made, or actions taken, or not taken, based on this article.

1 The term "damages" is used herein to represent various forms of monetary relief that may be available in a particular case, including the recovery of the profits of an infringer.

2 *See, e.g., VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1328 (Fed. Cir. 2014); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009) (citing *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 (Fed. Cir. 1995)). As is discussed *infra,* apportionment may be applicable to the determination of a reasonable royalty or to an accounting of the profits of an infringer.

3 Manual of Patent Examining Procedure (MPEP), Ninth Edition, March 2014, Section 1502.01.

4 *See* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

5 15 U.S.C. § 1117(a).

6 *Id.*

7 *Lindy Pen Co. v. Bic Pen Corp.*, 982 F.2d 1400, 1408 (9th Cir. 1993); *see also*, *e.g.*, *Holiday Inns, Inc. v. Airport Holiday Corp.*, 493 F. Supp. 1025 (N.D. Tex. 1980), *aff'd*, 683 F.2d 931 (5th Cir. 1982); *Int'l Star Class Yacht Racing Ass'n v. Tommy Hilfiger U.S.A., Inc.*, No. 94-CIV-2663(RPP), 1999 WL 108739, at *4 (S.D.N.Y. Mar. 3, 1999), on remand from 146 F.3d 66 (2d Cir. 1998), *aff'd*, No. 99-7329, 2000 WL 220504 (2d Cir. Jan. 12, 2000).

8 17 U.S.C. § 504(b) (emphasis added).

9 309 U.S. 390 (1940); *see also, e.g., Frank Music Corp. v. Metro-Goldwyn-Mayer, Inc.*, 886 F.2d 1545 (9th Cir. 1989).

10 *Ericsson, Inc. v. D-Link Systems, Inc.,* Nos. 2013-1625, -1631, -1632, -1633, 2014 U.S. App. LEXIS 22778 at *53, *54 (Fed. Cir. Dec. 4, 2014) (citing *VirnetX*, 767 F.3d at 1326).

11 *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. May 28, 1970).

12 *VirnetX*, 767 F.3d at 1327-28 *Cornell Univ. v. Hewlett-Packard Co.,* 609 F. Supp. 2d 279, 286-87 (Fed. Cir. 2009) (citing *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1552 (Fed. Cir. 1997); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580 (Fed. Cir. 1989)).

13 *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1336 (Fed. Cir. 2009) (citing *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549-50 (Fed. Cir. 1995) (en banc)).

14 *See VirnetX*, 767 F.3d at 1327-28.

15 *Id.*

16 *Id.* at 1328 (citing *Unisplay, S.A. v. Am. Elec. Sign Co.,* 69 F.3d 512, 517 (Fed. Cir. 1995)).

17 35 U.S.C. § 289 (emphasis added).

18 *Nike Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1442–43 (Fed. Cir. 1998).

19 *See, e.g.*, *Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-LHK, 2012 WL 2571332 (N.D. Cal. June 30, 2012); *Nike*, 138 F.3d at 1442–43; *Bergstrom v. Sears, Roebuck & Co.*, 496 F. Supp. 476, 495 (D. Minn. 1980).

December 2014/January 2015 IP Media Links

*By Jayson Cohen**

Quick Updates on Marvel Superheroes and the Washington Redskins

As reported by Sadie Gurman of the Associated Press in December 2014, Stan Lee Media Inc. ("SLM") lost again to Disney in its attempt to claim rights to Marvel Superheroes created by Stan Lee. The Tenth Circuit upheld a District of Colorado decision rejecting any rights to SLM's ownership, just as the Ninth Circuit had before. (*See* http://entertainment.verizon.com/news/read/category/Entertainment/article/the_associated_press-company_loses_bid_for_rights_to_marvel_superheroes-ap.)

The Justice Department has intervened on the side of the Native Americans in the lawsuit brought by the Washington Redskins. The NFL team seeks to save the trademarks in the team's name and logo by challenging the constitutionality of the Lanham Act's provision allowing cancellation of trademarks that may disparage or bring people into "contempt or disrepute." (*See* http://www.washingtonpost.com/local/justice-department-intervenes-in-redskins-trademark-protection-lawsuit/2015/01/09/5840c07c-9815-11e4-8005-1924ede3e54a_story.html.)

Coke Keeps on Smiling

Victoria Slind-Flor writes regularly for Bloomberg on Intellectual Property issues. On January 8, 2015, she reported interesting news about Coke, Kodak, and James Bond. (*See* http://www.bloomberg.com/news/2015-01-08/liberty-ammunition-ibm-coca-cola-intellectual-property.html.)

Coca-Cola filed trademark applications for two Twitter hashtags—#smilewithacoke and #cokecanpics. Not surprisingly, Coke "plans to use the marks with soft drinks."

Kodak has licensed its name to Bullitt Group, a UK manufacturer of optoelectronic products, for the sale of Android-based, Kodak-brand smartphones and other consumer products.

In a private settlement, M-G-M agreed to dismiss a lawsuit against an NBC Universal movie project with a screenplay entitled "Section 6." M-G-M had claimed infringement of its copyrights in James Bond. Apparently because the NBC project is at an early stage, the dismissal is without prejudice to M-G-M refiling suit at a later time should it be unsatisfied that "Section 6" steers clear of its iconic super-spy.

Toyota Seeks to Spur Fuel-Cell Refueling Station Growth

In a widely reported story, Toyota is offering royalty-free licenses to its patent portfolio relating to refueling stations for hydrogen fuel cells. In order to stimulate the practical feasibility of and market for efficient hydrogen fuel cell cars among consumers, automakers for these cars need third parties to open refueling stations. Toyota's license offer is an apparent step to accelerate development of these "gas" stations of the future. Toyota also finances and partners with refueling station developers. (*See* http://business.financialpost.com/2015/01/06/toyota-opens-fuel-cell-patents-to-competitors-in-bid-to-spur-development-of-hydrogen-powered-vehicles.)

(Endnotes)

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Notable Trademark Trial and Appeal Board Decisions

By Stephen J. Quigley[*]

(Unless noted, all decisions are precedential.)

The Title of a Single Book May Be Registrable

Generally, the title of a single book cannot be registered, but a common title for two or more books in a series (e.g., *Harry Potter*) can be registered. A single book title, however, may be registered if it has acquired distinctiveness under Section 2(f) of the Trademark Act.

In this instance, the Board noted that the book and DVD title ROCK YOUR BODY could function as a trademark if the applicant demonstrated that "consumers would view ROCK YOUR BODY not merely as a title of the book or the DVD, but as a trademark indicating source[.]" The applicant, however, sold fewer than 1000 copies, a quantity that was insufficient to overcome the descriptiveness refusal.

In re King Productions, Inc., Serial No. 76/703,458 (T.T.A.B. Nov.19, 2014) [not precedential].

Cancellation Dismissed for Misconduct

A petition to cancel Microsoft's XBOX 360 registration for computer-related publications was dismissed because the *pro se* petitioners failed to establish standing and there was no basis for their claims of fraud and misrepresentation of source.

The petitioners claimed that use of the term "Huck" in Microsoft's user manual infringed their HUCK trademarks. However, since HUCK was not part of the opposed trademark, the petitioners had no standing to pursue the cancellation.

The Board noted that these petitioners have a long history of filing meritless inter partes proceedings. In addition to dismissing the claim with prejudice, the Board ordered the petitioners to show cause why sanctions should not be imposed to deter future frivolous petitions. These sanctions could include requirements to hire outside counsel and never filing a notice of opposition or petition for cancellation against a mark that bears no resemblance to the HUCK marks.

NSM Resources Corp. and Huck Doll LLC v. Microsoft Corp., Cancellation No. 92/057,932 (T.T.A.B. Nov. 25, 2014).

No Likelihood of Confusion Between REDNECK RACEGIRL and RACEGIRL

Although both marks identified identical items of clothing, the depictions of the two "R" letters in the applicant's mark, along with the difficult to see "ACE" portion of RACEGIRL in the mark were sufficient to avoid a likelihood of confusion. The word components of a mark are not always dominant and because prospective purchasers are likely to encounter the applicant's mark on hang tags or garment labels, "the visual impression of the mark is likely more important."

In re Covalinski, Serial No. 85/685,983 (T.T.A.B. Dec. 18, 2014).

CAFC Reverses TTAB on Similarity of Goods/Services and Channels of Trade

The U.S. Court of Appeals for the Federal Circuit reversed the Board's affirmance of the refusal to register TAKETEN for health care services on the basis of the TAKE 10! registration for printed materials used in connection with physical fitness activities.

While the court agreed that the marks were similar, because the relatedness of the parties' goods and services was not generally recognized, there must be a showing of "something more" than the mere fact that the TAKE 10! materials could be used with the TAKETEN services. The court also found that Internet advertising by both parties did not result in overlapping channels of trade. "Advertising on the Internet is ubiquitous and proves little, if anything, about the likelihood that consumers will confuse similar marks used on such goods or services."

In re St. Helena Hospital, No. 2014-1009, 2014 U.S. App. LEXIS 23564 (Fed. Cir. Dec. 16, 2014).

(Endnotes)

[*] Stephen J. Quigley is Of Counsel to Ostrolenk Faber LLP, where his practice focuses on trademark and copyright matters. He is also a member of the NYIPLA Board of Directors.

HISTORIAN'S CORNER

As Time Goes By – Legal Ed 2045

As we enter the New Year, we might speculate about what legal education might be like several generations from now. Although the time span until 2045 might seem like an eternity from the vantage point of the ten generations of law students passing through school by then, it accounts for at most a couple of career spans for practitioners as measured back-to-back.

Recent disruptions in the nation's economy have spurred a re-thinking as to how legal education is delivered, how long it should take, and how much it should cost. Moreover, the financial crisis of 2008 led to the failure of several prominent law firms and decreased hiring of new lawyers, including IP lawyers, within corporations and law firms alike. A downstream effect is that law school applications are down a whopping thirty to forty percent from where they were a decade ago.

A debate is raging in academic circles as to whether the typical three years needed to complete a Juris Doctor degree is still appropriate, or whether it is too long. Some law schools are experimenting with the idea of cramming the traditional credits needed for a J.D. into two calendar years by having the students attend school twelve months a year. Others are experimenting with distance learning, particularly in the context of non-core courses, as a way to reduce costs.

If you consider your own legal education in terms of how it laid the foundation for a career in intellectual property, you might envision why distance learning is likely to be a mixed bag for legal education, at least insofar as current distance learning technology is concerned. One reason is that the Socratic method, often perceived as the core of legal education since the 1870s when it was introduced by Harvard's Christopher Columbus Langdell, does not lend itself to delivery over the Internet.

Although current distance learning provides a passable tool for a lecture, particularly if the lecturer is comfortable "talking to a wall," so to speak, it does not lend itself well to the Socratic method. Indeed, the lecture style of delivering education can be perceived as the antithesis of the Socratic method, with the former allowing the student to passively absorb, or not absorb, information and the latter encouraging active, "in the moment" participation between student and professor.

Certain law schools are experimenting with creative ways to shorten the total time it takes to obtain a combined bachelor's and J.D. degree by allowing some credits needed for one degree to count towards the other. Although study of the liberal arts and social sciences might lend themselves to such a combined curriculum with law, the hard sciences and engineering that are key to a career in IP likely would not, due to program rigors and lab time needed.

The good news is that the technology for delivering distance learning will likely improve over time. The better news is that the economy surely will improve, leading to a renewed interest in the study of law and a surge in demand for IP practitioners. When that happens, the recent economic downturn will doubtless become but a dim memory.

Throughout the economic cycles, up and down, our Association will undoubtedly, to its credit, continue to support law students and practitioners through a diverse variety of continuing legal education programs.

Here's to a Happy 2015, and an even happier 2045!

With kind regards,

Dale Carlson

Dale Carlson, a retired partner at Wiggin and Dana, is "distinguished practitioner-in-residence" at Quinnipiac University School of Law, NYIPLA historian, and a Past President. His email is dlcarlson007@gmail.com.

Annual One-Day Patent CLE Seminar

By Mark Bloomberg, Colman Ragan and Robert Rando

On Thursday, November 20, 2014, the NYIPLA Programs Committee hosted its annual One-Day Patent CLE Seminar at the Princeton Club. The program included four panels, a Luncheon Keynote Speaker, and an interactive ethics presentation on social media. Panel I was directed to some issues commonly faced by in-house attorneys; Panel II was directed to litigation issues; Panel III was directed to a legal update from the Supreme Court, the Federal Circuit, and the Patent Trial and Appeal Board (PTAB); and Panel IV was directed to prosecution issues. The Luncheon Keynote Speaker was the Honorable Jerome B. Simandle, Chief Judge of the United States District Court for the District of New Jersey.

Panel I – Corporate

The members of Panel I included Programs Committee Member and Moderator, David Bomzer from Pratt & Whitney, and Speakers Anna Erenburg from Fuse, Valerie Boccadoro from American Express, Betty Ryberg from Novartis Services, Colman Ragan from Actavis, and Frank Sedlarcik from IBM Corporate. The panel addressed "Indemnification Issues" and "Coordination of Multi-forum Litigation."

The panel discussion of indemnification issues addressed a variety of practical considerations from the perspectives of a vendor indemnitor and a customer indemnitee. These considerations included what notice should be required and when notice should be made to be manageable; who should control litigation, including the advantages and disadvantages of having the right to control litigation; how liability caps are often set in practice; the practical difficulty for in-house counsel to keep abreast of the indemnity requirements set forth in a multitude of contracts; and the difficulty of defining and applying indemnification provisions when the products that are sold by a vendor are used in a system or method that includes products that are not provided by that vendor. The panel discussed how there is no "one size fits all" answer to indemnification and the issues that their respective companies often consider to determine what indemnification provisions are appropriate for a particular agreement.

The panel discussion of multiple forums noted that, even if litigation is not ongoing in multiple forums, the activities that are relevant to the action often take place in multiple forums. Thus, the documents, personnel, and operations that are relevant to an action for infringement filed in a United States district court may be in multiple countries, thereby giving rise to a number of issues. For example, the requirements to invoke attorney-client privilege may differ, resulting in disparate waiver implications.

The panel also discussed how multiple forums may impact discovery. Notably, it may be illegal for personnel in some foreign countries to comply with discovery requests, even if ordered by a district court. Another issue that may arise in the context of multi-forum litigation is the potential violation of privacy laws of foreign countries that do not apply in the United States. Also, when documents are located in foreign countries, it may create challenges for compliance with litigation hold orders because people outside the United States often have difficulty understanding the nature of discovery in the United States.

Panel II – Litigation

The members of Panel II included Programs Committee Co-Chair and Moderator, Mark Bloomberg from Zuber Lawler & Del Duca LLP, and Speakers Thomas Fleming from Kirkland & Ellis LLP, David Leichtman from Robins, Kaplan, Miller & Ciresi LLP, and Philip Hirschhorn from Buchanan Ingersoll & Rooney PC.

Tom Fleming presented on "Practical Issues of Litigation Holds." He described what is generally required to ensure that a party complies with its

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document preservation obligations so that it does not find itself in the position of having failed to preserve relevant documents and potentially incurring sanctions that could prove disastrous for its case. He described several pitfalls that can easily arise if attorneys fail to take early and active control over the process, and provided a number of recommendations concerning how to avoid those pitfalls.

David Leichtman presented on "Rule 12 Issues." He described several instances in which courts have used various provisions of Rule 12 of the Federal Rules of Civil Procedure to dismiss cases under 35 U.S.C. §101 following the Supreme Court's *Alice Corp. Pty. Ltd. v. CLS Bank International* decision. He noted that Rule 12 has been used with increasing frequency, discussing cases finding declaratory judgment jurisdiction, cases concerning the adequacy of pleadings for indirect infringement, and cases concerning the adequacy of pleadings for design patent infringement.

Phil Hirschhorn presented on "Strategies Dealing With Inconsistent Judgments From Different Forums." He explored the mechanisms by which inconsistent rulings on validity can result when the validity of patents is simultaneously challenged in the Patent and Trademark Office (PTO) and in the district courts, where different standards apply. He also outlined the potential issues that are likely to arise concerning how inconsistent judgments will affect parties, for example, the extent to which an adjudicated infringer continues to be bound by an injunction when the infringed patent is subsequently held to be invalid by the PTO. He explained that these issues remain largely unresolved, but provided helpful insights concerning the views of judges who have addressed these issues.

Keynote Speech

The Keynote Speaker, Chief Judge Jerome B. Simandle of the District of New Jersey, provided an outstanding presentation on how attorneys can work better with judges to streamline the litigation process without diminishing the quality of legal representation. In this regard, he gave the audience an appreciation for how active the dockets are for district court judges. He also provided helpful advice about how attorneys can, and should, work with each other to make their lives more civilized, for example by granting extensions liberally to accommodate personal issues that arise from time to time. Chief Judge Simandle also discussed the District of Delaware's 6 p.m. electronic filing deadline, and asked whether that was a good idea to cut down on the phenomenon of "11:58 p.m. filings."

We were privileged and honored to have such an accomplished jurist as the Keynote Speaker. His discussion was vibrant, engaging, and informative.

Interactive Ethics Presentation on Social Media

An Interactive Ethics Presentation on Social Media, which followed lunch, gave program attendees the chance to test their knowledge of legal ethics relating to the use of social media by voting by table on the correct responses to a series of multiple choice questions relating to the March 18, 2014 Social Media Ethics Guidelines of the New York State Bar Association. This program segment was well received by the attendees and was identified as an excellent way to provide recent information concerning ethics issues, some of which are not intuitive. The audience particularly enjoyed the opportunity to collaborate with each other.

The questions were prepared by Ira Levy of Goodwin Procter LLP and Patrice Jean and Tamara Coley of Kenyon & Kenyon LLP, and presented by Patrice Jean, who is a member of the Programs Committee. At the conclusion of the presentation, a victory prize was awarded to the participants at the table that had the most correct answers – and a remedial ethics prize was awarded to the participants at the table that had the fewest correct answers.

Panel III – Legal Update

The members of Panel III included Programs Committee Co-Chair and Moderator, Robert Rando from the Rando Law Firm PC, and Speakers Robert Isackson from Orrick, Herrington & Sutcliffe LLP, Eugene Chang from Willkie Farr & Gallagher LLP, and Janice Christensen from Jellins Christensen, LLP.

Rob Isackson presented a thorough discussion of the six Supreme Court patent cases from last term. He provided an excellent analysis of the impactful *Alice Corp. Pty. Ltd. v. CLS Bank International* and *Highmark Inc. v. Allcare Health Management Systems,*

Inc./Octane Fitness, LLC v. ICON Health & Fitness, Inc. decisions, and covered the two trademark and two copyright cases decided by the Court. His thoughtful commentary on all of the cases was quite beneficial, and the written material he provided is a great resource for all who attended.

Eugene Chang presented an extensive review of recent key Federal Circuit cases. These cases involved important patent issues that were not the subject of the recent Supreme Court cases. His discussion covered cases involving inequitable conduct, damages, double patenting, laches, jurisdictional ownership issues, and various types of claim scope disclaimers. His presentation identified and distilled the Federal Circuit's treatment of myriad patent law issues that practitioners often confront.

Janice Christensen presented a comprehensive review of Patent Trial and Appeal Board (PTAB) cases. Her statistical analysis of the AIA petitions, trials, disposals, and technology breakdowns was useful and enlightening. Her discussion and in-depth analysis of several IPR cases, post-*Alice* CBM cases, and PGR cases was also insightful and informative. Her astute advice on PTAB practice provided helpful and meaningful guidance for all of the practitioners in the audience.

The Legal Update panel provided valuable take-away information for the attendees on the topics that each of the panelists discussed.

Panel IV – Prosecution

The members of Panel IV included Programs Committee Member and Moderator, John Resek from Resek, Liang & Frank LLP, and Speakers Andrew Reibman from K&L Gates LLP, Brian Rothery from Stroock, Stroock & Lavan LLP, and Larry Coury from Regeneron Pharmaceuticals, Inc.

Andrew Reibman presented on "Writing Claims to Win Litigation." Andrew's presentation provided a practical guide on drafting claims for litigation when both the law and technology change over the life of a patent. Andrew's presentation considered how patent law has changed as the result of several recent

Supreme Court and Federal Circuit decisions, and the effect of these changes on claim drafting. Andrew's discussion provided an excellent and useful resource for practitioners on the interrelationship between litigation and patent prosecution.

Brian Rothery presented on "Disclosure Requirements." Brian's presentation included a discussion of the standard of materiality in an inequitable conduct analysis under the *Therasense, Inc. v. Becton, Dickinson & Co.* decision; the current standard of materiality under 37 CFR § 1.56(b); the proposed new Rule 56(b) offered by the PTO in response to *Therasense*; and the use of Supplemental Examination as a procedure for addressing disclosure issues. His discussion and analysis provided much needed clarity regarding the current state of the law on disclosure requirements and provided a useful guide to the ongoing effect of the *Therasense* decision.

Larry Coury presented on "Strategies for Using Various Post-Grant Procedures." Larry's presentation provided a practical guide and focused review of strategies for using post-grant procedures in combination with district court litigation. His discussion was an excellent complement to presentations made earlier in the day that focused exclusively on recent PTAB case law. His talk enabled practitioners to understand what they need to know when bringing a post-grant proceeding in the PTO.

Summary

The Program was well received and was a huge success, adhering to the high quality and standards of NYIPLA CLE programs and exceeding expectations both in style and substance. The presenters provided clear guidance on a variety of topical issues, and the feedback from attendees was very positive. The Programs Committee members all invested substantial time and energy enlisting outstanding presenters to provide informative and engaging discussions and analyses of the issues at the forefront of patent litigation and prosecution practice. The Programs Committee achieved or exceeded that goal.

Storytelling for Lawyers

By Aparnaa Saini

On December 3, 2014, the Women in IP Law Committee hosted a program entitled, "Storytelling for Lawyers." The program, presented by Jo Ellen Livingston, Ph.D., and Jeff Isler and moderated by Aparnaa B. Saini (Willkie Farr & Gallagher LLP), focused on successfully telling clients' stories to the judge and jury. Dr. Livingston, who has provided consulting services to litigators on all aspects of the trial process since 1990, discussed various moral dichotomies such as care or harm, fairness or cheating, authority or subversion, and the use of these in successful storytelling before the jury. She explained that a successful tactic is not to employ each of the moral dichotomies. Rather, one should pick one particular moral dichotomy and make it a consistent theme in the presentation to the jury. Dr. Livingston also demonstrated that an understanding of juror attitudes towards inventors, companies, and the Patent and Trademark Office prior to developing a trial tactic is of utmost importance. Based on scientific knowledge about the human brain and listeners' responses, Dr. Livingston demonstrated that listeners' initial reactions often remain throughout the trial.

Mr. Isler, Principal Owner and Senior Consultant at Infographics, who has been helping attorneys tell their stories to both the judge and the jury through trial graphics and other demonstratives for over 40 years, provided insights into the persuasive power of visual aids. Mr. Isler discussed the power of using visual aids as a prop while telling complex stories involving otherwise unwieldy timelines and scientific facts. He also discussed the advantages of putting a "face to the name" where even big companies could be portrayed with a favorable image that the jury or judge could remember while rendering a decision. Mr. Isler also provided examples of how the most complex software code could be presented in a way, via a diagram or a relatable object, that would be easy for a decision maker to visualize.

Conversations With Judges: A Luncheon CLE Program

By Robert Rando

On Thursday, December 11, 2014, the NYIPLA Programs Committee hosted its annual Conversation with a Judge Luncheon CLE Program at The Union League Club. This year we were privileged to have two Judges included in our program: the Honorable Leonard D. Wexler, District Judge for the Eastern District of New York ("EDNY"), and the Honorable Michael Tierney, Lead Administrative Patent Judge for the Patent Trial and Appeal Board ("PTAB").

Judge Wexler, in addition to providing useful insight about how he handles matters in his courtroom (including his unique style of complying with mandatory sentencing guidelines in criminal matters), shared his personal experience as a World War II veteran, including a short video produced by the United States Judicial Conference profiling him and four of his colleagues on the EDNY bench who served during World War II. His openness and candor was greatly appreciated and well received by the attendees.

Judge Tierney provided a comprehensive presentation on practice before the PTAB, entitled "PTAB AIA Trials: Overview, Tips and Strategies." Judge Tierney's discussion was extremely helpful for all practitioners and certainly enhanced our understanding of the substantive and procedural aspects of the Leahy-Smith America Invents Act ("AIA") proceedings before the PTAB. His candid responses to numerous audience member questions were beneficial for all in attendance.

The program was well attended and another huge success, achieving the high standards of substance and style that NYIPLA CLE programs provide, including useful, insightful, and informative guidance for practitioners.

BOARD MINUTES

MINUTES OF OCTOBER 8, 2014

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

The Board meeting was held at The Water Club. President Anthony Lo Cicero called the meeting to order at 4:45 p.m. In attendance were:

Dorothy Auth	Charles Hoffmann
Jessica Copeland	Denise Loring
Kevin Ecker	Stephen Quigley
Walter Hanley	Peter Thurlow
Annemarie Hassett	Jeanna Wacker

Garrett Brown, Matthew McFarlane, Wanli Wu and Richard Parke participated by telephone. Raymond Farrell was absent and excused from the meeting. Feikje van Rein was in attendance from the Association's executive office.

The Board approved the Minutes of the September 9, 2014 Board meeting.

Treasurer Kevin Ecker reported that the Association continues to be in sound financial condition.

Kevin Ecker reported that the number of new members had once again increased, particularly the number of new student members. The Board discussed ways in which to keep the student members, enrolled in an accredited law school, engaged in the Association. The Board approved admission of the new members.

Matthew McFarlane reported on the activities of the Amicus Brief Committee. The Committee is preparing a draft amicus brief to be filed in the *B&B Hardware, Inc. v. Hargis Industries, Inc.* Supreme Court case and will circulate a draft for consideration by the Board in advance of the due date.

Denise Loring and Annemarie Hassett reported on efforts by the Legislative Action Committee to retain a public policy group to facilitate communication to members of Congress and regulatory agencies of the Association's views on proposed legislation and regulations of interest to Association members. The Committee recommended that the Association retain American Continental Group ("ACG"), a pre-eminent public policy group with expertise on IP issues. The Board approved the Committee's request to continue its discussions with ACG.

The joint NJIPLA/NYIPLA program on September 18 at McCarter & English was well attended. Dorothy Auth is working on another joint program scheduled for February 12, 2015. The program will focus on Intellectual Property Practice in China.

The Rensselaer Polytechnic Institute ("RPI") program scheduled for October 27 has a diverse program and great speakers. It is currently being marketed.

Treasurer Kevin Ecker requested and received Board approval to retain an accountant for up to 10 hours to resolve Quick Book entries. The Board also approved movement of funds currently in the checking account into a savings account, leaving $250,000 in the checking account.

The meeting adjourned at 6:00 p.m.

The next Board meeting will take place on November 19, 2014 at 12:00 p.m.

MINUTES OF NOVEMBER 19, 2014

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

The Board meeting was held at the offices of Amster, Rothstein & Ebenstein LLP. President Anthony Lo Cicero called the meeting to order at 12:30 p.m. In attendance were:

Garrett Brown
Walter Hanley
Annemarie Hassett
Charles Hoffmann
Denise Loring

Kevin Ecker, Raymond Farrell, Richard Parke, Stephen Quigley and Jeanna Wacker participated by telephone. Dorothy Auth, Jessica Copeland, Matthew McFarlane, Peter Thurlow and Wanli Wu were absent and excused from the meeting. Feikje van Rein was in attendance from the Association's executive office.

The Board approved the Minutes of the October 8, 2014 Board meeting.

Treasurer Kevin Ecker reported that the Association continues to be in sound financial condition. Excess funds currently in checking accounts will be moved to savings accounts/CDs to maximize interest on the funds. The Board approved movement of funds into a savings account to leave a balance of $100,000 in the main checking account and a balance of $25,000 in the secondary checking account.

Kevin Ecker reported that the Association continues to show strong gains in new student members. The Board approved admission of the new members to the Association.

President Lo Cicero, on behalf of Matthew McFarlane, reported on the activities of the Amicus Brief Committee. The Association filed a brief on behalf of respondents in the *B&B Hardware, Inc. v. Hargis Industries, Inc.* Supreme Court case on October 31, 2014. The brief was a collaborative production of the Trademark Law & Practice Committee and the Amicus Brief Committee. The Amicus Brief Committee is monitoring a number of cases and will consider whether to recommend filing briefs, as appropriate.

President Lo Cicero reported on a lunch he attended with the Secretary General of WIPO. Attendees included many General Counsel-level individuals from a variety of industries. The Secretary General solicited comments regarding WIPO and its performance. President Lo Cicero will reach out to Board liaisons of the Patent Litigation, Patent Law & Practice, Trademark Law & Practice and Corporate Committees to determine whether there is any interest in providing WIPO with comments.

Denise Loring and Annemarie Hassett reported on a proposed agenda prepared by American Continental Group Advocacy ("ACG") for NYIPLA activities relating to proposed legislation and regulations of interest to Association members. Kathleen Slattery and Steve Pincus of ACG joined the meeting by telephone and reported on activities in Congress relating to Intellectual Property legislation.

Richard Parke reported on plans for upcoming CLE programs. Proposed topics for the Day of the Dinner luncheon were discussed. Also discussed were potential events for young lawyers during the Judges Dinner.

Kevin Ecker reported on potential events for a corporate members-only event.

President Lo Cicero reported that Chief Judge James Smith of the Patent Trial and Appeal Board ("PTAB") will be the recipient of this year's Outstanding Public Service Award. Judge Smith will accept the award, not only on his own behalf, but also on behalf of his colleagues who have worked so hard in connection with the PTAB.

The Board discussed a Women's Entrepreneurship Symposium to be held by the Patent and Trademark Office in NYC on March 28, 2015, the Saturday following the Judges Dinner.

President Lo Cicero announced that the Association has entered into a three-year contract with RRR Associations, which has responsibility for administrative functions for the Association.

The meeting adjourned at 2:10 p.m.

The next Board meeting will take place on December 17, 2014 at 12:00 p.m.

Happy Hour!

➤ TUESDAY, FEBRUARY 24, 2015 ◄

Faces & Names, 159 West 54th Street, New York, New York 10019

Roundtable: IP Transactional Practice

Young Associates - NYIPLA Members Only

➤ THURSDAY, MARCH 5, 2015 ◄

Fox Horan & Camerini LLP, 825 Third Avenue, New York, New York 10022

Keeping It Profitable: Creating and Managing Alternative Fee Agreements in IP Cases

➤ TUESDAY, MARCH 10, 2015 ◄

Thomson Reuters, 3 Times Square, New York, New York 10036

Day of Dinner CLE Luncheon

The Changing Patent Landscape:
Issues Affecting Practice in the District Courts and the Patent Office

A Panel Discussion on Patent Law Reform, Supreme Court Decisions, and Other Recent and Potential Changes to Patent Law

followed by

93rd Annual Dinner in Honor of the Federal Judiciary (Judges Dinner)

➤ FRIDAY, MARCH 27, 2015 ◄

The Waldorf Astoria New York Hotel, 301 Park Avenue, New York, New York 10022

Diverse Careers in IP Law and Strategies for Achieving Success

➤ MONDAY, APRIL 13, 2015 ◄

Quinnipiac University School of Law, 370 Bassett Road, North Haven, Connecticut 06473

The Rapidly Changing Patent Law Landscape: What Entrepreneurs, Investors, Inventors, Lawyers and Judges Need To Know

Hosted by New York Intellectual Property Law Association in conjunction with Rensselaer Polytechnic Institute and Intellectual Property and Innovation American Inn of Court

➤ WEDNESDAY, APRIL 15, 2015 ◄

Hilton Garden Inn Troy, 235 Hoosick Street, Troy, New York 12180

Joint Program with Accelerate, LIFT, and LISTnet

➤ THURSDAY, APRIL 23, 2015 ◄

LaunchPad Huntington, 315 Main Street, 2nd Floor, Huntington, New York 11743

Last Name	First Name	Firm/Company/School	Membership Type	State
Biggs	Brian	DLA Piper LLP	Associate	Delaware
Chun	Nathan (ChangKun)	Indiana University Maurer School of Law	Student	Indiana
Counihan	Robert	White & Case LLP	Active 3+	New York
Cross	Robert	Cadwalader, Wickersham & Taft LLP	Active 3-	New York
Davis	Kira A.	Paul, Weiss, Rifkind, Wharton & Garrison LLP	Active 3+	New York
Durnford	Dillon	Byrne Poh LLP	Active 3-	New York
Economou	John	Economou Patent Law	Active 3+	New York
Epner	Mitchell	Hughes, Hubbard & Reed LLP	Active 3+	New York
Frank	Lawrence	Resek, Liang & Frank, LLP	Active 3+	New York
Friedman	Ana J.	Paul, Weiss, Rifkind, Wharton & Garrison LLP	Active 3-	New York
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Grunsfeld	Gerry	Lazar Grunsfeld Elnadav	Active 3+	New York
Honig	David A.	Brooklyn Law School	Student	New Jersey
Hulseberg	Daniel	Baker Botts LLP	Active 3+	New York
Jagoda	Aaron H.	Fordham University School of Law	Student	New York
Kavalerchik	Miriam	Brooklyn Law School	Student	New York
Keshwani	Sarfraz	American University Washington College of Law	Student	Washington, D.C.
Koatz	Ronald	Unilever	Corporate	New Jersey
Koopersmith	Matthew	Hofstra University School of Law	Student	New York
Korotkin	Lindsay	Sabety & Associates PLLC	Active 3-	New York
Lin	Peng	Cadwalader, Wickersham & Taft LLP	Active 3-	New York
Linne	Anna L.	ADP LLC	Corporate	New Jersey
Luksenberg	Steven Ze'ev	King & Spalding LLP	Active 3-	New York
Lynch	Kelly A.	New York Law School	Student	New York
Matza	Arielle D.	Benjamin N. Cardozo School of Law	Student	New York
May	Philip S.	Paul, Weiss, Rifkind, Wharton & Garrison LLP	Active 3-	New York
Mohaghegh	Dorna	Willkie Farr & Gallagher LLP	Active 3-	New York
Natter	Benjamin	Natter & Natter	Active 3+	New York
Naumann	Nadin	Hofstra University School of Law	Student	New York
Ng	Kristina	Northeastern University School of Law	Student	New York
Niedbala	Jacqueline K.	Drexel University Kline School of Law	Student	New York
Noyes	Christopher R.	Wilmer Cutler Pickering Hale and Dorr LLP	Active 3+	New York
Owens	Miya T.	Robins, Kaplan, Miller & Ciresi LLP	Student	New York
Owens	Eric	Emory University School of Law	Student	Georgia
Pelletier	Monique M.	Quinnipiac University School of Law	Student	Connecticut
Prutzman	Sarah	Morrison & Foerster LLP	Active 3+	New York
Ring	Justin	Duquesne University School of Law	Student	New York
Roche	Shawn	Byrne Poh LLP	Active 3-	New York
Russell	Cydney	University of North Carolina School of Law	Student	North Carolina
Saltzman	Jaclyn	Benjamin N. Cardozo School of Law	Student	New York
Shin	Stephen R.	King & Spalding LLP	Student	New York
Siebens	Christopher J.	Orrick Herrington & Sutcliffe LLP	Associate	Washington, D.C.
Splichal	Clark S.	Levin College of Law - University of Florida	Student	New York
Stellabotte	John C.	Proskauer Rose LLP	Active 3+	New York
Sullivan	Peter	Hughes, Hubbard & Reed LLP	Active 3+	New York
Wang	Catrina W.	Orrick Herrington & Sutcliffe LLP	Active 3-	New York
Willgoos	Christine	Kramer Levin Naftalis & Frankel LLP	Active 3+	New York
Woo	Eileen	New York University School of Law	Student	New York

The New York Intellectual Property Law Association, Inc.

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The *Bulletin* is published bi-monthly for the members of The New York Intellectual Property Law Association.
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