mbhb

snippets®

Review of Developments in Intellectual Property Law

Spring 2012 Volume 10, Issue 2

Inside this issue:

Enter at Your Own Risk: FDA Draft Guidance Highlights the Uncertainty in the Abbreviated Biosimilar Approval Pathway

By 2015, sales of biosimilars in the United States are expected to reach as high as $2.6 billion.[1] Recognizing this market opportunity, biotech companies of all sizes are devoting significant resources to developing these biologic products, which are novel yet dependent on currently approved biologic drug products (at least in part). Following the passage of the *Biologics Price Competition and Innovation Act* (BPCIA) on March 23, 2010, an entity seeking to bring a biosimilar product to market now has two pathways to consider for securing Food and Drug Administration (FDA) approval. One pathway allows the biosimilar applicant (BA) to seek FDA approval of the product as a new biologic by filing a biologic license application (BLA) under § 351(a) of the Public Health Service Act (PHSA).[2] Alternatively, the BA can follow the newly enacted abbreviated pathway under PHSA § 351(k), which created a new approval pathway for biologics that the FDA determines are "biosimilar" to a BLA-approved reference product (RP). This second option has been available since the passage of the BPCIA on March 23, 2010, yet the FDA still awaits the filing of the first § 351(k) application (referred to as abbreviated biologic license application – "ABLA").

The statutory language of the BPCIA outlines the structure of the pathway, but contains minimal guidance on the standards used by the FDA to determine biosimilarity as required for ABLA approval. Faced with this uncertainty, it comes as no surprise that BAs have been hesitant to test the ABLA approval pathway. In a first step toward addressing this uncertainty, on February 9, 2012, the FDA released three draft guidance documents on the development of biosimilar products. These guidance documents were published in the *Federal Register* on February 15, 2012,[3] with a 60-day period for comment ending April 16, 2012. Commentary and reaction to these long-awaited guidances have been mostly negative,[4] with common criticisms being that these supposed "guidances" provide only broad conceptual ideas, lacking any sufficient detail to set BA expectations, and do not resolve any uncertainty over the FDA's decision for awarding ABLA approval. Despite the lack of explicit guidance in the documents, the FDA does provide some clarity regarding the most pressing of issues facing BAs in the early stages of biosimilar development. Whether intentional or not, the FDA message that manifests from this clarity is that there is little to gain, but much to lose, by following the ABLA pathway.

A Brief Introduction to the Guidance

The FDA draft guidances were intended to implement the follow-on biologic drug pathway mandated by the BPCIA, and are set forth in three separate guidance documents, forming a "suite" of guidances that references one another throughout each document. The first draft guidance, titled *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*,[5] is considered the "core" document by the FDA and is directed to the scientific issues in proving biosimilarity. As recited in the statute, to qualify for approval of a biologic using an ABLA, the BA must prove that its biologic product is "biosimilar," which

continued on p. 2

Enter at Your Own Risk: FDA Draft Guidance Highlights the Uncertainty in the Abbreviated Biosimilar Approval Pathway

continued from p. 1

requires the product to be highly similar to an approved biologic with no clinically meaningful differences in the safety, purity, and potency of the product.[6]

The first guidance, which is limited to therapeutic proteins,[7] suggests the FDA will determine biosimilarity by applying a "step-wise" approach.[8] The first step is analytical studies, which compare the physicochemical characteristics and functional properties of a candidate biosimilar drug with the reference drug product. Following this determination, if the differences in the two products are not "clinically meaningful," the FDA will require fewer or narrower studies in the subsequent approval step. As it hinted at last year,[9] the FDA intends to evaluate the data presented at each step based on its long-standing "totality-of-the-evidence" standard,[10] while focusing on assessment of the effects of any differences in the products, rather than requiring an independent safety determination of the biosimilar product. In this way, the FDA seeks to eliminate human or animal clinical studies that are redundant or only incrementally aid the biosimilarity determination, a practice the agency considers highly unethical.[11] Based on the analytical results, the FDA will determine the scope of animal toxicity testing it considers necessary, as expressly required by the statute.[12] Finally, based on the results of the first two steps, other RP studies, and any other relevant data (*i.e.,* the "totality-of-the-evidence"), the FDA will decide as the final step which human pharmacokinetic (PK) and pharmacodynamic studies (PD), immunogenicity studies, and clinical safety and effectiveness trials are required.[13] The list of public comments on the *Scientific Considerations* guidance is available at *Regulations.gov* under FDA Docket No. FDA-2011-D-0605.[14]

The second draft guidance, titled *Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,*[15] is specifically concerned with chemistry, manufacturing, and controls (CMC) of biosimilar products. The draft guidance also advocates a "risk-based" approach, which will permit variances in biologic drug properties and characteristics if justified by the biosimilar applicant. Assessments will be made under a "totality of the analytical data" standard, intended to take into account interactions between various measured parameters. Specific aspects of biologic drug production falling within the scope of this guidance include the expression system, manufacturing processes, assessments of physicochemical properties, functional assays, receptor binding (when appropriate) and immunochemical properties, impurities (both product- and process-related), reference product and reference standards, the finished drug product, and stability studies. Public comment on the *Quality Considerations* guidance is available at FDA Docket No. FDA-2011-D-0602.[16]

snippets®

The FDA draft guidances were intended to implement the follow-on biologic drug pathway mandated by the BPCIA, and are set forth in three separate guidance documents, forming a "suite" of guidances that references one another throughout each document.

The third guidance document, titled *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,*[17] is presented as a response to questions raised during public hearings on the FDA rulemaking. Generally, the agency said it will take a permissive approach to changes in formulation, delivery device, or container, and to changes involving fewer than all the routes of administration, presentations, or conditions of use of the reference biologic drug, provided that the BA can establish biosimilarity. The FDA also indicates in this draft guidance that animal and/or clinical data from non-U.S. licensed biosimilar products will be considered in support of an ABLA, but only under specific circumstances set forth in the guidance. The list of public comments on the *Q&A Guidance* is available at FDA Docket No. FDA-2011-D-0611.[18]

Industry Comments and Reactions

Several industry commentators have criticized the draft guidances as severely disappointing to anyone looking for clear FDA expectations for biosimilar applications.[19] In contrast to European Medicines Agency (EMA) guidelines, which recite more specific standards for biosimilarity for different classes of biologics,[20] the FDA guidances advocate

a product-specific inquiry in every case. Many comments suggest that the FDA should strive to harmonize with the EMA and publish class-specific guidance for complex proteins,[21] and the FDA has not ruled this out in the future.[22] The guidances spend a great deal of time reciting well-known concepts, continually reminding the reader (in each of the three documents) that therapeutic proteins have inherently more variability and chemical complexity than small molecule drugs.

Without clear guidelines on the requirements for biosimilarity, BAs possess no ability to project the costs of taking a biosimilar drug product successfully through the approval process. Since the financial commitment required for development of a biosimilar product is enormous, failure to secure approval on the first try can spell doom for many small-to-medium-sized biotech firms. The estimated cost for development of a biosimilar product is $50 million to $60 million, with an additional $250 million to $1 billion for the manufacturing facility, whereas generic small molecule drugs typically require an investment of about $5 million.[23] When the fate of a company depends on a finding of biosimilarity by the FDA, until more details on this determination become available, BAs are unlikely to follow the ABLA pathway. There always will be some uncertainty on these costs, as they depend on positive data resulting from each study. But without a better idea regarding the expectations on testing, the traditional BLA approach is a safer, albeit more expensive, option for FDA approval.

Clinical trials (arguably) represent the largest expense in the biologic drug approval process regardless of pathway choice. In the months leading up to publication of the guidances, many industry representatives expressed concern that the FDA would require several clinical studies to establish biosimilarity. As clinical trial requirements for biosimilarity increase, the cost savings of the ABLA pathway compared to a traditional BLA begin to evaporate. This pre-guidance concern remains, for the FDA falls short in defining which clinical studies the agency considers most persuasive. As expected, innovator companies have advocated that extensive clinical studies must be required for all biosimilar products, while BAs argue that many products may not call for such studies. Patient groups generally call for the FDA to promote greater safety by requiring more extensive clinical testing and robust pharmacovigilance.[24] With these competing interests in mind, rather than take a definitive position, the FDA guidance instead lists generalities and non-standards, such as requiring the trials be "state-of-the-art" and "rigorous," which are not defined in any way.

The FDA reserves the right to waive any of the clinical trial requirements at the discretion of the agency, with the exception of the statutorily-mandated clinical trials such as those directed to pharmacokinetics/pharmacodynamics and immunogenicity.[25] The FDA's reservation of waiver of these studies has been criticized by several innovator companies, such as Genentech and Novo Nordisk.[26] These innovator companies, as well as industry organizations such as the Biotechnology Industry Organization (BIO), take issue with the agency's word choice regarding these analytical and comparative studies, particularly the use of "should" and "where available and appropriate," as these imply that these studies do not need to be done.[27,28] BIO prefers definitive terms

continued on p. 4

McDonnell Boehnen Hulbert & Berghoff LLP to Exhibit at 2012 BIO International Convention in Boston

Visit us at Booth #1335 in the BIO Exhibit Hall

McDonnell Boehnen Hulbert & Berghoff LLP ("MBHB") is pleased to announce it will be participating as an exhibitor at the 2012 BIO International Convention ("BIO") in Boston. Visit us at Booth #1335 in the exhibit hall to meet our attorneys, learn more about our services and enter our raffle. Taking place from June 18-21 and billed as the largest global event for the biotechnology industry, 2012 BIO is organized by the Biotechnology Industry Organization. The organization represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

2012 BIO covers the wide spectrum of life science innovations and application areas. Drug discovery, biomanufacturing, genomics, biofuels, nanotechnology, and cell therapy are just a few of the industries represented at the BIO International Convention. More than 15,000 leaders from over 65 countries are expected to attend 2012 BIO. The key elements of the event are education, networking, partnering and the 1,800 companies showcasing the latest technologies, products and services in the BIO Exhibition. View complete details at http://convention.bio.org/

Enter at Your Own Risk: FDA Draft Guidance Highlights the Uncertainty in the Abbreviated Biosimilar Approval Pathway

continued from p. 3

such as "is expected to" or "will need to." BIO further asserts that language in the guidance is inconsistent with the statute, for it implies that clinical trials are only a "residual requirement" that is triggered if there are gaps in the analytical, PK/PD, and safety results. Instead, BIO advocates for a more extensive clinical trial requirement for biosimilarity, requesting the FDA necessarily require several additional studies beyond the statutory minimum, including animal toxicity studies and human clinical trials evaluating safety and efficacy.[29] The vague language choice in the guidance supports the FDA's "totality of the evidence" approach, where the FDA is able to maximize agency flexibility while minimizing the need to take a position on the evidence required to prove biosimilarity.

The most detailed guidance provided in the FDA documents is by reference in the *Quality Considerations* guidance. This guidance references several FDA and *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH) guidances relating to biologic drug regulations, particularly the production of recombinant protein products. The ICH guidances provide detailed information on key assays, controls, and statistical analyses (among others) that BAs should consult when initiating study design and development.[30] By integrating the study design principles disclosed in the ICH guidances with the newest assay technology, a BA can develop a more complete package of early-stage study plan materials to present at its next meeting with the FDA.

Amino Acid Sequence Identity and Biosimilarity

The FDA's strict position on requiring amino acid sequence identity for biosimilarity is a significant message from the guidance. The guidance documents authorize only small changes at the N- and C- terminal truncations in amino acid chains with scientific justification.[31] As has been seen with small molecule drugs, a BA will specifically design its product such that it achieves RP biosimilarity, yet still falls outside the scope of the patent claims protecting the RP. Many of the currently approved biologic drugs are protected by patent claims directed to the specific amino acid sequence of the therapeutic protein. Since the FDA guidance requires identical amino acid sequences (outside of the terminal regions) for a finding of biosimilarity, the BA's product must share the amino acid sequence with the RP to qualify for the ABLA pathway. Therefore, for the FDA to make a finding of biosimilarity, a BA necessarily would infringe the patents covering most current RPs.

The BA thus has two alternatives: Enter the ABLA pathway with the hopes of invalidating the patent, or make changes in the amino acid sequence of its new product, abandon the ABLA pathway, avoid potential infringement, and file a BLA. There is minimal incentive for a BA to force an infringing product through the ABLA pathway, unless the patent covering the RP is particularly weak and the BA's invalidation argument is bulletproof. Both options will be expensive, but the BLA pathway choice also enjoys the PHSA's exclusivity provisions for new approvals, which has indeterminate, yet significant, value. Considering all of the unresolved issues surrounding the ABLA pathway in the United States, a third potential strategy for a BA that is ready to file may be to seek approval in Europe first, then seek approval in the United States. The FDA, in an effort for harmonization with the EMA, is currently exploring a proposal for expedited U.S. approval if the biosimilar is already approved in Europe.[32] Depending on how the FDA adopts the EMA biosimilarity determination, this "end-around" strategy could prove to be a more predictable approval option, at least in the short-term.

This imbalance favoring BLA over ABLA filings is unlikely to remain for long. The FDA is likely to relax these strict amino acid identity requirements for biosimilarity in the future, or at minimum provide for a clear mechanism to scientifically justify amino acid changes, based on the knowledge that human proteins in nature are variable and there are many "neutral" amino acid sequence variants. Biosimilar producers will certainly push for FDA tolerance of amino acid changes. For example, Biocon has suggested that the FDA should allow for intermediate processing steps, provided that the final protein comprises the same primary amino acid sequence as the reference product.[33] However, innovator representatives in turn will resist allowing any differences in amino acids, as seen in comments to the guidances by Amgen, Novo Nordisk, and BIO.[34,35] Innovators cite safety concerns as justification for requiring strict identity of amino acid sequences, while others request that the FDA reject all ABLAs that include intentional differences with the RP in host cell type, primary structure, formulation, or immediate packaging.[36] Indeed, the FDA must begin conservatively because all is not known regarding the equivalence of these neutral variants. What is neutral in an evolutionary sense may not be neutral pharmacologically, and the importance of 3-D structures and post-translational modifications in protein function must be addressed. Most likely, more expansive analytical and clinical studies will be required to scientifically justify any difference in

amino acid sequence between the RP and the BA product. Hypothetically, a BA product comprising a well-characterized silent mutation (outside of the N- or C- termini) could readily be proven as biosimilar to the RP with carefully designed studies. Both BA and BLA holders should take an active role in FDA approval meetings to educate as well as advocate their respective positions.

Interchangeability Still Remote

The BPCIA biosimilars framework is unique in that it permits a finding of "interchangeability" with the RP,[37] which is considered the most enticing aspect of the ABLA pathway. A finding of interchangeability allows substitution of the biosimilar for the RP without requiring specific intervention from the health care provider.[38] Thus, just as a generic pharmaceutical drug can be substituted for the brand name drug at the pharmacy counter, a biosimilar product could be substituted for the RP.[39] In this scenario, the biosimilar is a true "biogeneric," and therefore the BA can benefit from the marketing, promotion, and educational resources devoted to the RP. However, to prove interchangeability, the BA product must meet a stricter compatibility standard with the RP by establishing that a provider can switch back and forth between the biosimilar product and the RP without any additional risks.[40]

The *Q&A Guidance* explicitly discusses the issue of interchangeability, but unsurprisingly, the only guidance is a proposed "stepwise" approach. Under this approach, the FDA must first find biosimilarity with the RP, followed by FDA meetings to determine which additional studies are needed to prove interchangeability. The FDA has noted that it expects to require at least one additional human study, but expects that multiple studies are more likely.[41] The *Q&A Guidance* further notes that while requests for interchangeability can be filed, the FDA is not close to deciding how to evaluate interchangeability, and believes that the technology has not progressed enough to make such a determination.[42]

This is welcome news for BLA holders, and a disappointment for BAs, as it is clear that the first biosimilar with interchangeability is years away from being approved (if ever).

snippets

While the FDA has indicated its plan is to issue more guidance in the near future, without significant departure from the uncertain format of the instant FDA biosimilar draft guidances, the FDA will have quite a challenge to rehabilitate the disincentives presented by the ABLA approval pathway as it sits today.

Innovator drug developers have advocated that interchangeability should not be available if the biosimilar requires additional training on its use, particularly for new devices or systems; a common route of administration for many currently available reference products.[43] Industry leaders estimate the year 2020 will bring the FDA's first determination of interchangeability.[44] Until that time, BLA holders can rest assured the RP will maintain its dominant position in the market. Against only competing biosimilar products, the RP is expected to maintain 70 percent to 90 percent of the market share, as switching a patient from the RP to a biosimilar product is expected to encounter significant barriers from patients, providers, and insurance companies.[45] Industry comments charged the FDA with evaluating how a determination of interchangeability will interact with state laws governing pharmacy substitution of prescribed drugs.[46] Patient groups such as the Global Healthy Living Foundation (GHLF) have expressed worry over pharmacist or insurer automatic substitution of interchangeable products while insufficient data is available.[47] With other more pressing concerns, providing guidance on interchangeability is currently a low priority at FDA, and the agency likely will defer any guidance on interchangeability until at least one ABLA has been approved as biosimilar. This first ABLA holder is expected to move quickly in requesting interchangeability, which could spur the FDA to publish more guidance on that concept. By then, the FDA should possess the requisite experience to provide more detailed standards than the instant guidance on biosimilarity.

Conclusions

After considering the comments submitted to the docket, the FDA held a public hearing on the biosimilars guidance on May 11, 2012. While most of the hearing testimony praised the FDA for their initial efforts, a recurring theme throughout was that these FDA guidances fail to provide enough clarity to justify the substantial risk in ABLA filing. Without significant FDA

continued on p. 6

Enter at Your Own Risk: FDA Draft Guidance Highlights the Uncertainty in the Abbreviated Biosimilar Approval Pathway

continued from p. 5

revisions, the clinical trial requirements for establishing biosimilarity remain uncertain – setting up a BA for unpredictable and potentially enormous expenses should unexpected trials be required under the "totality of evidence." The amino acid identity standards for biosimilarity are set at such a high level that ABLA filers may have difficulty providing colorable arguments of non-infringement of RP patents. The FDA admits that interchangeability is years away, and frankly does not believe the current technology has progressed far enough to determine interchangeability.[48] Thus, the guidances provide BAs minimal optimism for interchangeability in the near future, or even hope for timely detailed information on the issue. While the FDA has indicated its plan is to issue more guidance in the near future, without significant departure from the uncertain format of the instant FDA biosimilar draft guidances, the FDA will have quite a challenge to rehabilitate the disincentives presented by the ABLA approval pathway as it sits today. Without more guidance, it could be several years before any applicant decides to seek FDA approval via the ABLA pathway, thus delaying the development of a prosperous biosimilar market in the United States and the resulting improvement in health care, reduced patient costs, job growth, and advancement in the field of biologics.

Endnotes

1 IMS Health, *Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape (December 2011),* available at http://www.imshealth.com/ims/Global/Content/Home%20Page%20Content/IMS%20News/Biosimilars_Whitepaper.pdf (accessed April 17, 2012).

2 The *Public Health Service Act (PHSA)* provisions regulating BLA filings now represent the only pathway for FDA approval of a new therapeutic protein. In the past, certain biologic products have been approved under the *Federal Food, Drug and Cosmetic Act (FDCA)*, using the NDA approval process. However, the addition of the term "protein" to § 351 of the PHSA exemplifies the intent of the legislature to consolidate approval of all new proteins using the BLA process. "Protein" is defined in the guidance documents as a polypeptide that is greater than 40 amino acids. Anything smaller is considered merely a "peptide" and thus akin to a small molecule drug. For "peptides," filing of an NDA under the FDCA may still be appropriate.

3 77 Fed. Reg. 8885 (Feb. 15, 2012).

4 Alex Philippidis, *Comments Sent to FDA on Its Draft Biosimilars Guidance Mostly Conveyed Discontent,* Genetic Eng. & Biotech. News (April 16, 2012).

5 *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (Feb. 2012) (hereinafter "Scientific Considerations"), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

6 PHSA § 351(i)(2)(A) and (B).

7 The guidance states that the general scientific principles may be informative for the development of other proteins, such as in vivo protein diagnostic products. *Quality Considerations*, at 163-164.

8 *Scientific Considerations* at 7.

9 Steven Kozlowski, et al., *Developing the Nation's Biosimilars Program*, NEJM 365: 385-8 (2011); *also see* James V. DeGiulio, *FDA Looks to Multiple Sources, Including EMA Guidelines, in Developing Biosimilar Approval Standards*, Patent Docs Weblog (August 11, 2011), available at http://www.patentdocs.org/2011/08/fda-looks-to-multiple-sources-including-ema-guidelines-in-developing-biosimilar-approval-standards.html.

10 *Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (May 1998), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072008.pdf.

11 Rachel E. Sherman, Associate Director for Medical Policy at the Center for Drug Evaluation and Research, *FDA Biosimilar Biological Products Webinar*, Feb. 15, 2012, available at https://collaboration.fda.gov/p13473376/.

12 PHSA § 351(k)(2)(A)(i)(I)(cc).

13 *Id.*

14 Docket No. FDA-2011-D-0605, *Draft Guidance for Industry on Scientific Considerations in Demonstrating Biosimilarity to Reference Product; Availability*, available at http://www.regulations.gov/#!docketDetail;rpp=25;po=0;D=FDA-2011-D-0605.

15 *Guidance for Industry: Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product* (Feb. 2012) (hereinafter "Quality Considerations"), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf.

16 Docket No. FDA-2011-D-0602, *Draft Guidance for Industry on Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product; Availability*, available at http://www.regulations.gov/#!docketDetail;rpp=25;po=0;D=FDA-2011-D-0602.

17 *Guidance for Industry: Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009* (Feb. 2012) (hereinafter "Q&A Guidance"), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM273001.pdf.

18 Docket No. FDA-2011-D-0611, *Draft Guidance for Industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009; Availability*, available at http://www.regulations.gov/#!docketDetail;rpp=25;po=0;D=FDA-2011-D-0611.

19 *See, e.g.,* Philippidis, *supra*, at note 6.; Kevin E. Noonan, *More on FDA Draft Guidelines for "Follow-on" Biologic Drug*

Approval Pathway, Patent Docs Weblog (Feb. 14, 2012), available at http://www.patentdocs.org/2012/02/more-on-fda-draft-guidelines-for-follow-on-biologic-drug-approval-pathway.html.

20 *See* European Medicines Agency, *Multidisciplinary: Biosimilar*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000408.jsp&mid=WC0b01ac058002958c.

21 James C. Shehan, Corporate VP of Legal, Gov't, and Quality Affairs, Novo Nordisk, Inc., FDA-2011-D-0611-0004, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0004.

22 *See* Sherman, *supra*, at note 13.

23 Federal Trade Commission Report, *Emerging health care issues: follow-on biologic drug competition*, June 2009.

24 Andrew Spiegel, CEO, Colon Cancer Alliance, FDA-2011-D-0611-0003, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0003; and Seth Ginsberg, Global Healthy Living Foundation, FDA-2011-D-0611-0008, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0008.

25 PHSA § 351(k)(2)(A)(i)(I)(cc); *Scientific Considerations*, at 16.

26 *See* Philippidis, *supra*, at note 6.

27 Kelly Lai, BIO Director of Science & Regulatory Affairs, FDA-2011-D-0605-0049, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0605-0049.

28 Earl Dye, Genentech, FDA Docket No. FDA-2011-D-0611, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611.

29 *See* BIO, at note 29.

30 ICH guidance documents can be found on the FDA website at http://www.fda.gov/regulatoryinformation/guidances/ucm122049.htm.

31 *See Scientific Considerations*, at 17 ("the expression construct for a proposed product will encode the same primary amino acid sequence as the reference product.").

32 *See Q&A Guidance*, at 7; Sherman, at note 13.

33 Siriam Akundi, Associate VP, Biocon, FDA-2011-D-0611-0009, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0009.

34 *See e.g.*, Paul R. Eisenberg, Sr. VP of Global Regulatory Affairs and Safety, Amgen Inc., FDA-2011-D-0611-0033, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0033.

35 *See* Novo Nordisk, at note 23.

36 *Id.*; BIO, *supra*, at note 29.

37 The EU pharmaceutical legislation does not address interchangeability, which remains with the authority of the member states. Therefore, individual EU member states control prescription switching, not the EMA. *See* Howard Levine *et al.*, *EMA Still Not Supporting Biosimilar Interchangeability*, Bioprocess Weblog, Oct. 30, 2011, *available at* http://www.bioprocessblog.com/archives/351 (accessed April 15, 2012).

38 PHSA § 351(i)(3).

39 PHSA § 351(k)(4).

40 *Id.*

41 *See* Sherman, *supra*, at note 13.

42 *Q&A Guidance*, at 11-12 ("At this time, it would be difficult as a scientific matter for a prospective biosimilar applicant to establish interchangeability in an original 351(k) application given the statutory standard for interchangeability and the sequential nature of that assessment.")

43 *See* Novo Nordisk, at note 23.

44 Deena Beasley, *Slow, costly process stymies generic biotech drugs*, Reuters, Mar. 5, 2012, available at http://www.reuters.com/article/2012/03/05/us-generic-biotech-drugs-idUSTRE8240ZI20120305 (accessed April 12, 2012).

45 *See* FTC Report, at note 25.

46 Jonathan Mitchell, Aphelion Consultants, FDA-2011-D-0611-0006, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0006.

47 Seth Ginsberg, Global Healthy Living Foundation, FDA-2011-D-0611-0008, available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0008.

48 *Q&A Guidance*, at 11-12.

Adapted with permission from *Life Sciences Law & Industry Report*, 6 LSLR 467, 04/20/2012, Copyright 2012, The Bureau of National Affairs, Inc. (800-372-1033) www.bna.com.

James V. DeGiulio, Ph.D., an MBHB associate, has broad experience in intellectual property portfolio development, management, and enforcement in the life sciences area, with a particular emphasis on pharmaceutical, biotechnology, and medical device litigation. He is a contributor to the Patent Docs weblog (http://www.patentdocs.org/).

degiulio@mbhb.com

The Murky Morass of Section 101

What qualifies as patentable subject matter? In theory, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" qualifies for patent protection.[1] According to the Supreme Court, 35 U.S.C. § 101 essentially allows a person to receive a patent for any man-made invention.[2]

However, while § 101 may act as a "coarse eligibility filter,"[3] it is not without boundaries. Unfortunately, the courts have struggled to identify those boundaries. As a consequence, challenges to patentability under § 101 are becoming frequent.[4] Thus, the "murky morass that is § 101 jurisprudence"[5] can pose a significant problem for patentees.

Wading into the Morass

Perhaps the more practical question is: what is *not* patentable subject matter? The Supreme Court has identified three implicit exceptions to the admittedly broad scope of § 101: laws of nature, physical phenomena, and abstract ideas.[6] While an *application* of one of these exceptions may receive patent protection,[7] a patented invention cannot foreclose others from using a concept that is "part of the storehouse of knowledge" available to the public at large.[8]

Whether an invention is directed toward a law of nature or a natural phenomenon is (allegedly) straightforward. Though there is no bright-line rule, the Supreme Court's cases discussing the exceptions to § 101 "provide workable guidance" in resolving the patentability issue.[9] What qualifies as an abstract idea is considerably less clear. As Justice Stevens has admitted in the well-known *Bilski* case, "[t]he Court [did not provide] a satisfying account of what constitutes an unpatentable abstract idea."[10] Method claims are most likely to be challenged as being directed to allegedly abstract ideas that are unpatentable.[11] However, the Federal Circuit has also found computer-readable medium claims that involve only steps that could be performed mentally or with pencil and paper to be unpatentable under § 101.[12]

At surface level, the Federal Circuit seems to have recently adopted a more passive approach to patentability. Rather than attempting to craft a new test, the court no longer "presume[s] to define 'abstract' beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories" of § 101.[13] Perhaps the court is saying that it knows an abstract idea when it sees one.

snippets

Perhaps the more practical question is: what is *not* patentable subject matter? The Supreme Court has identified three implicit exceptions to the admittedly broad scope of § 101: laws of nature, physical phenomena, and abstract ideas.

Not surprisingly, this abstract approach to identifying abstract ideas has led to considerable disagreement between Federal Circuit judges in recent decisions addressing the issue. Panels have internally disagreed on the patentability of methods for storing data in a database,[14] methods for processing credit applications,[15] methods for determining when to immunize patients,[16] and methods for comparing or analyzing DNA sequences.[17] In the Supreme Court, five justices held that at least some business methods are patentable, while the other four thought that all business methods are, by definition, abstract ideas.[18]

However, a familiar, common thread may link some of these decisions. Despite the court's assertions to the contrary, a close analysis of the recent § 101 case law suggests that Federal Circuit panels may still be applying the machine-or-transformation test to resolve issues of subject-matter eligibility. For instance, consider two recent cases decided by the Federal Circuit: *Ultramercial, LLC v. Hulu, LLC*,[19] and *Dealertrack, Inc. v. Huber*.[20] The claimed technologies involved in these two cases were very similar, yet only one was found to meet the requirements of § 101. While the outcomes may appear to conflict, the machine-or-transformation test may offer a clue as to why the courts reached different conclusions.[21]

In *Ultramercial*, a Federal Circuit panel considered a patent claiming a means of monetizing a display of an advertisement.[22] The exemplary claim of the patent-in-suit described a method in which a user would watch an advertisement in lieu of paying to download copyrighted media, such as a song or video, which would be paid for by the advertiser.[23] The court found that the method passed the patentability threshold of § 101 because implementing the method was "likely to require intricate and complex computer programing."[24] Furthermore, the court noted that some of the steps "clearly

require specific application to the Internet and a cyber-market environment."[25] While the court was quick to note these factors did not guarantee subject-matter eligibility, it found that the claimed invention was "a practical application of [an] idea," namely the idea of using advertising as a form of currency.[26]

The panel in *Dealertrack* dealt with a similar type of technology. One of the patents in that case claimed an automated process for processing credit applications for automobile loans.[27] The process involved a "central processor" that acted as a clearinghouse for receiving credit applications from car dealers, selectively forwarding the applications to banks, receiving approval statuses from the banks, and forwarding the approval statuses back to the car dealers.[28] The majority held that the claims did not meet the eligibility threshold of § 101 because they were "directed to an abstract idea preemptive of a fundamental concept or idea that would foreclose innovation in this area."[29] Although the preamble of the claims indicated that a computer would aid in performing the method, the majority noted that "[s]imply adding a 'computer aided' limitation to a claim covering an abstract concept, without more, is insufficient to render a claim patent eligible."[30] The majority also noted that "[t]he claims do not require a specific application, nor are they tied to a particular machine,"[31] in part because "[t]he claims are silent as to how a computer aids the method, to what extent a computer aids the method, and the significance of a computer performance of the method."[32] Thus, the majority held that the patent was invalid for failure to claim patentable subject-matter.[33]

Comparing these two cases, the primary difference is in how the subject matter was claimed. The claims in *Ultramercial* were tied to a specific application of an abstract idea that involved performing concrete steps and using the Internet. According to the court, this necessitated using a computer and was sufficient to pass through the "coarse eligibility" filter of § 101. The claims in *Dealertrack*, in contrast, did not specifically involve a machine—the only reference to the computer was in the preamble of the claims. Likewise, the steps disclosed were open-ended and could conceivably—though unrealistically—be performed without a computer. In other words, the claimed invention in *Ultramercial* was tied to a machine, while the claimed invention in *Dealertrack* was not tied to a machine (the patentee conceded that the transformation prong did not apply).[34]

snippets

While the courts continue to struggle to identify what is patentable subject matter, patentees should evaluate their patents and pending patent applications for potential issues with claims that may cover an abstract idea.

Thus, one invention passed the machine-or-transformation test, while the other did not. Even though the panels did not explicitly say they were applying the machine-or-transformation test, these opinions, as well as other recent opinions dealing with § 101, show that the test may still play a significant role in resolving subject-matter eligibility. Nonetheless, there is a general disagreement among the Federal Circuit judges as to where the line between patentable and unpatentable subject matter is, as is evident by the number of recent split decisions on the matter. Thus, distinguishing an abstract idea from patentable subject matter is likely to remain a difficult area of jurisprudence for the courts, litigants, and claim drafters.

Navigating the Swamp

From a patentee's perspective, finding a balance between claims that provide the broadest coverage the patentee is entitled to and claims that avoid § 101 complications is an imperative. While patents generally enjoy a presumption of validity,[35] the courts do not seem to provide any deference to the USPTO's determination that a patent covers patentable subject matter.[36] Thus, even though an examiner may allow an application to issue without ever mentioning § 101, a court may subsequently find the claims impermissibly directed to unpatentable subject matter.

To avoid this risk, patentees should carefully evaluate the claims to ensure that at least some dependent claims are directed toward physical applications of potentially abstract ideas (or laws of nature or natural phenomena). Based on the foregoing analysis, it seems that passing the machine-or-transformation test is still the primary gateway to subject-matter eligibility. Thus, ensuring that the claims pass this test provides the best odds of avoiding invalidity under § 101.

continued on p. 10

The Murky Morass of Section 101

continued from p. 9

For instance, simply adding a recitation of a computer or system applying an algorithm or process in the preamble is not likely to make a claim patentable unless the claims of a method or process are tied to a machine or specify how the machine performs the method.[37] Likewise, attempting to limit the scope of the invention to a particular field of use is not likely to pass muster.[38] However, in some cases, attaching specific steps of a particular algorithm, directed to a specific application of a method and using a computer or system, may be enough to get over the § 101 threshold.[39] Including a physical element (in addition to a computer or computer processor) as an active component of a claim also seems to increase the likelihood that a patent will pass through the "coarse eligibility filter" of § 101.[40]

If the question of patentability did not arise during prosecution, a patentee may consider addressing the issue in a reexamination or reissue proceeding. While it is unclear how much deference the courts will give to these proceedings, reexamination and reissue offer a means of amending the scope of the claims prior to enforcing them through litigation. An *ex parte* reexamination may also be an option for a party that is a potential target for an infringement suit. Initiating an *ex parte* reexamination may avoid—or at least delay—costly litigation if the patentability of the claimed subject matter was not considered during prosecution.

In the context of patent litigation, when to raise the patentability issue with the trial court has significant strategic implications for the parties. Patentability can be raised at an early stage of the litigation in either a motion to dismiss or a motion for summary judgment.[41] Raising the issue early on may allow an alleged infringer to avoid a lengthy discovery process and trial (and the costs associated with each).

One recent suggestion from the Federal Circuit is for district courts to resolve issues of validity under §§ 102, 103, and 112 before tackling the potentially more cumbersome issue of patentable subject matter under § 101.[42] Theoretically, this would allow the district court to deal with the more conventional issues of novelty, non-obviousness and written description before entering "the murky morass that is § 101 jurisprudence."[43] Both plaintiffs and defendants should consider the strategic impact of asking the court to defer the § 101 issue until other issues are settled.

From one perspective, a district court may have a better appreciation of the technology involved in a patent dispute after resolving any novelty, non-obviousness, or written description issues. Even if not dispositive, having a clearer understanding of the state of the art may assist the court in determining whether or not the patent claims an abstract idea.

On the other hand, determining subject matter eligibility under § 101 is a "threshold test,"[44] leading some Federal Circuit judges to question the providence of addressing other issues of patentability without first determining whether a claimed invention qualifies for patent protection under § 101.[45] The Supreme Court has rejected a similar suggestion raised by the Government, though the Government seemed to suggest that the courts should completely refrain from addressing patentability under § 101.[46] Another factor to consider is that invalidity contentions under §§ 102 and 103 might require at least some discovery (*e.g.*, expert testimony), whereas § 101 can be addressed purely as a matter of law.

Conclusion

In order to increase the likelihood that a claim directed to a series of steps that might be considered an abstract idea will survive scrutiny under § 101, a patentee should frame the claimed invention as being directed toward a machine or device that implements the steps.[47] The patentee should avoid claiming the invention as a disembodied series of steps that could conceivable be performed mentally or with pencil and paper. While no one test proposed by the Federal Circuit is dispositive, showing how a claimed invention passes the machine or transformation test may improve the persuasiveness of the arguments in favor of patentability.

Alleged infringers will want to direct the court's attention away from any specific application by arguing that the scope of the claims reaches far beyond any purported limitations. The arguments should explain why the claims are either pure mental steps, or not limited to a specific application and, instead, act to restrict others from using an abstract idea.[48]

There is no easy way to determine whether an invention impermissibly claims an abstract idea. While the courts continue to struggle to identify what is patentable subject matter, patentees should evaluate their patents and pending patent applications for potential issues with claims that may cover an abstract idea. And while issues of patentability might require wading into the murky morass, both patentees and alleged infringers should carefully consider the strategic implications of raising the issue at different points during litigation.

Endnotes

1 35 U.S.C. § 101 (2006).

2 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

3 *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).

4 *See, e.g., Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *Dealertrack, Inc. v. Huber*, No. 06-CV-2335, 2012 U.S. App. LEXIS 1161 (Fed. Cir. Jan. 20, 2012); *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. 2011); *Research Corp. Techs.*, 627 F.3d at 859.

5 *MySpace v. Graphon*, No. 2011-1149, 2012 U.S. App. LEXIS 4375, at *25 (Fed. Cir. Mar. 2, 2012).

6 *Chakrabarty*, 447 U.S. at 309.

7 *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

8 *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

9 *Myspace*, 2012 U.S. App. LEXIS 4375, at *25.

10 *Bilski*, 130 S. Ct. at 3236 (Stevens, J., concurring).

11 *See, e.g., Bilski*, 130 S. Ct. at 3223-24; *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *1; *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d at 1324-25 (Fed. Cir. 2011); *Research Corp. Techs.*, 627 F.3d at 865.

12 *Cybersource Corp. v. Retail Decisions, Inc.*, 654 F. 3d 1366, 1375 (Fed. Cir. 2011) ("[T]he incidental use of a computer to perform the mental process . . . does not impose a sufficiently meaningful limit on the claim's scope.").

13 *Research Corp. Techs.*, 627 F.3d at 868.

14 *Myspace*, 2012 U.S. App. LEXIS 4375, at *36 (Mayer, J., dissenting).

15 *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *52-53 (Plager, J., dissenting in part).

16 *Classen v. Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1076 (Fed. Cir. 2011) (Moore, J., dissenting).

17 *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (Bryson, J., dissenting in part), *vacated sub nom., Ass'n for Molecular Pathology v. Myriad Genetics*, No. 11-725, 2012 WL 986819 (U.S. Mar. 26, 2012).

18 *Bilski*, 130 S. Ct. at 3252-57 (Stevens, J., concurring).

19 *Ultramercial*, 657 F.3d at 1323.

20 *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *1.

21 *See In re Bilski*, 545 F. 3d 943, 954 (Fed. Cir. 2008) (under this test, a process is patentable if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.").

22 *Ultramercial*, 657 F.3d at 1324.

23 *Id.* at 1324-25.

24 *Id.* at 1328.

25 *Id.*

26 *Id.*

27 *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *3.

28 *Id.* at *6-9.

29 *Id.* at *47.

30 *Id.* at *49.

31 *Id.*

32 *Id.* at *48.

33 *Id.* at *52.

34 *Id.* at *44.

35 *Research Corp. Techs.*, 627 F.3d at 870.

36 The presumption of patent validity is omitted from the opinions in *Biliski*, *Dealertrack*, *Classen*, *Ultramercial*, and *Ass'n for Molecular Pathology*.

37 *Prometheus*, 132 S. Ct. at 1294; *Dealertrack*, 2012 U.S. App. LEXIS 1161, at *48-49.

38 *Bilski*, 130 S. Ct. at 3231.

39 *See, e.g., Ultramercial*, 657 F.3d at 1328-29.

40 *Research Corp. Techs.*, 627 F.3d at 868-69; *see also Ultramercial*, 657 F.3d at 1328-29.

41 *See, e.g., Ultramercial*, 657 F.3d at 1325.

42 *Myspace*, 2012 U.S. App. LEXIS 4375, at *23-24.

43 *Id.*at *24.

44 *Bilski*, 130 S. Ct. at 3225.

45 *Myspace*, 2012 U.S. App. LEXIS 4375, at *35 (Mayer, J., dissenting); *Dealtertrack*, 2012 U.S. App. LEXIS 1161, at *52-53 (Plager, J., dissenting in part).

46 *Prometheus*, 132 S. Ct. at 1303-04.

47 *See Research Corp. Techs.*, 627 F.3d at 868-69; *Ultramercial*, 657 F.3d at 1328-29.

48 *See, e.g., Dealtertrack*, 2012 U.S. App. LEXIS 1161, at *51.

John (Jay) M. Schafer, an MBHB associate, has a focus on patent litigation and prosecution. His industry experience includes computing, telecommunications, electrical engineering, and mechanical and materials.

schafer@mbhb.com

Richard A. Machonkin, an MBHB partner, represents clients in prosecution, litigation, and counseling matters. He has helped obtain U.S. and foreign patents for clients involved in a wide range of technologies, including telecommunications, software, diagnostics, optical, and mechanical technologies.

machonkin@mbhb.com

Exploring the Dichotomy Between Patent and Antitrust Law

Introduction

The interplay between patent and antitrust laws creates an interesting, if not confusing, area of the law. Patent law, on the one hand, grants rights that are frequently (albeit loosely) referred to as a "monopoly." On the other hand, antitrust laws are intended to protect competition by preventing unlawful monopolies and other activities that create an unfair playing field between competitors. The potentially conflicting policies underlying these two bodies of law have created tension between them. But the existence of both areas of law means that a patent owner needs to understand both in order to steer clear of patent enforcement activities that can run afoul of the antitrust laws, as antitrust violations can result in patent unenforceability, civil damages, and criminal penalties.

Background of Patent and Antitrust Laws

Patents and the Right to Exclude

The United States Constitution gives Congress the power to promote the progress of science and the useful arts by securing for a limited time to inventors the exclusive right to their discoveries.[1] Congress has exercised its Constitutional power by allowing inventors to obtain patents on their inventions. In particular, patents provide the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process."[2] This right to exclude, however, does not provide inventors with "any exemption from the provisions of the Sherman [Antitrust] Act beyond the limits of the patent monopoly."[3]

The Sherman Antitrust Act and Its Limitations on Monopolies

Antitrust law seeks to prevent unlawful monopolies and promote competition by encouraging multiple sellers to compete against one another to attract business. Such competition is presumed to benefit consumers because, in order to attract customers, rival firms will often lower prices, provide better quality and service, and generally be more responsive to customer needs. While competition is generally favorable, agreements between competitors to restrain trade are unfavorable and have long been held to be unenforceable under common law.[4] Congress codified this common law as well as a number of anti-price-fixing provisions in the Sherman Act of 1890 (the Sherman Act). Section 2 of the Sherman Act focuses on monopolization, and provides, in relevant part: "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony…."[5,6]

snippets

One of the most common forums where patent and antitrust laws collide is in the courtroom when a patent owner attempts to exclude others from making, using, importing, offering for sale, or selling the patent owner's patented inventions.

When Patent and Antitrust Laws Collide

One of the most common forums where patent and antitrust laws collide is in the courtroom when a patent owner attempts to exclude others from making, using, importing, offering for sale, or selling the patent owner's patented inventions. This clash occurs, in part, because the Sherman Act prohibits unfair methods of competition by one or more actors. Section 1 of the Sherman Act condemns concerted action by two or more actors to engage in activity that decreases competition.[7] Section 2 of the Sherman Act makes it improper for a person to monopolize, or attempt to monopolize, any part of trade or commerce among the States or with foreign nations.[8] The courts, however, have recognized an exception to these general rules when the "restraint upon trade or monopolization is the result of a valid governmental action," such as filing a patent infringement lawsuit to protect a legal monopoly.[9]

The act of filing a patent infringement lawsuit does not, however, allow a patent owner to escape the antitrust laws carte blanche. Rather, depending on the facts, an alleged infringer may assert that the patent owner violated antitrust laws by (1) procuring the patent through intentional fraud on the Patent Office, or (2) bringing the patent litigation in bad faith as a "sham" litigation.[10] If the alleged infringer successfully establishes either of these grounds, that party has overcome the first hurdle of proving an antitrust claim, but

must still prove each element of a claim under the Sherman Act to prevail.

A party asserting that a patent was procured through intentional fraud on the Patent Office must prove "knowing and willful fraud" by clear and convincing evidence.[11] Typically, "knowing and willful fraud" involves some affirmative dishonesty, such as a "deliberately planned and carefully executed scheme to defraud [the Patent Office]."[12] For example, intentional fraud may occur when the patentee "knowingly and willfully" misrepresented or omitted facts to the Patent Office.[13] To support a finding of fraud, the misrepresentation or omission must also have been material such that, "if the Patent Office had been aware of the complete or true facts, the challenged claims would not have been allowed."[14] However, *enforcement*, and not merely the procurement of a fraudulent patent, is necessary to give rise to antitrust scrutiny. "[W]ithout some effort at enforcement, the patent cannot serve as the foundation of a monopolization case."[15]

A party asserting that a litigation is a "sham" must prove a number of objective and subjective criteria by clear and convincing evidence.[16] The objective criteria are used to determine whether the lawsuit is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[17] Typically, "[t]he existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation."[18] If the lawsuit is found to be objectively baseless, the subjective criteria are then used to determine whether the baseless lawsuit "conceals an attempt to interfere *directly* with the business relationships of a competitor" through the use of governmental process as an anticompetitive weapon.[19] Exemplary subjective criteria include an assessment of whether the patent owner is intentionally pursuing a meritless lawsuit to harass a competitor or to deter others, regardless of the outcome of the litigation.[20] If both the objective and subjective criteria are met, the litigation is a "sham" litigation and is therefore not exempt from antitrust laws.[21]

If a party can successfully demonstrate that the patent litigation is not exempt from antitrust laws, that party must then prove the elements of the alleged Sherman Act violation.[22] The elements of an antitrust allegation under section 2 of the Sherman Act include "(1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[23]

snippets

Patent law grants the right to exclude competition while antitrust law targets those who exclude competition. This dichotomy creates the possibility that a patent owner who attempts to enforce its patent rights will be subject to a suit for antitrust liability.

Monopoly power is "the power to control prices or exclude competition."[24] Monopoly power may "ordinarily be inferred from the predominant share of the market" coupled with barriers to entry into the market.[25] However, monopoly power may not be inferred by the mere existence of a patent.[26] Indeed, it is rare for a patent to confer monopoly power in a market.[27] One reason for this is because many new technologies build on existing technologies that are already offered to consumers, *i.e.*, there are already competing products in the market place.[28] Another reason is because many inventions may have little to no commercial value, *i.e.*, other products or processes may be superior substitutes and the invention may be unable to drive all or most substitutes from the market.[29] Only a small number of basic, or "pioneer," patents embody truly novel innovations that either supersede a given field or create an entirely new field.[30] These "pioneer patents" are recognized to confer market power because, absent any prior art in the field, there is an opportunity for the patentee to draft broad claims that cover the entire market.[31]

The mere acquisition or maintenance of a monopoly through growth or development is not illegal.[32] The Sherman Act does, however, condemn the use of anti-competitive conduct to acquire or maintain a monopoly.[33] One example of anti-competitive conduct is tying, which occurs when the sale of a patented product that has market power (such as a printer) is conditioned on the purchase of another unpatented product (such as ink or paper).[34] Such an arrangement extends the patentee's economic control

continued on p. 14

Exploring the Dichotomy Between Patent and Antitrust Law

continued from p. 13

to unpatented products.[35] Another example is the maintenance of market power by unilaterally refusing to license or deal with other entities.[36] The courts have held that such anti-competitive conduct violates the Sherman Act and is unlawful.

Conclusion

Patent law grants the right to exclude competition while antitrust law targets those who exclude competition. This dichotomy creates the possibility that a patent owner who attempts to enforce its patent rights will be subject to a suit for antitrust liability. While such possibility should not paralyze a patent owner, it should cause a patent owner to consider the impact of its actions to enforce its patent rights. A good threshold question to consider is: does the activity extend beyond what can be excluded under the patent? If the answer to that question is anything other than an unqualified no, the activity should be carefully scrutinized because of the potential for antitrust allegations.

Endnotes

1 U.S. Const. art. 1, § 8, cl. 8.

2 35 U.S.C. 154(a)(1) (1965).

3 *U.S. v. Line Material Co.*, 333 U.S. 287, 308 (1948).

4 Indeed, leading antitrust thinkers are "skeptical…about the dangers to competition that is posed by unilateral firm action." Richard A. Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, at 932 (2000). At the same time, it is recognized that "the danger that heavy-handed antitrust enforcement may suppress a practice that may seem anticompetitive but actually is efficient, or at least neutral, from the broader social standpoint." *Id.*

5 15 U.S.C. § 2 (2004).

6 Another antitrust provision, the Clayton Act, 15 U.S.C. § 12, *et seq.*, is beyond the focus of this article. The Clayton Act prohibits price discrimination between purchasers and sellers of goods. In the patent context, this provision is principally used to address tying agreements.

7 15 U.S.C. § 1 (2004).

8 15 U.S.C. § 2 (2004).

9 *See E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 136 (1961) (recognizing exceptions to the Sherman Act); *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 996 (9th Cir. 1979) (identifying patent infringement lawsuits as a valid governmental action).

10 *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965); *Glaverbel Societe Anonyme v. Northland Mktg. & Supply*, 45 F.3d 1550, 1558 (Fed. Cir. 1995); *Handgards*, 601 F.2d at 990.

11 *Handgards*, 601 F.2d at 996.

12 *Id.*

13 *Walker Process Equip.*, 382 U.S. at 177.

14 *Norton v. Curtiss*, 433 F.2d 779, 794 (C.C.P.A. 1970).

15 *California E. Lab., Inc. v. Gould*, 896 F.2d 400, 403 (9th Cir. 1990).

16 *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); *Handgards*, 601 F.2d at 996.

17 *Prof'l Real Estate Investors, Inc.*, 508 U.S. at 60.

18 *Id.* at 62.

19 *Id.* at 60-61 (citing *Noerr*, 365 U.S. at 144) (emphasis in original).

20 *Id.* at 75 (Stevens, J. & O'Connor, J., concurring).

21 *Prof'l Real Estate Investors,* 508 U.S. at 61.

22 *In re Indep. Serv. Org. Antitrust Litig. CSU*, 203 F.3d 1322, 1328 (Fed. Cir. 2000).

23 *U.S. v. Grinnell Corp.*, 384 U.S. 563, 570-571 (1966).

24 *Id.* at 571.

25 *Id.*

26 *Illinois Tool Works v. Independent Ink*, 547 U.S. 28 (2006).

27 Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vand. L. Rev. 1727, 1730 (2000).

28 *Id.*; *see also* Posner, *supra* note 4, at 939 (noting that "law time" moves slow relative to the speed of innovation, potentially resulting in antitrust litigation lagging current industry conditions).

29 *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984).

30 Kitch, *supra* at 1730.

31 *Id.*

32 15 U.S.C. § 2 (2004).

33 *Id.*

34 *See, e.g., Illinois Tool Works,* 547 U.S. at 32 (addressing claims brought under Sections 1 and 2 of the Sherman Act).

35 *U.S. v. Loew's Inc.*, 371 U.S. 38, 45-46 (1962) (addressing claims brought under Section 1 of the Sherman Act).

36 *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602-05 (1985) (addressing claims brought under Section 2 of the Sherman Act).

Paula S. Fritsch, Ph.D., an MBHB partner, has experience in all aspects of intellectual property law, with a particular emphasis on litigating and counseling clients on patent, trade secret, and unfair competition issues.

fritsch@mbhb.com

Sarah J. Duda, an MBHB associate, has a broad background in prosecution and litigation. Her industry expertise includes computing, telecommunications, electrical engineering, mechanical and materials, and business methods.

duda@mbhb.com

Jordan Pringle is an MBHB law clerk with an electrical engineering background.

The *Coach Services, Inc. v. Triumph Learning, LLC* Case: What it Means for a Trademark to Be "Famous" for Trademark Dilution Purposes

A holder of a "famous" trademark has the right to prevent dilution of its mark—that is, to stop uses of the mark by others that are likely to blur or tarnish the famous mark even in the absence of potential customer confusion.[1] However, the Federal Circuit's decision in *Coach Services, Inc. v. Triumph Learning LLC*[2] clarified the high burden that trademark owners have in demonstrating that its mark is famous in order to support a dilution claim. Coach Services, Inc. ("CSI"), the producer of well-known luxury handbags and accessories, learned that its famous COACH trademark is not so famous after all.

In its recent decision, the U.S. Court of Appeals for the Federal Circuit affirmed, in large part, Triumph Learning's ("Triumph") victory against CSI, holding that the Trademark Trial and Appeal Board ("TTAB" or "Board") of the U.S. Patent and Trademark Office did not err in finding that (i) that there was no likelihood of confusion between CSI's use of its COACH mark for luxury products and Triumph's use of the COACH mark in connection with educational products, and (ii) that CSI had failed to introduce sufficient evidence to establish that its COACH mark was famous for dilution purposes.[3] The Federal Circuit, however, ruled that the Board made evidentiary errors on its analysis of whether Triumph's COACH marks had acquired secondary meaning and remanded the case for further proceedings on that issue instead of affirming the TTAB's decision to dismiss CSI's opposition outright.[4] This decision highlights the different standards for showing that a mark is famous for likelihood of confusion and dilution and reaffirms earlier Federal Circuit precedent finding that fame, while important, may be insufficient standing alone to establish a likelihood of confusion where other factors set forth in *In re E.I. DuPont DeNemours & Co.*[5] weigh heavily against finding a likelihood of confusion.

Facts

Triumph is a test preparation company that publishes books and software for standardized test preparation.[6] The company claims that it had used its COACH mark since at least 1986.[7] In December 2004, Triumph filed three use-based trademark applications for the COACH mark.[8]

In March 2006, CSI filed notices of opposition with the TTAB, opposing Triumph's registration of all three COACH marks, claiming priority of use and the likelihood of confusion, dilution, and that Triumph's COACH marks are "merely descriptive when used on goods in the educational and test preparation industries."[9] In support of its bases for opposing Triumph's registration, CSI claimed that it had been using the COACH mark with its luxury products since at least December 1961; that it made over $10 billion in sales during 2000-2008; that its sales reached $3.5 billion in 2008; and that it spent $30-60 million a year on advertising in fashion magazines such as Elle, Vogue, Mademoiselle, and Vanity Fair.[10] CSI also claimed that it had joint marketing efforts with other well-known brands such as LEXUS and CANON; that it received unsolicited media attention referring to the mark; that its 2007 internal market study showed that 96% of women between the ages of 18-24 recognized the COACH brand; and that it had taken steps to stop past infringement of its COACH mark.[11] It has also filed 16 trademark registrations for the COACH mark, including 15 in which the mark was issued before December 2004.[12] CSI is not in the standardized test preparation business, does not compete with Triumph, and presented no evidence of actual confusion from Triumph's use of the COACH mark for educational products.[13]

The TTAB dismissed CSI's oppositions, holding that CSI's likelihood of confusion and dilution claims failed.[14] The TTAB also dismissed CSI's argument that Triumph's COACH mark was merely descriptive, finding that Triumph sufficiently demonstrated acquired distinctiveness.[15] While the Board found that the COACH mark was famous for the purposes of determining likelihood of confusion, the Board concluded that CSI did not provide sufficient evidence of widespread fame of its COACH mark for dilution purposes.[16]

A Trademark's Fame, Standing Alone, Is Not Determinative of the Likelihood of Confusion Analysis

With respect to CSI's likelihood of confusion claim, CSI argued that the TTAB improperly applied the *DuPont* factors in determining that that people would not confuse Triumph's goods with CSI's.[17] The Federal Circuit reviewed the TTAB's findings with respect to certain *DuPont* factors: (1) the strength or fame of CSI's COACH mark; (2) the similarity of the parties' goods; (3) channels of trade; (4) the classes of consumers; and (5) the similarity of the marks.[18] In reviewing the TTAB's decision, the Federal Circuit concluded that the TTAB's ruling was supported by substantial evidence, despite CSI's showing that its mark was famous through evidence of use and promotion of the mark.[19] The Federal Circuit agreed with the TTAB that:

> [D]espite their undisputed similarity, the marks have different meanings and create distinct commercial impressions. This is particularly true given that the word 'coach' is a common English word

continued on p. 16

The *Coach Services, Inc. v. Triumph Learning, LLC* Case: What it Means for a Trademark to Be "Famous" for Trademark Dilution Purposes

continued from p. 14

> that has many different definitions in different contexts.
>
> . . . Triumph's COACH mark, when applied to educational materials, brings to mind someone who instructs students, while CSI's COACH mark, when used in connection with luxury leather goods, including handbags, suitcases, and other travel items, brings to mind traveling by carriage.[20]

The Federal Circuit noted that "these distinct commercial impressions outweigh the similarities in sound and appearance, particularly since . . . the parties' goods are unrelated."[21]

While the Federal Circuit acknowledged that there was some potential for overlap in the classes of purchasers for the parties' products (age 18-25 females), the Federal Circuit agreed with the TTAB that purchasers are smart enough not to be confused in thinking that CSI, a seller of handbags, had entered the field of preparing educational materials for standardized tests.[22]

The Federal Circuit acknowledged that CSI's COACH mark had acquired fame, noting evidence that $30-$60 million a year was spent on advertising and evidence of CSI's use of the mark since 1961, but Federal Circuit held that CSI's establishment of the fame factor for its COACH mark, standing alone, is insufficient to outweigh the other applicable *DuPont* factors and establish a likelihood of confusion.[23] The Court reasoned that the fame of CSI's mark was outweighed by evidence that the respective goods were unrelated, that the marks had different meanings and distinct commercial impressions with respect to the goods, and that the channels of trade were different.[24]

Sufficient Evidence of Widespread Recognition of a Mark by the General Public Is Needed to Support a Dilution Claim

With respect to the issue of the likelihood of dilution, CSI argued that since the TTAB found that CSI's COACH trademark was famous in making its likelihood of confusion analysis, the Board could not refuse to find that its famous mark was being diluted.[25] The Federal Circuit disagreed, siding with the Board's ruling that CSI failed to establish with sufficient evidence that its COACH mark was famous for dilution purposes and further declining to address the likelihood of dilution by blurring factors.[26] The Federal Circuit noted that fame for dilution purposes has a higher burden of proof than fame for likelihood of confusion.[27] According to the Federal Circuit, a mark is considered famous for dilution purposes when it "is widely recognized by the general consuming public of the United States as a designation of source of the goods or services of the mark's owner."[28] The question of whether a mark is "famous" is determined by considering four non-exclusive factors: (1) duration, extent, and geographical reach of advertising and publicity of the mark, whether advertised or publicized by the owner or third parties; (2) the amount, volume, and geographic extent of sales of goods or services offered under the mark; (3) the extent of actual recognition of the mark; and (4) whether the mark was registered on the Principal Register.[29]

snippets

The decision in *Coach Services Inc. v. Triumph Learning LLC* emphasized two key points: (1) that there is a higher burden for showing that a mark is famous for dilution purposes than likelihood of confusion purposes; and (2) that a mark famous for likelihood of confusion purposes does not automatically establish that the mark is famous for dilution purposes.

While the Federal Circuit acknowledged that CSI had established that its mark was famous for likelihood of confusion purposes, the Court declined to declare that CSI's COACH mark had achieved fame for the purposes of a trademark dilution analysis, noting that CSI's evidence fell short of establishing widespread recognition of its mark by the general population.[30]

The Federal Circuit acknowledged that fame for dilution purposes is difficult to prove particularly in a case where the mark is a common English word with multiple meanings in different context.[31] In this instance, while CSI had demonstrated that the mark had achieved a substantial degree of recognition, it failed to demonstrate that its use of COACH mark had "eclipsed" the other uses of the term and has become a "household name" when encountered by

the general public.[32] The Court observed that many of the published articles that CSI relied on for supporting dilution fame were published after Triumph filed its trademark applications and CSI was required to show that its mark was famous prior to Triumph's filing dates.[33] The Federal Circuit ultimately concluded that evidence was insufficient to support the dilution claim.[34]

In reaching its decision concerning likelihood of dilution, the Federal Circuit acknowledged that "[w]e do not hold that CSI could never establish the requisite level of fame for dilution purposes. We hold only that, on the record presented to it, the Board had substantial support for its conclusion that CSI's evidentiary showing was just too weak to do so here."[35]

Conclusions

The decision in *Coach Services Inc. v. Triumph Learning LLC* emphasized two key points: (1) that there is a higher burden for showing that a mark is famous for dilution purposes than likelihood of confusion purposes; and (2) that a mark famous for likelihood of confusion purposes does not automatically establish that the mark is famous for dilution purposes.[36] Though CSI could likely prove widespread recognition of its COACH brand among women, it may be more difficult to demonstrate the "household name" level of recognition of the brand among men. The Federal Circuit acknowledged that while the burden to demonstrate fame in the dilution context is high, it is "not insurmountable," giving CSI and other well-known brand owners hope that widespread fame can be established in other situations with stronger evidence.

Endnotes

1 *E.g.*, Trademark Dilution Revision Act of 2006, 15 U.S.C. § 1125(c)(1) (2006) ("Subject to the principles of equity, the owner of a famous mark that is distinctive, inherently or through acquired distinctiveness, shall be entitled to an injunction against another person who, at any time after the owner's mark has become famous, commences use of a mark or trade name in commerce that is likely to cause dilution by blurring or dilution by tarnishment of the famous mark, regardless of the presence or absence of actual or likely confusion, of competition, or of actual economic injury."); *Enterprises Rent-A-Car Co. v. Advantage Rent-A-Car, Inc.*, 330 F.3d 1333, 1334 (Fed. Cir. 2003) ("[T]he owner of a famous mark can oppose the registration of a diluting mark without establishing likelihood of confusion."); *Ameritech, Inc. v. American Information Technologies Corp.*, 811 F.2d 960, 965 (6th Cir. 1987) ("Under [the] theory [of dilution], an infringement can occur even where the products are non-competing and no confusion is possible.").

2 668 F.3d 1356 (Fed. Cir. 2012).

3 *Id.* at 1360.

4 One error was "the Board's failure to consider all pre-decision [non-Triumph] use of the term 'coach' for educational materials." *Id.* at 1380. A second error was the Board's consideration of non-authenticated advertising materials in its secondary meaning analysis. *Id.*

5 476 F.2d 1357, 1360 (C.C.P.A. 1973).

6 *Coach Services*, 668 F.3d at 1360.

7 *Id.*

8 *Id.*

9 *Id.* at 1362.

10 *Id.* at 1361, 1367.

11 *Id.* at 1362, 1367, 1374-1375.

12 *Id.* at 1373.

13 *Id.* at 1362.

14 *Id.*

15 *Id.*

16 *Id.*

17 In *DuPont*, the Court of Customs and Patent Appeals held that, "[i]n testing for likelihood of confusion under Sec. 2(d), . . . the following, when of record, must be considered:"

(1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression. (2) The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use. (3) The similarity or dissimilarity of established, likely-to-continue trade channels. (4) The conditions under which and buyers to whom sales are made, *i.e.*, "impulse" vs. careful, sophisticated purchasing. (5) The fame of the prior mark (sales, advertising, length of use). (6) The number and nature of similar marks in use on similar goods. (7) The nature and extent of any actual confusion. (8) The length of time during and conditions under which there has been concurrent use without evidence of actual confusion. (9) The variety of goods on which a mark is or is not used (house mark, "family" mark, product mark). (10) The market interface between applicant and the owner of a prior mark: (a) a mere "consent" to register or use. (b) agreement provisions designed to preclude confusion, *i.e.*, limitations on continued use of the marks by each party. (c) assignment of mark, application, registration and good will of the related business. (d) laches and estoppel attributable to owner of prior mark and indicative of lack of confusion. (11) The extent to which applicant has a right to exclude others from use of its mark on its goods. (12) The extent of potential confusion, *i.e.*, whether *de minimis* or substantial. (13) Any other established fact probative of the effect of use.

In re E.I. DuPont DeNemours & Co., 476 F.2d 1357, 1361 (C.C.P.A. 1973). The Federal Circuit reviews the Board's legal conclusions *de novo* and its factual findings for substantial evidence. *In re Coors Brewing Co.*, 343 F.3d 1340, 1343 (Fed. Cir. 2003).

18 *Coach Services*, 668 F.3d at 1366-71.

19 The Federal Circuit spent a considerable portion of its opinion discussing mistakes made by CSI and Triumph in their attempts to put evidence of into the record of the opposition proceedings. *Coach Services*, 668 F.3d at 1363-65.

continued on p. 18

The *Coach Services, Inc. v. Triumph Learning, LLC* Case: What it Means For a Trademark to Be "Famous" for Trademark Dilution Purposes

continued from p. 17

20 *Id.* at 1369.

21 *Id.*

22 *Id.* at 1370-71. For example, the Federal Circuit did not disturb the Board's finding that "educational professionals are likely to exercise a high level of care in making purchasing decisions, which would minimize likelihood of confusion." *Id.* at 1371.

23 Some earlier cases, particularly those from the TTAB, found that while fame is an important factor in a likelihood of confusion analysis, fame alone does not outweigh other *DuPont* factors, particularly those factors that weigh heavily against finding a likelihood of confusion. *E.g., Univ. of Notre Dame Du Lac v. J.C. Gourmet Food Imports Co., Inc.*, 703 F.2d 1372, 1374 (Fed. Cir. 1983); *Christian Broadcasting Network, Inc. v. ABS-CBN Int'l*, 84 U.S.P.Q.2d (BNA) 1560 (T.T.A.B. July 31, 2007); *Blue Man Productions, Inc. v. Tarmann*, 75 U.S.P.Q.2d (BNA) 1811 (T.T.A.B. Aug. 18, 2005); *Burns Philp Food, Inc. v. Modern Products, Inc.*, 1 F.3d 1252 (Fed. Cir. 1993) (unpublished opinion); and *Hormel Foods Corp. v. Spam Arrest, LLC*, 2007 WL 4287254 (T.T.A.B. Nov. 21, 2007).

However, most cases decided by the Federal Circuit prior to *Coach Services, Inc. v. Triumph Learning, LLC* emphasized that fame was the dominant factor in balancing the *DuPont* factors. *E.g., Palm Bay Imports, Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772*, 396 F.3d 1369, 1374 (Fed. Cir. 2005); *Bose Corp. v. QSC Audio Products, Inc.*, 293 F.3d 1367, 1371 (Fed. Cir. 2002); *Recot, Inc. v. Becton*, 214 F.3d 1322, 1328 (Fed. Cir. 2000); and *Kenner Parker Toys Inc. v. Rose Art Indus., Inc.*, 963 F.2d 350, 352 (Fed. Cir. 1992).

24 *Coach Services*, 668 F.3d at 1366-71.

25 *Id.* at 1373.

26 *Id.* at 1373-76.

27 *Id.* at 1372 ("Fame for likelihood of confusion and fame for dilution are distinct concepts, and dilution fame requires a more stringent showing."); *Id.* at 1376 ("[T]he burden to show fame in the dilution context is high—and higher than that for likelihood of confusion purposes."). Moreover, fame for dilution "is an either/or proposition—it either exists or does not," while "fame for likelihood of confusion is a matter of degree along a continuum." *Id.* at 1373.

28 *Id.* at 1372 (citing 15 U.S.C. § 1125(c)(2)(A) (2006)). The Court noted the requirements to establish fame for dilatation as follows:

> To establish the requisite level of fame, the mark's owner must demonstrate that the common or proper noun uses of the term and third-party uses of the mark are now eclipsed by the owner's use of the mark. An opposer must show that, when the general public encounters the mark in almost any context, it associates the term, at least initially, with the mark's owner.
>
> *Id.* at 1373 (internal citations and quotations omitted) (quoting *Toro Co. v. ToroHead Inc.*, 61 U.S.P.Q.2d (BNA) 1164, 1180 (T.T.A.B. Dec. 12, 2001)).

29 *Id.* at 1372-73; 15 U.S.C. § 1125(c)(2)(A)(i)-(iv).

30 *Id.* at 1373-76.

31 *Id.* at 1373.

32 *Id.* at 1373 (quoting *Nissan Motor Co. v. Nissan Computer Corp.*, 378 F.3d 1002, 1011 (9th Cir. 2004) ("In other words, a famous mark is one that has become a 'household name.'"); *Toro*, 61 U.S.P.Q.2d at 1180); *see also supra* note 28.

33 *Id.* at 1375.

34 *Id.* at 1373-76.

35 *Id.* at 1376.

36 The decision reminds trademark owners that the failure to observe the differences in evidentiary requirements under the TTAB and the Federal Rules of Evidence could lead to the exclusion of evidence needed to support claims.

Emily Miao, Ph.D., an MBHB partner, has broad experience in all aspects of intellectual property practice, including patent, trademark and copyright procurement and portfolio management; client counseling on validity, infringement, freedom-to-operate (FTO), due diligence reviews, and patent strategy matters; and licensing/secrecy agreements.

miao@mbhb.com

Alan W. Krantz, an MBHB associate, prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement, and patentability analyses, patent application preparation and prosecution, and litigation matters in the computing field.

krantz@mbhb.com

McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709

312 913 0001 phone
312 913 0002 fax
www.mbhb.com
snippets@mbhb.com

McDonnell Boehnen Hulbert & Berghoff LLP recognizes the ever-increasing importance of intellectual property. Our mission is to enhance the value of our clients' businesses by creating and defending their intellectual property assets. We have built our reputation by guiding our clients through the complex web of legal and technical issues that profoundly affect these assets. We are keenly aware of the trust placed in us by our clients – *Fortune* 100 corporations, universities, individuals, and start-up companies – and we always remain focused on their ultimate business goals.

With offices in Chicago, North Carolina and Washington State, MBHB provides comprehensive legal services to obtain and enforce our clients' intellectual property rights, from navigating the U.S. Patent and Trademark Office procedures to litigating complex infringement actions. We don't merely procure rights and litigate cases; we craft winning strategies that achieve our clients' business objectives.

Our entrepreneurial spirit, combined with the wealth of our legal experience and technological expertise, gives McDonnell Boehnen Hulbert & Berghoff LLP the power to achieve success for our clients.

Partners
Lawrence H. Aaronson
Jeffrey P. Armstrong
Alison J. Baldwin
Michael H. Baniak
Paul H. Berghoff
Daniel A. Boehnen
Christina L. Brown
S. Richard Carden
Christopher M. Cavan
Y. Elaine Chang, Ph.D.
David L. Ciesielski
Michael D. Clifford
Grantland G. Drutchas
Thomas A. Fairhall
David M. Frischkorn
Paula S. Fritsch, Ph.D.
Jori R. Fuller
Michael D. Gannon
Patrick G. Gattari
Michael S. Greenfield, Ph.D.
James C. Gumina
David S. Harper, Ph.D.
Joseph A. Herndon
Lisa M. W. Hillman, Ph.D.
A. Blair Hughes
Bradley J. Hulbert
Paul A. Kafadar
Nicole Keenan
Jennifer M. Kurcz
George I. Lee
Thomas J. Loos, Ph.D.
Richard A. Machonkin
James M. McCarthy
Michelle L. McMullen Tack, Ph.D.
Emily Miao, Ph.D.
Scott M. Miller
Eric R. Moran
Jeremy E. Noe
Kevin E. Noonan, Ph.D.
Sherri L. Oslick, Ph.D.
Anthoula Pomrening
Nicole E. Reifman
Joshua R. Rich
Kurt W. Rohde
Matthew J. Sampson
Steven J. Sarussi
Rory P. Shea
Leif R. Sigmond, Jr.
James V. Suggs
Sean M. Sullivan
Kirsten L. Thomson
Marcus J. Thymian
Paul S. Tully, Ph.D.
Thomas E. Wettermann
Daniel P. Williams
Andrew W. Williams, Ph.D.
Donald L. Zuhn, Jr., Ph.D.

Of Counsel
Sandra B. Weiss

Associates
Michael S. Borella, Ph.D.
Christopher D. Butts
James V. DeGiulio, Ph.D.
Sarah J. Duda
Sarah E. Fendrick, Ph.D.
Christian B.E. Hines
Brandon J. Kennedy
Sydney R. Kokjohn
Alan W. Krantz
Hersh Mehta
Kwame N. Mensah, Ph.D.
Gavin J. O'Keefe
Andrea K. Orth
Ann C. Palma
John M. Schafer
Lisa M. Schoedel
J. Dan Smith
Dmitriy A. Vinarov, Ph.D.
Cato Yang

Law Clerks
Michael D. Anderson
Erick K. Hasegawa
Timothy M. Long, Ph.D.
Cole B. Richter

Technical Advisors
Isadora F. Bielsky, Ph.D.
Joshua D. Bosman, Ph.D.
Willy Chen
Kader S. Gacem
Alexander D. Georges
David A. Grabelsky, Ph.D.
Gregory M. Huffman
A. Grace Klock
James L. Korenchan
Nicholas M. Leonard, Ph.D.
Jelena Janjic Libby, Ph.D.
Amir Shenouda, Ph.D.

snippets®

Review of Developments in Intellectual Property Law

We'd like to hear from you!

Please return your completed form to:

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606-6709
312 913 0001 phone
312 913 0002 fax
snippets@mbhb.com

Thank you for your interest in snippets.

Please share your comments on how we can improve snippets.

Suggestions for topics of interest, as well as general comments on snippets. content and presentation are welcome:

If you would like more information about McDonnell Boehnen Hulbert & Berghoff LLP, please check one or more of the boxes below and return this form to the address at the left:

I am interested in MBHB's:

- ☐ Biotechnology Practice
- ☐ Chemical Practice
- ☐ Computing Practice
- ☐ Electrical Practice
- ☐ Mechanical Practice
- ☐ Litigation Practice
- ☐ Prosecution Practice
- ☐ Other

Name

Company

Address

Phone

E–mail

snippets®

Review of Developments in Intellectual Property Law

McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709