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In This Issue

IMPACT OF GENERICS AND BIOSIMILAR PATHWAYS ON PATENT PROTECTION

by Daniel M. Lorentzen

For most technologies, the U.S. patent protection system does not commonly intersect with U.S. regulatory pathways. Biotechnology and pharmaceutical patents are unique in this regard. The two particularly relevant regulatory pathways are established by the "Hatch-Waxman Act" (i.e. Drug Price Competition and Patent Term Restoration Act) and the "Biosimilars Act" (*i.e.* Biologics Price Competition and Innovation Act). Both of these statutory regimes were enacted in efforts to assist generic products to market in a timely fashion without discouraging the innovation and experimentation stimulated by the granting of intellectual property rights—namely patents—to those who develop the original, first-to-market product.

GENERIC PHARMACEUTICALS: HATCH-WAXMAN ACT

The Hatch-Waxman Act provides both extension of patent term for patented pharmaceuticals (providing benefit to brand name companies) in combination with the opportunity for abbreviated approval pathways for generic drugs. At least part of the intended purpose of the Hatch-Waxman Act was to give generic companies an inventive to challenge weak patents and to compete.

With respect to patent term restoration, Hatch-Waxman provides a patented drug an extension of patent term up to one-half of the time of the investigational new drug (IND) period (i.e. the time from initiation of human clinical trials to the submission of a new drug application (NDA)). In addition, extensions for the period of NDA review can also be provided for a patent owner. These combined extensions may provide up to 5 years of patent extension.

On the side of the statutory regime, abbreviated pathways for approval of generic pharmaceuticals can create a significant interaction between a patent holder (i.e. most often the brand name pharmaceutical company) and a company wishing to enter the market with a competing drug (in some instances prior to the expiration of the patented product or challenging such patent). The Hatch-Waxman Act gives authorization for Abbreviated New Drug Applications (ANDAs), which—among other things—prevents the Food and Drug Administration (FDA) from requiring more than bioavailability studies for approval. An ANDA also provides a period of exclusivity, which precludes further generic versions of the subject pharmaceutical from entering the market for five years.

One seemingly unintended consequence of the Hatch-Waxman Act is the increased incidence of "reverse payment" settlements between brand-name and generic pharmaceutical companies. These arrangements involve payment from the patent holder to a generic company in exchange for the generic company agreeing to delay development or marketing of the generic drug. The Supreme Court decision in *Federal Trade Commission v. Actavis* held that such reverse payment arrangement settlements are not *per se* illegal, but rather must be assessed by weighing traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents. Although the Court provided little guidance as to what would be "improper" under this test, such settlements are proper at least in instances where (1) the brand-name company pays the generic company the amount it would otherwise cost the brand-name company to litigate, and (2) the brand company pays for some concrete consideration, i.e. payment for creation of a marketing arm for the drug.

BIOSIMILARS: THE BIOSIMILAR ACT

The Biosimilar Act sets forth an abbreviated approval pathway for biologics through a regulatory demonstration of biosimilarity (*i.e.* interchangeability). Biosimilars refer to generic biological products, including for example, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (excluding chemically synthesized polypeptides) and the like for the prevention, treatment, or cure of a disease. The pathway for biosimilars is not as well established as for pharmaceuticals. Thus, the FDA's current approach toward regulating and approving

continued on page 4

CHINA'S REVISED TRADEMARK LAW AND ITS PROMISE FOR GREATER TRADEMARK PROTECTION

by Christine Lebrón-Dykeman

China's revised Trademark Law, which is designed to strengthen intellectual property protection and ensure a fair market for trademark holders in China, took effect on May 1, 2014. Here are some of the highlights.

1. Trademark prosecution procedures are simplified:
   a. The China Trademark Office will accept electronic filing for trademark applications;
   b. Applications can be filed for multiple classes of goods and services;
   c. The initial examination period for a trademark application will be shortened to 9 months and reviews of refusals must be completed within an additional 9 months (with a possible 3 month extension);
   d. Under the new law, if an opposition against a pending application fails at the Trademark Office level, which is the first level of review for an opposition, the applied-for mark will immediately proceed to registration; and
   e. Opposition and invalidation proceedings must be completed within 12 and 9 months respectively (with a possible six month extension).
2. There is a broader scope of protection:
   a. The new law offers protection for "well-known" trademarks, giving owners the right to ban others from registering their trademarks or using similar ones even on dissimilar goods/services if the use would potentially prejudice the owners of the well-known mark; and
   b. The new law allows for registration of sounds.
3. There is a crackdown on infringement:
   a. The new law expressly includes a requirement for a "likelihood of confusion" analysis in any trademark infringement claim making the infringement standards more analogous with other countries' rules;
   b. The new law mitigates trademark holders' responsibility in providing proof of damages from infringement, saying the alleged offenders shall provide their account books or other materials for investigation;
   c. Under the new law, Chinese courts may now award significantly greater statutory damages in infringement cases ranging from RMB 500,000 (about $80,000 USD) to RMB 3 million (just under $500,000 USD), effectively increasing the previous limit by six times;
   d. Infringers who have engaged in infringement of a trademark more than twice within five years will be punished more severely. Those who run an illegal business whose profit value exceeds 50,000 RMB will be fined a maximum of 20 percent of that amount; if the value is less than 50,000 RMB, they will be fined a maximum of 10,000 RMB;
   e. A newly added Article 7 states that the trademarks shall be registered and used in accordance with the principle of "good faith," and the law expressly prohibits distributors, agents and others who have business contacts with a particular trademark owner from registering, in "bad faith," the same or similar trademarks, for the same or similar goods/services

CONCLUSIONS AND RECOMMENDATIONS:

While many of these changes should be seen as a positive step by the Chinese government in protecting IP rights, one particular change may have an equally negative impact in regards to bad-faith filers. China is still a first to file country, which means that the first entity to file for registration is normally granted registration, unless the application is opposed and the opposer proves it has prior use in China or, if not, that the application was filed in bad faith. Currently, if the Trademark Office rejects an opposition, the opponent may appeal the decision to the Trademark Review and Adjudication Board, which typically has more discretion to rule in the opponent's favor even where there is not concrete evidence of a bad faith filing (e.g., where the applicant is not in any type of business relationship with the original trademark owner). Under the revised law, where an opposition is rejected by the Trademark Office, the opposed mark will proceed straight to registration, after which the only recourse available to the opposing party will be to apply to invalidate or cancel the registration.

Thus, our advice regarding registration in China remains the same. If you have any current or future interest in using your trademarks in China, or in preventing others from doing so, you should:

1. Register your trademarks in China as soon as you have reason to believe you want to sell goods or services there, have your goods manufactured or distributed there by others, or license others to use your marks there;
2. Ensure that any trademark registrations you own or apply for in China are sufficiently broad in terms of the goods and/or services covered; and
3. Depending on the intended extent of use of your marks in China, consider registering your marks both in your own language as well as in Chinese script.

INTER PARTES REVIEW: A BRIEF REVIEW

by Cory McAnelly

The Inter Partes Review ("IPR") procedure of the America Invents Act ("AIA"), which went into effect on September 16, 2012, is no longer in its infancy. Since replacing the pre-AIA "Inter Partes Reexamination," Inter Partes Review has been the subject of much examination and analysis by scholars and practitioners alike. The statistics regarding the IPR process have been extensively scrutinized, with much of the attention focusing on whether patent claims can survive the review of the Patent Trial and Appeal Board ("PTAB"). As of March 2014, the eighteen-month anniversary of the IPR process, nearly 1,000 IPR petitions had been filed, and more than twenty final written decisions had been issued by the PTAB. Of the claims challenged in these early decisions, more than 80 percent were found invalid. Needless to say, patent owners are facing an uphill battle when it comes to keeping those claims that face the IPR procedure.

While it is only in the last few months that we have begun to see the resultant effects of the IPR procedure on the validity of patent claims, practitioners have the benefit of over a year and a half of decisions from the PTAB regarding the procedural mechanisms of

continued on page 3

IPR. IPR is a unique procedure, far different from the pre-AIA Inter Partes Reexamination, and it follows a set of standards and rules that the PTAB has taken a strict stance on enforcing. Practitioners who are thinking about initiating an IPR would be wise to first familiarize themselves with the full set of rules set forth in both 35 U.S.C. § 311 et seq. and 37 C.F.R. §§ 42.1 et seq (and particularly Subpart B). Further, the United States Patent and Trademark Office ("USPTO") has published a "Trial Practice Guide"—found in Vol. 77, No. 157 of the Federal Register—which provides a rather comprehensive analysis of the procedure of the IPR. That said, even after reviewing all of the materials provided by the USPTO and the PTAB, certain questions can only be answered by reviewing specific decisions of the PTAB.

Some of these questions might be answered clearly. For example, when a civil action is instituted alleging infringement of the patent, the time for filing an IPR is dictated by statute: "[a]n inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent."—35 U.S.C. § 315(b). Upon inspection, this language seems straightforward. However, the PTAB's ruling in *Apple. Inc. v. Virnetx, Inc. and Science Application International Corp.* (IPR2013-00348) further outlined the boundaries of the one-year bar. In the *Apple Inc.* case, the petitioner was served with a complaint alleging infringement on a patent in 2010—before the effective date of the AIA and the IPR statute. The Petitioner was again served with a complaint alleging infringement of the same patent in 2012 and attempted to initiate an IPR pursuant to the statute. The PTAB held that under the plain meaning of § 315(b), any complaint, even those served before the effective date of the AIA, "qualifies as 'a complaint' that time bars the Petition." This decision was affirmed on rehearing and has been consistently applied by the PTAB.

In certain circumstances, even a diligent exploration of PTAB decisions might not suffice to provide an adequate answer to what may seem like a simple question. For example, what constitutes a "party in privy" or "real-party in interest" under 35 U.S.C. § 315(b)? Chief Judge James Donald Smith of the PTAB has explained that, "[w]ho constitutes a real party in interest or privy is a highly fact-dependent question, especially on the issue of whether a party who is not a named participant in a given proceeding nonetheless constitutes a "real party in interest" or "privy" to that proceeding." While a practitioner may find a decision to shed light on a particular scenario, the PTAB will continue to leave the rule open to interpretation in order to provide "the Board the flexibility to consider the specific facts and relevant case law in resolving a standing dispute." While the rules may not always provide the greatest guidance to the practitioner, it is clear that strict compliance with the guidelines—clear or unclear—is critical for the survival of the IPR petition.

The remainder of 2014 will be a critical period in the development of IPR. As the PTAB continues to issue final written decisions, we will begin to gain a clearer picture as to the effectiveness of the IPR as a tool for invalidating patents. Further, as the PTAB's rulings and determination on procedural issues follow these decisions through appeal, we will begin to have a sharper understanding of the true boundaries of IPR. While Inter Partes Review is no longer in its infancy, keeping a sharp eye on its growth and development will be crucial to a successful IPR practice.

A REMARKABLE WEEK OF INTELLECTUAL PROPERTY ARGUMENTS AT THE SUPREME COURT

by Daniel M. Lorentzen

The 2014 session has seen a remarkable number of intellectual property cases granted *certiorari* and argued at the U.S. Supreme Court. The Court has agreed to take up several key issues of trademark, copyright, and patent law, which could provide some long awaited guidance to intellectual property owners. During one nine-day stretch from April 21 to April 30, the Court heard oral arguments in four different notable IP cases. The following is a summary of the key issues and developments for these cases.

Limelight Networks, Inc. v. Akamai Technologies, Inc. (U.S., No. 12-786): Inducing patent infringement without direct infringement.

The question posed to the Court in this case is whether a defendant may be held liable for inducing patent infringement under 35 U.S.C. § 271(b) even though no one has committed direct infringement under § 271(a). For method and process patents, the state of the law to this point has required proof of at least one direct infringer—a "single entity" that performs all of the patented steps—in order to hold another liable for inducing that infringement. In this case, however, the defendant is alleged to only practice a portion of the whole invention, but expressly encourage its customers to perform the rest, but nonetheless induce infringement.

The Federal Circuit dismissed the "single-entity" rule for finding induced infringement of a method/process claim, finding that steps taken by multiple parties can result in induced infringement. The Federal Circuit stated, "To be clear, we hold that all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity." If the Supreme Court upholds the Federal Circuit's ruling, a patentee has increased opportunity to assert induced infringement for method/process claims in the marketplace.

Oral arguments were heard in this case on April 30th, 2014.

Nautilus, Inc., v. Biosig Instruments, Inc. (U.S., No. 13-369): Patent claim ambiguity without indefiniteness.

There are several related questions for the Supreme Court in this case. The first is whether a court should accept ambiguous patent claims with multiple reasonable interpretations—so long as the ambiguity is not "insoluble" by a court. The second, related question is whether accepting such ambiguous claims defeats the statutory requirement of particular and distinct patent claiming. The final question is whether the presumption of validity dilutes the requirement of particular and distinct patent claiming.

The Federal Circuit reversed a district court decision that a patent claim to a heart rate monitor was invalid for indefiniteness as a matter of law because of its use of the claim term "spaced relationship" in describing the positioning of two electrodes with respect to each other. The appellate court held that this claim term was not one that is "insolubly ambiguous" when the intrinsic evidence is considered from the perspective of a person of skill in the art. It considered the functionality of the claimed monitor,

continued on page 4

as described in the specification, as did the USPTO when the claim was under reexamination, holding that "the claims provide inherent parameters sufficient for a skilled artisan to understand the bounds of 'spaced relationship." Judge Schall concurred in the result but would have used a more narrow analysis, explaining that he would not have used the functional limitation to address the definiteness issue. If the Supreme Court upholds the Federal Circuit's decision, it may provide some additional claim scope to patent owners.

Oral arguments were heard in this case on April 28th, 2014.

POM Wonderful LLC v. The Coca-Cola Company, U.S. (No. 12-761):

The question for the Supreme Court in this case is whether a private party can bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act.

The case arises out of the 9th Circuit, where the appellate court affirmed judgment in favor of Coca-Cola, finding that POM's Lanham Act challenge to Coca-Cola's "Pomegranate Blueberry" name was barred under the Food Drug and Cosmetic Act (FDCA). The Court will address issues of whether Section 43(a) of the Lanham Act, 15 U.S.C. 1125(a) (authorizing actions of false/misleading description of goods), and/or state law claims can be applied to food, drug, and cosmetic labels, or whether the FDCA precludes such claims. The outcome of this case will have important implications for who may bring a false advertising claim, and under what circumstances, potentially opening up another avenue for litigation.

Oral arguments were heard in this case on April 21, 2014.

American Broadcasting Companies, Inc. v. Aereo, Inc. (U.S., No. 13-461):

In this case, the question presented to the Supreme Court is whether a company "publicly perform" a copyrighted television program when it retransmits a broadcast of that program to thousands of paid subscribers over the Internet?

A panel decision from the Second Circuit held that an online streaming of TV programs to individual subscribers is not an infringing public performance. The panel found that the creation of a copy of a broadcast that is transmitted to individual subscribers failed to establish infringement as streaming "to the public." The Second Circuit *en banc* denied review of the panel decision.

The Supreme Court's decision in the case could have broad ranging implications for a wide variety of internet-based businesses, including cloud computing services and companies that provide the equipment used to stream content over the Internet.

This case was argued to the Supreme Court on April 22nd, 2014.

Decisions in all of these cases can be expected in the next several months.

Impact of Generics continued

biosimilars presents a moving target, much like the moving target on patent eligibility.

Although the Biosimilars Act has a similar goal as the Hatch-Waxman Act of encouraging the market entry of generic products, the Act does not have any connection with patents (including issues of infringement or litigation). Due to the more recent enactment of the statute in 2010, the FDA has not fully implemented the regulations. However, the general process for biosimilars will include conducting meetings with the FDA to document the "interchangeability" of the biosimilar product.

133 S.Ct. 2223.

WE'RE THERE

May 7
Kirk Hartung attended the MPF Leadership Conference for law firm leaders in Atlanta, Georgia.

May 8
Jill Link presented an IP seminar at the Iowa State Bar Association "Bridge the Gap" conference in Des Moines, Iowa.

May 19
Jill Link spoke at the Montgomery Small Business Association Business Planning seminar in Montgomery, Alabama.

May 28
John Goodhue presented on *Intellectual Property Essentials for Engineers: Patents, Trademarks, Copyrights, and Trade Secrets* at the Iowa Engineering Law conference sponsored by Half Moon Seminars in Johnston, Iowa.

June 12-13
Ed Sease will attend the *Fundamentals of Copyright Law and the Fundamentals of Trademark in a Global Market Place* in Chicago, Illinois sponsored by the Practicing Law Institute.

June 19-21
Kirk Hartung will attend the LEGUS annual meeting in Rome, Italy

July 14-16
Heidi Nebel, Kyle Coleman, Daniel Lorentzen and Cory McAnelly will attend the AUTM Central Regional Meeting in St. Louis, Missouri where MVS will also sponsor.

July 24
Kyle Coleman will attend the TEDxFargo Conference in Fargo, North Dakota.

August 10-14
Jonathan Kennedy and Daniel Lorentzen will attend the American Chemical Society's Fall National Meeting in San Francisco, California.

September 16-18
Heidi Nebel and Jill Link will attend the Livestock Biotech Summit conference on *Developing Global Solutions Through Animal Biotechnology* in Sioux Falls, South Dakota.

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