

# ATTORNEY REVIEW

## *An Update on Intellectual Property News*

**By: Clifford M. Davidson, Esq.**

There is much going on in the world of patents. In the US, certain pending legislation may lead to some of the most extensive changes to patent law in more than 50 years. Particular aspects of these bills include: (1) conversion to a first-inventor-to-file system, (2) adoption of opposition proceedings, (3) reformation of infringement damages calculations, and (4) addition of an abbreviated pathway for FDA approval of biopharmaceuticals. If approved, these bills would greatly alter the landscape of patent procurement and patent litigation. No less significant, the *Tafas/Smithkline Beecham Corp. v. Dudas* summary judgment ruling was a cause of celebration for patent practitioners. US District Court for the Eastern District of Virginia Senior Judge James C. Cacheris granted Tafas' and Smithkline Beecham Corp's (GSK) motions for summary judgment and voided the claims and continuation rules (the Final Rules) as not in accordance with law and in excess of statutory jurisdictional authority.

### **PENDING LEGISLATION**

#### *Change to First to File*

Unlike the rest of the world, the US utilizes a first-to-invent patent system. In the case of two patent applications claiming the same invention, the USPTO will determine the first inventor(s) through what is called an interference proceeding. An interference proceeding is a quasi-judicial system used by the USPTO to determine the first inventor, and typically involves proving invention dates through evidentiary proceedings and production of supporting documents (eg, lab notes, memos, etc). In contrast, the rest of the world follows a first-to-file patent system wherein the first person/entity to file a patent application receives the filing date and opportunity to obtain a patent.

*The Patent Reform Act of 2007* was passed by the House of Representatives this past September and is awaiting a vote in the Senate. This act, if approved, would change the US to the first-to-file system, which eliminates interference proceedings. Proponents, such as the biotech industry, argue that this will save time from the lengthy and expensive years of proceedings, improve fairness, result in greater legal certainty, and move toward a more harmonized international patent system. Opponents maintain that such a system would favor those with deep pockets and disadvantage small and independent inventors who lack the resources to race to the patent office.

#### *Opposition Proceedings in the US?*

Under the current US patent system, after a patent is granted, a third party may file for an ex parte or inter partes reexamination challenging the patent's validity with arguments and evidence based on prior art not considered by the examiner in the initial patent issuance. The arguments within the examination request are limited to anticipation rejections under 35 U.S.C. § 102 and obviousness rejections under 35 U.S.C. § 103. If the USPTO agrees to reexamine the application, it is then up to the patent holder to correspond with the USPTO to prove the validity of the patent, likely faced with new prior art that hadn't been considered previously. The patent holder may make amendments to the claims to preserve the patent in light of the prior art.

Congress is currently reviewing foreign opposition systems in an effort to establish a patent opposition system in the US. In Europe, anyone can file for an opposition with the European Patent Office (EPO) challenging the patent's validity within 9 months from the publication of the mention of the grant. During an opposition, the patent holder contends with the opponent. The case is presented during Oral Proceedings at the

EPO in Munich, where a decision is reached. Afterward, both parties can file an appeal that may lead to another Oral Proceeding. Oppositions permit a greater depth of evidence to be presented to challenge a patent. The proposed bill states that the USPTO shall treat any *ex parte* or *inter partes* reexamination request during the 9 months following the patent grant as a request for an opposition proceeding. A request made after the 9-month opposition period and during the pendency of an opposition proceeding will be stayed by the USPTO. It is hoped that this new procedure will increase the quality of US patents by making it simple, speedy, and less expensive to review patents after allowance. The problem with this bill is that it leads to overlap and redundancy between the proposed and existing systems. The experience of Japan and China shows that multiple systems for challenging a patent have the potential to complicate matters by creating undue harassment and consuming valuable and limited patent office resources. Further, the relatively short 9-month opposition period is a disadvantage to small companies who do not have the resources to constantly monitor competitors' patents. In 2003, Japan abolished its post-grant opposition limited window in favor of an invalidation proceeding that allows a challenger to bring a request at anytime during the patent life.

## *Changes in Damages*

Generally, in the US, a patentee is entitled to the lost profits damages it would have made based on the infringer's sales. However, in no way can damages be less than a reasonable royalty. Either the judge or jury makes the calculation for reasonable royalty as guided by the *Georgia Pacific* 15-factor test. This analysis involves envisioning the parties in a hypothetical negotiation for patent licensure. An amount is estimated for what the infringer would have paid and what the inventor would have accepted at the beginning of the infringement.

The proposed rule would ensure damages as the economic value attributable to the invention minus the value attributable to the incorporation of "process of features or improvements, whether or not themselves patented, that contribute economic value to the infringing product." In other words, courts would apportion damages to the patented innovation only. Under this proposal, the court must first look

at the relationship of damages to contributions over prior art. Damages may be based on the entire market value of the product if the patented invention is deemed to be the driving force behind market demand for the product. Once there is an appropriate showing that the patentee's specific contribution over the prior art is the predominant basis for market demand, then damages may be based upon other factors, such as the terms of any non-exclusive marketplace licensing of the invention, an established royalty rate based on past licensing, and any other relevant factors. The bill would require the patent holder to establish that the economic value is due to the patent's specific improvement and not from any other features added by the infringer.

Section 5(a) of the bill is set to ensure clarity in the application of damages, which is often an open-ended guessing game as applied by the entire-market-value rule. The current standard bases damage calculations on the value of an entire product, patented and unpatented features, and significant and insignificant components. The damages awards may be inflated to many times the true market value of the innovation.

Proponents say this measure brings the excessive royalty awards more in line with economic realities. Large technology companies that have complex products containing an insignificant patented component are often dragged into frivolous litigations in which patentees base their damage calculations on the value of an entire end product.

Opponents to the proposed bill worry the opposite may happen: artificially low damage awards, unpredictable royalty rates, undermined licenses, voluminous increases in litigation resulting in lengthening damages phases of trials, high cost, and delays to the patent litigation system. The value of patents could be greatly diminished in fields that build upon incremental advances and prior technologies, for example, biotech and pharmaceuticals. An infringing company could reduce damages by limiting an infringed patent to a miniscule part of its product's overall functionality.

Many believe that apportioning damages based on the economic value gained from specific contributions over prior art weakens patent protection by making it easier to infringe, and is viewed as highly favoring infringers who may find it cheaper to copy a patent than to license it.

## HATCH-WAXMAN - BIOSIMILARS

The *Hatch-Waxman Act of 1984* created an abbreviated pathway for FDA approval of small molecule drugs, but not generic biopharmaceuticals. Each New Drug Application (NDA) holder is required to list its patent information in the Approved Drug Products with Therapeutic Equivalence Evaluations, known as the *Orange Book*. If the NDA holder has listed patents in the *Orange Book*, the generic drug company can submit an Abbreviated New Drug Application (ANDA) to the FDA. The generic drug companies may obtain marketing approval without conducting expensive clinical trials to demonstrate safety and efficacy. Instead, generic applicants are required to show that their products are bioequivalent, ie, similar in dosage form, strength, route of administration, quality, performance characteristics, and intended use. An ANDA applicant is required to notify an NDA holder of any Paragraph IV certification stating that the status of the drug for which it seeks approval does not infringe in any way. If the patent holder decides to bring suit within 45 days of receiving the notice, then the FDA may stay the final approval of the ANDA for 30 months. The new bills in Congress seek to eliminate the automatic 30-month stay.

On February 14, 2007, Rep. Henry Waxman introduced the first of the four biosimilars bills, the *Access to Life-Saving Medicine Act*. Instead of filing a patent certification with the FDA, the biosimilar applicant may, at any time, send notice to the patent holder exchanging patent information and giving full details, facts, and legal basis for its belief that the patent may be invalid, unenforceable, or not infringed. The patentee may sue for infringement based only on the patent in the notice and only in a judicial district court of its choosing. In certain cases, the proposed Waxman bill would limit infringement damages to only reasonable royalty as the sole and exclusive remedy.

Rep. Jay Inslee introduced the second biosimilar bill, *Patient Protection and Innovative Biologic Medicines Act of 2007 on April 19, 2007*. The Inslee bill, favored by brandname companies, does not begin patent litigation until after the generic company starts to market its biosimilar drug product.

The third bill, *Biologics Price Competition and*

*Innovation Act of 2007* introduced by Sen. Edward Kennedy on June 26, 2007, is the most complex of the four biosimilars bills. Unlike the voluntary patent exchange under the *Waxman Act*, the Kennedy bill mandates participation in the exchange. The generic drug company is required to send notice to the patent holder either (1) to exchange patent information giving full details, facts, and legal basis for its belief that the patent may be invalid, unenforceable, or not infringed or (2) to promise that there be no commercial marketing of generic products before patent expiration.

Lastly, the bill introduced by Rep. Anna Eshoo on March 13, 2008, is the *Pathway for Biosimilars Act*. The biosimilar applicant provides a copy of its FDA application to the brandname company. The brand company would then reply with listed reasons why it believes there may be patent infringement. The generic company would also send the same notice as under the Kennedy bill. The biosimilar applicant must wait until at least 120 days after it provides a detailed written detailed explanation before it can bring an action for declaratory judgment of invalidity, unenforceability, or non-infringement. Other components of the bill would give the innovator company 12-year exclusivity after initial licensure or 14 years if a medically significant new indication is filed during the 8-year period following licensure of the reference product. Another 6 months will be added to the 12-year or 14-year exclusivity periods for pediatric-indicated products. In addition, the user fees would be the same for biosimilar and brandname product applicants.

The interactions between brand and generic biologics involving patent challengers during the approval process will likely be different from the small molecule drugs under the *Hatch-Waxman Act*. Any new biosimilar legislation will probably have bits of elements from each of the proposed bills.

## NEW USPTO RULES: TAFAS V. DUDAS

The USPTO promulgated a set of new rules culminating in final rules that were to go into effect in November 2007. The final rules permitted an applicant to file two continuation applications plus one request for continued examination (RCE) after the initial application (the 2 + 1 rule), with an

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additional application or RCE upon the filing of a petition and explaining why the amendment/argument could not have been previously presented; and permitted an applicant to present a total of 5 independent claims or 25 total claims for examination without providing any further information about those claims (the 5/25 rule). If the total claims exceeded either amount, the applicant would be required to submit an examination support document (ESD) containing detailed information about the claims to assist the examiner in determining patentability.

Following publication of these final rules, plaintiffs Tafas and GSK separately filed complaints seeking preliminary and permanent injunctions prohibiting the USPTO from implementing the Final Rules and a declaratory judgment that the Rules violated the US Constitution, the Patent Act, etc. On October 31, 2007, the court granted GSK's motion for a temporary restraining order and preliminary injunction. The plaintiffs then moved for summary judgment. On April 1, 2008, the US District Court for the Eastern District of Virginia granted summary judgment in favor of the plaintiffs. The court ruled that the USPTO's proposed limitations to the number of continuation applications and claims per patent were substantive in nature and exceeded the scope of the USPTO's rulemaking authority under 35 U.S.C.S. § 2 (b) (2), and therefore voided the Final Rules. 35 U.S.C.S. § 2 (b) (2) does not give the USPTO the statutory basis for fixing an arbitrary limit to the number of continuing applications that may be filed and that retain the benefit of the priority date.

It is noteworthy that the court held that the USPTO's 2 + 1 continuation rule placed a limit that "deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right." The court also ruled that the 5/25 rule limiting the number of claims was also substantive because the law prevents any strict limit on the number of claims.

The court further took note of the fact that the Federal Circuit has read 35 U.S.C.S. §§ 102, 103, and 131 as placing the burden of proof on the USPTO to make a prima facie case of unpatentability. The Court found that the ESD requirement would change the law by shifting the examination burden onto the applicants. Final Rule 265 would have required that applicants conduct a broad search of patents, patent

applications, and literature, and provide, among other things, a detailed explanation of how each of the independent claims is patentable over the cited references. The Court held that such would constitute a drastic departure from the terms of the Patent Act as they are presently understood effecting changes in GSK's and Tafas's existing rights and obligations.

The USPTO filed an appeal on May 7, 2008. It is widely believed that this decision will be upheld. It is unlikely that the matter will be resolved in the coming months and quite possibly not until the end of the Bush administration. ♦

## BIOGRAPHY



**Clifford M. Davidson, Esq.** is a founding partner at Davidson, Davidson & Kappel, LLC, an Intellectual Property law firm with offices in New York City and Frankfurt, Germany. He counsels pharmaceutical clients in pharmaceutical patent-related matters, including patent prosecution, freedom to operate and infringement opinions, due diligence

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