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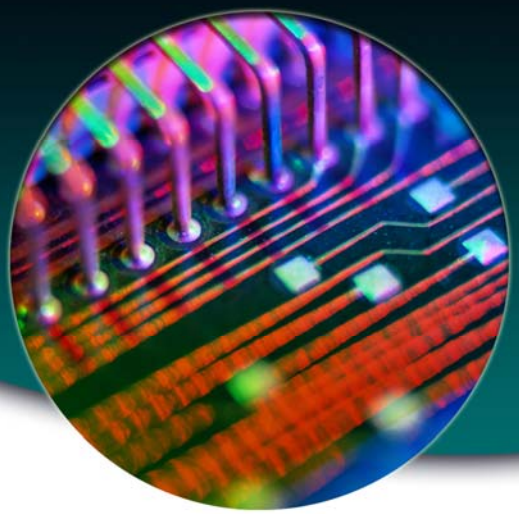

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Inside:

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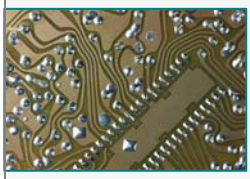
Patent Exhaustion: Conflicting Views on the Territoriality Requirement



The US Supreme Court's unanimous decision in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S. Ct. 2109 (2008)[1], reaffirming the patent exhaustion doctrine (also known as the first sale doctrine), was promptly followed by a line of cases testing this doctrine's reach. One line of cases held that patent exhaustion is territorial, and sales outside of the United States do not exhaust a patentee's US patent rights. A second line held that the doctrine has no territorial limits and a patentee's sales anywhere in the world exhaust its rights in the United States. Given these diametrically opposing views on an issue with significant implications for patentees, licensees and manufacturers doing business both inside and outside the United States, many were hopeful that the Supreme Court's decision on this issue in the copyright context in *Costco Wholesale Corp. v. Omega, S.A.* (argued in November 2010) would have provided some much needed guidance. Unfortunately, none was given. On December 13, 2010 the Supreme Court issued a split 4-4 affirmation of the Ninth Circuit decision. The split was due to Justice Elena Kagan's[2] recusal. With no Supreme Court precedent, the issue of whether the exhaustion doctrine has a territoriality requirement ultimately remains unsettled.

In its simplest terms, the patent exhaustion or first sale doctrine is premised on the notion that a patentee should be rewarded for the "first authorized sale" of its patented product, but once the product is sold the patentee's rights as to the product are "exhausted" – the patentee has no further right to interfere in or control the downstream purchasers' use or enjoyment of the product.[3] Exhaustion is, therefore, a common defense to claims of various IP infringement including patent and copyright infringement.

The question is, however, whether it matters where the first authorized sale took place. Proponents of the "territorial exhaustion" argument advocate that an authorized sale must have occurred in the jurisdiction where the exhaustion defense is being asserted. In contrast, those who claim that exhaustion has no territoriality requirement take the view that once a patentee has authorized sale of its product anywhere in the world, a patentee's rights as to those products are exhausted worldwide.

One Point of View: Only First Authorized Sale in United States Exhausts US Patent Rights

The territorial exhaustion argument is based on the idea that patent rights are fundamentally territorial in nature (e.g., a US patent alone does not confer any patent rights outside the United States) and, therefore, such rights cannot be exhausted by acts or conduct outside the relevant countries or territories. The often, albeit rather ill-advisedly, cited case for this argument is *Boesch v. Graff*, 133 U.S. 697 (1890). The case, however, was more accurately about whether a third party had the requisite right or authority to sell the patented products in the United States, and not about whether a patentee had exhausted its rights by a prior sale – in fact, in *Boesch* there was no first authorized sale by a patentee.[4]

Yet subsequent cases relying on *Boesch* have interpreted the case as standing for the proposition that patent exhaustion has a territoriality requirement, and by sheer momentum this has spawned a series of opinions reiterating the same.[5] Examples include *Jazz Photo Corp. v. Int'l Trade Comm.*, 264 F. 3d 1094, 1105 (Fed. Cir. 2001) (*Jazz 2001*) (citing *Boesch* "[t]o invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent") and *Fuji Photo Film Co., Ltd. v. Jazz Photo Corp.*, 394 F.3d 1368, 1376-77 (Fed. Cir. 2005) (*Fuji 2005*) (broadly construing *Boesch:* "the patentee's authorization of an international first sale does not affect exhaustion of that patentee's rights in the United States"). In fact, most recently in *Fujifilm Corp. v. Benun*, No. 09-1487 (Fed. Cir. May 27, 2010), the Federal Circuit[6] made it abundantly clear that in its opinion there is a territorial requirement to the exhaustion doctrine, and "*Quanta* did not eliminate the first sale rule's territoriality requirement."

An Alternative Point of View: First Authorized Sale Anywhere Exhausts US Patent Rights

In *LG Electronics, Inc. v. Hitachi, Ltd.*, 655 F. Supp. 2d 1036 (N.D. Cal. March 13, 2009), after reviewing the same license agreement that was at issue in *Quanta*, the court unequivocally held that the exhaustion doctrine has no territoriality requirement, and that once a patentee authorizes the sale of its products anywhere in the world, the patentee's rights as to those products are exhausted.[7] The *Hitachi* court reasoned that a territoriality requirement would in effect give a patentee the right to pursue downstream purchasers and users for infringement even though the product was initially "lawfully" acquired, which would be contrary to the fundamental tenet of the Supreme Court's decision in *Quanta* – that the exhaustion doctrine "prevents the patent holder from invoking patent law to control postsale use of the article" and "the danger of allowing such an end-run around exhaustion … would violate the longstanding principle, that, when a patented item is once lawfully made and sold, there is no restriction on its use to be implied for the benefit of the patentee." *Id.* at 1044. Squarely addressing the Federal Circuit's opinions in *Jazz 2001* and *Fuji 2005,* the *Hitachi* court noted that *Quanta* undercut and overruled these decisions,[8] and the patentee's first authorized sales of the products anywhere exhausted the patentee's rights as to those products. LG did not appeal the ruling and the case was subsequently terminated by the parties' stipulation in October 2009.

[R]eading Section 109 to include a territoriality requirement would effectively incentivize foreign outsourcing or manufacturing outside the United States.

Supreme Court's Review of the Exhaustion Doctrine in the Copyright Context: *Costco v. Omega*

Against this backdrop the Supreme Court received briefs and heard argument in *Costco v. Omega*, which considered whether the exhaustion or first sale doctrine has a territoriality requirement in the context of copyrights. The dispute in *Costco* revolved around a common problem faced by manufacturers – gray market goods or parallel imports – which primarily takes advantage of differences in manufacturers' pricing systems in different countries and markets (i.e., arbitrage).

In *Costco*, Omega made and sold watches to authorized distributors outside the United States. The watches subsequently passed through other third party dealers and distributors, and were eventually available for sale at Costco's California stores at a steep discount. Omega sued Costco for infringing distribution and unauthorized sale of watches that bore Omega's copyrighted designs, and argued that the exhaustion defense was unavailable to Costco because Omega made and sold the watches outside the United States. The Ninth Circuit agreed. In doing so, however, the Ninth Circuit essentially challenged the Supreme Court's unanimous decision in *Quality King v. L'anza Research International Inc.*, where the Court upheld the exhaustion doctrine for imported goods, and distinguished *Quality* on the grounds that the Omega watches were made and first sold abroad (and outside the "territorial" reach of the exhaustion doctrine), whereas in *Quality* the products were made in the United States.

During the *Costco* oral arguments, the Court seemed skeptical of both sides' positions on whether the "first sale" statute[9] (Section 109) implicitly included a territoriality requirement, repeatedly asking the lawyers to point out where in the text or legislative history support could be found for their respective arguments. The Justices appeared to agree that reading Section 109 to include a territoriality requirement would effectively incentivize foreign outsourcing or manufacturing outside the United States, and Congress certainly would not have enacted Section 109 with such an intent – "what earthly sense would it make to prefer goods that are manufactured abroad over those manufactured in the U.S." (J. Ginsburg).

On December 13, 2010 the Court issued a *per curiam* order affirming the Ninth Circuit's ruling against Costco. This order was issued because the court split 4 to 4 on the question and so by rule the lower court opinion was affirmed by an equally divided court. This division resulted after Justice Kagan had recused herself because she had participated as Solicitor General in submitting a brief to the Court urging it to not take the case because the decision of

the Ninth Circuit was correct. In effect, the Supreme Court's action left the Ninth Circuit's ruling against Costco undisturbed (i.e., the exhaustion doctrine is subject to a territoriality requirement), but it provided no clarification or further precedent to guide lower courts and interested parties. Thus, the conflicting views about the territorial scope of the exhaustion doctrine remain unsettled (at least outside of the Ninth Circuit).

Negotiating and Drafting the License Agreement ("First Authorized Sale")

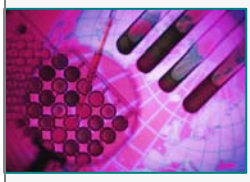
Notwithstanding the uncertainty surrounding the territoriality requirement, one thing *Quanta* makes clear is that the parties are free to limit the rights granted in the agreements they negotiate and execute. Notably in *Quanta*, the Court observed that the LG-Intel license agreement did not in any way restrict Intel's (the licensee's) right to sell the products, and LG (the licensor) "overlooked" an important aspect of the structure of the transaction that the parties negotiated. The Court indicated that the parties are free to negotiate and draft license agreements imposing certain conditions on sale and use of the products, which were incidentally missing in the LG-Intel license agreement.

In fact, license agreements can often have "field of use" conditions; geographic, regional or term limitations; conditions based on frequency of use; varying royalty structures contingent on, for instance, who the product is sold to (e.g., sales to licensee versus non-licensees); or any number of other such conditions to limit the use and/or sale of a patented product. If these conditions were violated, a licensor could have a potential breach of contract claim against a licensee – a point the Supreme Court raised in *Quanta*. This, however, is easier said than done, and can be challenging to negotiate and enforce, not only from a commercial perspective, but also because such terms may implicate antitrust, trade or other consumer protection laws.

Kate E. Kim, associate, Tokyo

1. In *Quanta*, the products at issue were Intel chipsets and microprocessors which incorporated several of LG Electronics' patents pursuant to a license agreement between Intel and LG. Intel, in turn, sold these chipsets/microprocessors to its customers, such as Quanta, which incorporated the products into other computer systems. Subsequently, LG sued Intel's customer, Quanta, for patent infringement. The Supreme Court held that LG exhausted its patent rights when it first sold the products to Intel and LG could not recover against Intel's customers who used and incorporated such products.
2. In her previous capacity as solicitor general, Justice Kagan filed a brief urging the Supreme Court to not review the Ninth Circuit's decision because the Ninth Circuit's ruling against Costco (upholding a territoriality requirement in the exhaustion doctrine, discussed further below) was correct and not erroneous.
3. This, in part, reflects the delicate balance between common law principles against restraints on alienation of property, a patentee's right to exclude others from practicing the invention for a limited period, and the public policy of promoting or incentivizing developments in technology and new inventions – "purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward for the use of his invention by the sale of the article, and that once that purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." *U.S. v. Univis Lens Co.*, 316 U.S. 241, 251 (1942).
4. In *Boesch*, a dealer in the United States had purchased and resold a patented product from someone *other than* the patentee – another inventor (Hecht) who had independently invented the same product as the patentee, and as such had the right to legally sell the product in Germany (based on a prior user right statute in Germany), but was *not* the actual patent holder. Thus, when Hecht, through a third party dealer, sold and distributed the products throughout the United States, the patentee, having successfully obtained patents in both the United States and Germany, had neither benefited from the "first" sale of the products, nor authorized the sale. The court, therefore, held that the US dealer could not circumvent the patentee's US patent rights simply by purchasing the product abroad and reselling it in the United States.
5. *Jazz Photo Corp. v. U.S.*, 439 F.3d 1344, 1350 (Fed. Cir. 2006) ("we reasoned that when a patented device has been lawfully sold in the United States, subsequent purchasers inherit the same immunity under the doctrine of patent exhaustion"); *Fuji Photo Film Co., Ltd. v. Int'l Trade Commission*, 474 F.3d 1281, 1288, 1293 (Fed. Cir. 2007) ("determining whether the patent rights were exhausted [involves examining], i.e., whether the cameras were first sold in the United States"; "affirmative defense of repair [to claim of patent infringement] only applies to products whose patent rights have been exhausted through a first sale in the United States").
6. Notably, the Supreme Court has reversed, vacated, or otherwise remanded at least 16 of the 21 Federal Circuit's decisions in patent related cases decided between 1990 and 2010.
7. Federal Circuit decisions are binding precedent on district courts, but here *Hitachi* was decided before *Benun. Benun* references *Jazz 2001*, but makes no mention of *Hitachi.* This is not unusual – on substantive issues, Federal Circuit decisions usually cite other Federal Circuit patent opinions.
8. The *Hitachi* court further held that even if patent exhaustion only applied to sales in the United States, because the license agreement between LG and Intel was to be governed by New York law, there was a "sale" in the United States and LG exhausted its rights with respect to products sold thereunder.
9. The exhaustion/first sale doctrine in patent law is based on common law, whereas in the copyright context it has been codified in 17 USC §109(a).

Inequitable Conduct Doctrine: Significant Changes on the Horizon?



On April 26, 2010, the Court of Appeals for the Federal Circuit granted a petition for *en banc* rehearing in *Therasense Inc. v. Becton, Dickinson & Co.* to clarify the inequitable conduct doctrine. The impetus for granting the petition may be to prevent the overuse of the inequitable conduct defense, and to preserve the defense for situations such as fraud and unclean hands. Thus, *Therasense* has the potential to significantly modify the inequitable conduct doctrine.

Inequitable conduct is an equitable defense to patent infringement under which "[a] patent may be rendered unenforceable … if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the [US]PTO during prosecution."[1] A party asserting the defense of inequitable conduct must prove two elements by clear and convincing evidence.[2] The first element is materiality, which requires proof that the patentee has made an affirmative misrepresentation of material fact, a submission of false material information or a failure to disclose material information.[3] The second element is intent to deceive the USPTO.[4] Although clear and convincing evidence is required to prove intent, intent can be proved through circumstantial evidence.[5] Upon making the threshold determinations of materiality and intent, the court must then weigh those determinations to decide whether the equities warrant a conclusion that inequitable conduct occurred (also identified as the "balancing inquiry").[6] If the court determines that inequitable conduct occurred in relation to the prosecution of one or more claims, the entire patent becomes unenforceable.[7]

In *Therasense,* the district court held that Abbott's asserted patent, U.S. Patent No. 5,820,551 (the '551 patent) was unenforceable due to inequitable conduct based on a failure to disclose statements made to the European Patent Office (EPO).[8] Specifically, with respect to materiality the district court found that the statements to the EPO were highly material to the prosecution of the '551 patent because they contradicted representations made to the USPTO regarding U.S. Patent No. 4,545,382 (the '382 patent) used to reject the '551 patent during prosecution, where the representations to the USPTO led to the grant of the '551 patent.[9] With respect to intent, the district court further found that: (1) the representations made to the USPTO regarding the '382 patent were absolutely critical to overcoming the rejection of the claims of the '551 patent; (2) the EPO statements would have been very important to an examiner because they contradicted the representations made to the USPTO; (3) Abbott's lawyer knew of the EPO statements and consciously withheld them from the USPTO; (4) Abbott's lawyer did not provide a credible explanation for failing to submit the EPO statements to the USPTO; and (5) the explanations for failing to submit the EPO statements were so incredible that they suggested an intent to deceive the USPTO.[10] The Federal Circuit panel that heard the appeal affirmed the district court's holding of inequitable conduct, stating that the district court's findings were not erroneous, with one member of the panel dissenting.[11]

In granting the petition for *en banc* rehearing, the Federal Circuit asked the parties to brief the following issues:

> (1) Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
>
> (2) If the answer to (1) is yes, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?
>
> (3) What is the proper standard for materiality? What role should the USPTO's rules play in defining materiality? Should a finding of materiality require that, but for the alleged misconduct, one or more claims would not have issued?
>
> (4) Under what circumstances is it proper to infer intent from materiality?
>
> (5) Should the balancing inquiry (balancing materiality and intent) be abandoned?

(6) Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent law context.[12]

The issues raised by the Federal Circuit suggest that it may be preparing to significantly modify the inequitable conduct doctrine by limiting the contours of the inequitable doctrine. The Federal Circuit will likely focus on: (a) the proper standard for materiality; (b) the proper standard for intent and whether materiality can be used to infer intent; and (c) the role of the balancing inquiry, and the role of fraud and unclean hands, in determining inequitable conduct.

The issues raised by the Federal Circuit suggest that it may be preparing to significantly modify the inequitable conduct doctrine by limiting the contours of the inequitable doctrine.

Regarding materiality, the Federal Circuit has articulated four different standards. Information is material:

(1) when a reasonable examiner would have considered the material important in deciding whether to issue a patent;

(2) where, objectively, a patent would have not issued but for the withholding/disclosure of the information;

(3) when, subjectively, the examiner would not have issued the patent but for the withholding/disclosure of the information; and

(4) when it is not cumulative and it either establishes a *prima facie* case of unpatentablity or refutes a position the application has taken on patentability (i.e., the Rule 56[13] standard).[14]

The Federal Circuit may select one of the aforementioned standards as the proper standard for materiality.

Regarding the proper standard for intent and whether intent can be inferred from materiality, the Federal Circuit previously held, in *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988), that intent to deceive cannot be inferred solely from a failure to disclose a material reference. In other words, intent cannot be based on a finding of gross negligence, but must be based on a finding of sufficient culpability. However, subsequent decisions that have held that a finding of a high degree of materiality may result in a lowered requirement of proof of intent appear to allow an inference of intent based solely on a failure to disclose a material reference.[15] The Federal Circuit may attempt to return to the *Kingsdown* standard, articulating that intent is a separate requirement from materiality, that materiality can never substitute for intent and that intent can only be inferred when it is the single most reasonable inference.

Regarding the balancing inquiry and fraud/unclean hands, it has been noted that once a court makes the requisite findings of materiality and intent, it almost always makes a determination of inequitable conduct, thus rendering the patent unenforceable.[16] The Federal Circuit may emphasize that a finding of materiality and a finding of intent need not result in an inequitable conduct determination, emphasizing the balancing inquiry. If it does emphasize the balancing inquiry, the Federal Circuit may signal that, in certain cases, an inequitable conduct determination may not be warranted even in the presence of materiality and intent, and should be reserved for the most severe situations that involve fraud on the USPTO or unclean hands.

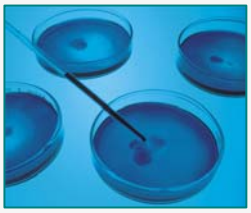
Whether the Federal Circuit clarifies existing standards for inequitable conduct or establishes new standards, *Therasense* is likely to be an important decision that will be scrutinized by lower courts in determining whether inequitable conduct has occurred. The patent community should, therefore, keep a close eye on *Therasense*.

Keith Mullervy, associate, Tysons Corner

1. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006).
2. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).
3. *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008).
4. *Id.*
5. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007).

6. *Purdue Pharma L.P. v. Endo Pharms., Inc.,* 438 F.3d 1123, 1128 (Fed. Cir. 2006).
7. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988).
8. *Therasense Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088, 1127 (N.D. Cal. 2008).
9. *Therasense*, 565. F. Supp. 2d at 1109-10.
10. *Therasense*, 565. F. Supp. 2d at 1113-16.
11. *Therasense Inc. v. Becton, Dickinson & Co.*, 2008-1511, -1512, -1513, -1514, -1595 (slip opinion, January 25, 2010).
12. *Therasense*, 2008-1511, -1512, -1513, -1514, -1595 (order, April 26, 2010).
13. 37 C.F.R. 1.56 Duty to disclose information material to patentability.
    …
    (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
    (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
    (2) It refutes, or is inconsistent with, a position that the applicant takes in:
    (i) Opposing an argument of unpatentability relied on by the Office; or
    (ii) Asserting an argument of patentability.
14. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003); *see also Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).
15. *See e.g., Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.,* 120 F.3d 1253, 1256-57 (Fed. Cir. 1997); *Ferring B.V. v. Barr Labs., Inc.,* 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Pfizer, Inc. v. Teva Pharms, USA, Inc.*, 518 F.3d 1353, 1366-67 (Fed. Cir. 2008).
16. *See* Brief for the United States as Amicus Curiae on Rehearing En Banc in Support of Neither Party at page 25.

A Look at The Biosimilar Act



The Biologics Price Competition and Innovation Act of 2009 ("Biosimilar Act") was signed into law by President Obama on March 23, 2010 as part of the Patient Protection and Affordable Care Act.[1] Some experts believe that biologics, such as vaccines, gene therapy drugs and recombinant therapeutic proteins, are the future of medicine, promising a new generation of life-saving drugs and a global market worth US$158 billion by 2015.[2]

FDA Review of a Biosimilar Drug

The Biosimilar Act established an abbreviated pathway for biologics shown to be "biosimilar" to or "interchangeable" with a licensed or an innovator's biologic. The abbreviated pathway for biologics was passed to encourage competition and reduce pricing by allowing the marketing of large molecule drugs without the extensive safety and efficacy testing normally required for new drugs.[3] Biologics pose special scientific challenges for abbreviated FDA review given their size, complex structure and sensitive manufacturing processes.[4]

The FDA standard for approval of a biologic is two-tiered – "biosimilar" and/or "interchangeable." To meet the baseline biosimilar standard of approval, the biosimilar applicant must show that the applicant's biologic is biosimilar to the innovator's biologic based on data derived from analytical, animal and clinical studies. The biosimilar applicant must also show that the biosimilar utilizes the same mechanism of action for conditions prescribed, that the conditions for use have been previously approved for the innovator's biologic, and that the route of administration, dose and strength are the same as the innovator's biologic.[5] This may be enough to get the biologic to market, but it may not be enough to make it competitive with the innovator's biologic since it might not be prescribed by hospitals or physicians over the brand named drug unless it meets the heightened interchangeability standard set in the new law.

To conclude that the biosimilar is interchangeable, the FDA must find that the biologic is biosimilar and that the biosimilar can be expected to produce the same clinical result in any patient as the innovator's biologic. In addition, the FDA must conclude that the risk in terms of safety or diminished efficacy of alternating between the biosimilar and the innovator's biologic is not greater than the risk of using the reference product without alternating or switching.[6] This standard may be very difficult to meet given the complexity of biologics and the uncertainties about related manufacturing processes.

Once found approvable under either standard, the biosimilar drug applicant must still wait 12 years from the time of the licensing of the innovator's biologic before marketing the biosimilar. This period of market exclusivity was at the long end of what Congress was debating when considering the legislation, with some members actually preferring no period of exclusivity and others up to 14 years.[7] On the other hand, the biosimilar drug manufacturer is granted a much shorter period of market exclusivity from other biosimilar competition for an interchangeable biosimilar (from one year to 42 months) based on the status of patent litigation pending between the biosimilar applicant and the innovator.[8]

Regardless of whether the biosimilar applicant discloses its own patent list, the applicant must still provide a detailed statement concerning the invalidity, unenforceability and noninfringement of the innovator's listed patents.

The Patent Resolution Process

The Biosimilar Act also established a not-so abbreviated pathway for resolution of patent disputes between the biosimilar applicant and the innovator of the biologic. Billed as streamlining the process for resolution of patent disputes, the patent provisions actually invite strategies by both sides that will likely lead to more protracted disputes than otherwise would have been the case if a simpler process would have been adopted.

This patent resolution process includes an extensive exchange of technical and patent information between the biosimilar applicant and the biologic innovator. Shortly after the FDA's acceptance of the biosimilar application, the biosimilar applicant must disclose the application to the innovator along with other information that describes the process used to manufacture the biosimilar.[9] This disclosure could promote "evergreening" of the innovator's patent portfolio to delay the entry of the biosimilar product even though the law contains some restrictions on the circulation of confidential information.[10] Shortly after the disclosure, the innovator must provide a list of patents believed to cover the biosimilar. And following shortly thereafter, the biosimilar applicant *may* disclose its own patent list where the biosimilar applicant believes that a reasonable infringement claim could be made.

Regardless of whether the biosimilar applicant discloses its own patent list, the applicant *must* still provide a detailed statement concerning the invalidity, unenforceability and noninfringement of the innovator's listed patents. The innovator must then provide a detailed counterstatement supporting the factual and legal basis that such patents will be infringed by marketing the biosimilar. Thus, prior to even filing suit, both parties must also essentially brief invalidity, infringement and unenforceability issues, apparently with the hope that one side or the other will see the light and curb patent litigation. The Biosimilar Act is silent on how and to what extent these requirements will be enforced. Apparently, enforcement is left to the courts since the FDA has no mandated legislative role in this process.[11]

The law also envisions a brief superficial patent negotiation period prior to the innovator filing (possibly multiple) patent infringement suits against the biosimilar applicant. The parties must engage in good faith negotiations for 15 days in an attempt to agree upon which patents should be licensed or litigated, but the Biosimilar Act does not authorize any supervision of these negotiations.

If the parties agree on the patents to be litigated, the patent infringement action can be filed within 30 days of that agreement. If the parties cannot agree on which patents to

litigate, they must simultaneously exchange a list of patents and those lists form the basis for the innovator's patent infringement case.[12] In these cases, the remedies are limited to a reasonable royalty.[13]

The Biosimilar Act also contemplates giving the innovator the opportunity to bring a preliminary injunction case against the biosimilar applicant based on the patents that were initially listed by either party but not included in the initial litigation. The preliminary injunction action can also include patents that were issued to the innovator following the required initial patent disclosure.[14] Thus, the innovator gets at least two opportunities to bring suit against the biosimilar applicant for patent infringement.

In addition, if the biosimilar applicant does not disclose its application to the innovator, then the innovator, not the biosimilar applicant, can bring a declaratory judgment action for infringement and may seek injunctive relief as well. The Biosimilar Act also provides for permanent injunctions against a biosimilar applicant in those cases where the biosimilar product has not been approved and there is a final, nonappealable court decision of infringement.

Conclusion

On November 2 and 3, 2010 an FDA panel held public hearings on the implementation of the Biosimilar Act. These two days of hearings were the FDA's first look at how to carry out the new law designed to establish an abbreviated pathway for biosimilar biologics.[15] Stakeholders expressed vastly different views on how the new law should be implemented. The FDA hearings showed just how difficult it is going to be to gain FDA approval for a biosimilar drug to advance the Biosimilar Act's lofty goals.

The Biosimilar Act also leaves open important questions about how patent litigation will be handled. The briefing of patent claims has the potential to bog down the process for determining which patents will be litigated even prior to any patent litigation. The enforcement mechanisms for these provisions are not described. The multi-tiered patent infringement actions may also add to the complexity of what is already recognized to be very complicated litigation. The Biosimilar Act is fraught with nuances and complexity that will likely occupy the FDA, the courts and all interested parties for many years.

Jerry Dodson, partner, San Francisco

1. 42 USC §262 (2010).
2. Global Industry Analysts' 2010 survey forecasts that "protein drug sales will be worth more than $158 bn (€122.6bn) by 2015 and expects therapeutic antibodies emerging as the market leader." In-Pharma Technologists.com (August 19, 2010).
3. The Biosimilar Act followed H.R. 5629 introduced by Rep. Eshoo (D. Calif.) who represents Silicon Valley where many biotech companies are located. See Cong. Record statement March 17, 2009 E 687-8.
4. The first FDA approval of a biologic for human use was human insulin in 1982, followed by human growth hormone in 1985, alpha interferon in 1986, tissue plasminogen activator in 1987 and erythropoietin in 1989. CRS Report RL34045 *FDA Regulation of Follow-on Biologics* by Judith A. Johnson (2009).
5. 42 USC §262(k)(2).
6. 42 USC §262(k)(4).
7. H.R. 1038 introduced by Rep. Waxman (D. Calif.) in the 110th Congress did not provide an exclusivity period for the innovator's biologic. On the other end, H.R. 1956 introduced by Rep. Inslee (D. Wa.) in the 110th Congress provided for a 14 year period of exclusivity.
8. 42 USC §262(k)(6).
9. 42 USC §262(l)(2).
10. *Id.*
11. According to FDA, patent procedures do not involve FDA and are not within the scope of its authority. Notice of Public Hearing on Approval Pathway for Biosimilar and Interchangeable Biological Products, p. 5 (2010).
12. 42 USC §262(l)(5).
13. 35 USC §271(e)(6).
14. 42 USC §262(l)(8).
15. Docket No. FDA-2010-N-0477, CDER 2010. Approved Pathway for Biosimilar and Interchangeable Biological Products; Public Hearing: Request for Comments. Pages 61497-61501 [FR Doc. 2010-24853].

Enhancing Appeals to the Board of Patent Appeals and Interferences (BPAI): Leveraging the New *Frye-Quist* Standard of Review

When patent applicants and patent examiners cannot reach an agreement about the patentability of an invention, applicants appeal to the Board of Patent Appeals and Interferences (BPAI) of the United States Patent and Trademark Office (USPTO). Recent binding decisions by the BPAI will affect strategies used in the course of future administrative appeals. In particular, the BPAI's decision in *In re Frye* (BPAI February 26, 2010) and its progeny *In re Quist* (BPAI June 2, 2010) demonstrate the need to plan ahead to present the strongest possible case for patentability.

The technology in *Frye* related to the fabrication of shoe soles. In particular, the slope of the sole, along the length of the foot (from the heel to the toe) was apparently the most significant feature. The key phrase of the claim to be construed was "substantially halfway." The BPAI reversed the examiner's rejection after taking the position that the examiner had not properly construed this claim limitation.

Although the merits of the decision in *Frye* may be of interest to those who manufacture shoes and those needing to determine what the term "substantially" means in patent claims, the most interesting aspect of the decision is the discussion of the standard of review and the appellate process. *Frye* indicated that the review of rejections process involves 1) the initial burden being on the examiner to set forth the basis for any rejection so as to put the patent applicant on notice for the reasons why the applicant is not entitled to a patent on the claim scope he seeks; 2) the presentation of a "*prima facie* case" shifting the burden of going forward to the applicant to produce evidence or argument rebutting the case of unpatentability; 3) after applicant's reply, the determination by the examiner of patentability on the totality of the record, by a preponderance of the evidence with due consideration; and 4) review by the BPAI of adverse decisions of examiners, based on the written appeal of the applicant.

Examiner's Burden

This notice requirement was intended by the BPAI in *Frye* to correspond with what is termed a *prima facie* case. However, a *prima facie* case must do more than merely place the applicant on notice regarding the reasons why the applicant is not entitled to a patent on the claim scope sought. It must, as the USPTO's Manual of Patent Examining Procedure (MPEP) explains, provide a "clear articulation of the reason(s)" why the claimed invention either is anticipated or would have been obvious (MPEP 2142). So, while the notice requirement might sound like a more minimal standard than the standard set forth in *In re Oetiker,* 24 USPQ2d 1443 (Fed. Cir. 1992), the BPAI apparently intended this merely to serve as a summary. The court in *Oetiker* emphasized that "[i]f examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *Oetiker* at 1444. This remains the standard at the initial stage of examination.

Burden Shifts to Applicant

In this phase, the applicant can simply identify logical or factual errors in the examiner's rejection, or the applicant can identify new evidence (such as affidavit evidence) that the examiner did not have during the initial phase of examination.

Patentability Determination and Appeal

At least in theory, the examiner's determination of patentability following the applicant's reply is based on a preponderance of the evidence with due consideration of the totality of the record. Often, applicants still do not agree with the examiner's conclusions. The next step is a written appeal by the applicant leading to the BPAI's review of the adverse decision of the examiner. As in the response to the examiner's attempt to provide a *prima facie* case, the applicant can submit evidence or arguments. The purpose of these submissions is to show that there is either an error in factual premise or an error in reasoning used to reach a

legal conclusion of unpatentability. A panel of the BPAI then reviews the examiner's decision in light of all the evidence and arguments within the appellate record.

[U]nless the appellant provides "some argument or evidence" against a contention the examiner made in rejecting the claims, the BPAI does not have the burden of reviewing that contention.

It is this step of BPAI review that is of particular interest. The key point that the BPAI wanted to emphasize was that the filing of an appeal does not *itself* entitle the appellant to a *de novo* review of all aspects of a rejection. Indeed, the BPAI will not normally decide the merits of any issues not raised by the appellant.

In short, unless the appellant provides "some argument or evidence" against a contention the examiner made in rejecting the claims, the BPAI does not have the burden of reviewing that contention, but instead can take those contentions as though they were admitted and arguments against that contention as waived, meaning that such arguments cannot be raised at a later stage.

Quist takes this procedural question a step further. In *Quist*, a panel of the BPAI had rendered a decision on an appeal. The appellant submitted a Request for Rehearing asking the BPAI to reconsider its original decision. The Request sought, in particular, review of the decision of the original panel by an expanded panel of the BPAI. The appellant's Request specifically identified alleged errors in the decision of the panel and requested that the expanded panel rectify these errors.

The expanded panel noted that the appellant had made a new argument regarding advantages of the invention in the Request for Rehearing. The expanded panel indicated that these alleged advantages would not be considered because the scope of review was limited to errors made by the original panel, and the original panel could not have erred by failing to consider advantages that had not previously been raised.

In both cases, the BPAI relied, at least in part, on the Federal Circuit's decision in *Hyatt v. Dudas*, 551 F.3d 1307 (Fed. Cir. 2008). *Hyatt* had two main aspects – one relating to the issue of what constitutes new grounds of rejection (a point very helpful to appellants) and one relating to waiver. The BPAI seems to be interpreting *Hyatt* as supporting broad concepts of waiver, whereas *Hyatt* was actually interpreting a rule (37 CFR 1.192(a)) that has since been removed. This broad concept of waiver suggests that panels of the BPAI will increasingly attempt to limit any new arguments raised late in the appellate process – not only in requests for rehearing, but even in reply briefs.

The practical conclusion in view of *Frye* and *Quist*, therefore, is that appellants should raise all of their arguments, including arguments regarding advantages of the invention, at the earliest possible opportunity in the appeal. In other words, the appeal brief should identify – as comprehensively as possible – all the errors in the examiner's rejection, and should traverse with arguments or evidence every point of the rejections that appellants do not wish to have taken as admitted. Be prepared with the new standard, and present at least a colorable argument against every portion of each rejection for which you want *de novo* review. Disfavored, however, are the strategies of reserving one's arguments for rebuttal purposes, or holding back advantages as a tool for rebutting conclusions of obviousness reached by a panel of the BPAI.

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Supreme Court to Review Standard for Inducing Infringement

We reported in our Spring 2010 Intellectual Property Update on the Federal Circuit's decision in *SEB S.A. v. Montgomery Ward & Co., Inc*.[1] There, the Federal Circuit lowered the threshold for establishing inducing infringement by holding that a patentee may succeed on an inducement claim even where it adduces only *indirect* evidence that the accused infringer actually knew of the patent-in-suit.[2] The court ruled that one of several accused infringers, Pentalpha Enterprises Ltd., induced infringement when it "deliberately ignored the possibility" that another company already held a patent for a cool-touch deep fryer. The court said the company had acted with "deliberate indifference of a known risk."[3]

Pentalpha petitioned the US Supreme Court for *certiorari*, arguing that the Federal Circuit incorrectly failed to apply the "purposeful, culpable expression and conduct" standard from the Supreme Court's 2005 decision in *MGM v. Grokster*.[4] Although *Grokster* was a copyright infringement case, the Court's opinion "borrowed" inducement concepts from patent law in reaching its conclusions. Pentalpha likewise borrowed from *Grokster*, submitting that the same "purposeful, culpable expression and conduct" should apply to inducing patent infringement, and that a contrary result would lead to a sweeping expansion of induced infringement liability. The Supreme Court granted Pentalpha's petition on October 12, 2010, setting the stage for a showdown in 2011 that promises to help further define the parameters of inducing infringement claims.

Christopher D. Mays, associate, Palo Alto
David S. Elkins, partner, Palo Alto

1. 594 F.3d 1360 (Fed. Cir. 2010).
2. *Id.* at 1376-78.
3. *Id.*
4. 545 US 913, 937 (2005).

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Alicia M. Choi focuses her practice on the area of patent law. Her work includes preparing and prosecuting utility patent applications in the areas of electrical and computer engineering including information technology, software systems, wireless communication, medical diagnostic devices, semiconductors, analog and digital circuitry, and consumer electronics such as optical storage media and audio devices for US and international clients. Her experience also includes conducting novelty, patentability, invalidity and infringement analyses for various electrical devices and systems. Before entering the practice of law, Ms. Choi was a lead engineer for Rockwell Automation where she was involved in the integration of various programmable controllers and electronic operators.

Jerry Dodson is one of the most highly regarded patent trial lawyers in the United States. Mr. Dodson has represented businesses in a wide range of industries including biotechnology, medical devices, optical, and electronic hardware and software. Since first entering private practice more than 20 years ago, Mr. Dodson's practice has focused on intellectual property issues, specifically patent litigation. With his engineering degree, he is able to direct both the litigation and technical aspects of cases. Before entering private practice, Mr. Dodson served as Chief Counsel for the Health and Environment Subcommittee in the US House of Representatives, with the Solicitor's Office in the US Department of the Interior and as Assistant County Solicitor for Allegheny County, Pennsylvania.

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Peter Flanagan focuses his practice on intellectual property matters. He has assisted clients in patent prosecution as well as in intellectual property litigation, including patent and copyright litigation. Mr. Flanagan has counseled clients regarding intellectual property portfolios and has helped clients analyze infringement and validity of US patents. He has prosecuted hundreds of patent applications in a broad spectrum of technologies, including computer hardware and software, control systems, communications systems, power electronics, electrochemical devices, semiconductors, mechanical systems, industrial systems and medical devices.

Kate E. Kim focuses her practice on corporate matters, particularly mergers and acquisitions. She represents buyers and sellers with stock and asset acquisitions and divestitures, mergers, joint ventures, strategic alliances and similar transactions. Ms. Kim has worked with clients in medical diagnostics, pharmaceuticals, electronic components manufacturing, and other industries including real estate, and information and communications technology. She also advises clients on US litigation and international arbitration matters. Ms. Kim has represented clients in general commercial, securities, intellectual property, insurance and complex construction litigation cases.

Christopher D. Mays is a registered patent attorney focusing his practice on intellectual property and complex commercial litigation. Mr. Mays has experience in high technology disputes concerning patent infringement. While in law school, Mr. Mays competed in numerous advocacy competitions including the Carr Mock Trial, where he was a semifinalist, and the King Hall Negotiations competition. Mr. Mays is a member of the American Bar Association, the American Intellectual Property Law Association, and the San Francisco Intellectual Property Law Association.

Keith Mullervy focuses his practice on intellectual property matters with a focus on patent prosecution. His experience includes patent preparation and prosecution in several technologies including wireless communication systems, computer software, automotive systems, robotics, mechanical systems, imaging systems and radiation detection systems. Prior to law school, Mr. Mullervy worked in the information technology industry as a software developer and systems analyst for several consulting companies.

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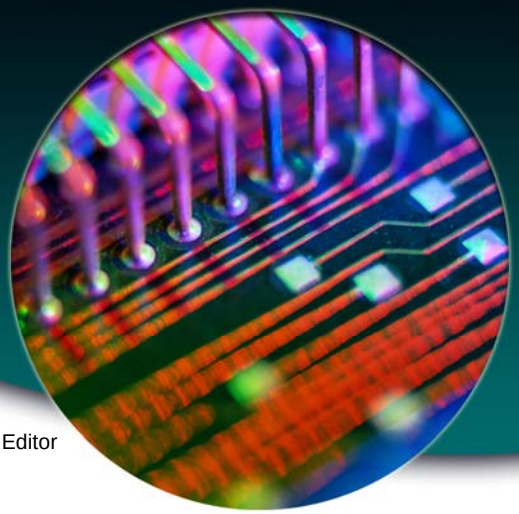

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