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Note from the Editors

It was a busy fall for IP law, thanks in part to the Federal Circuit's ruling in *In re Bilski* (click on the case name to read our analysis). With patent law getting so much attention lately, we wanted to make sure this edition of the newsletter covered some important developments in copyright and trademark law. We first assess the effects of the Supreme Court's decision in *eBay v. MercExchange* on copyright cases. Next, we take a look at trademark enforcement, which got a boost from Congress and the president with the October signing of the Prioritizing Resources and Organization for Intellectual Property Act. Not to neglect the ever-changing landscape of patent jurisprudence, we include articles on the Federal Circuit's findings in *Broadcom v. Qualcomm* and *Proveris v. InnovaSystems*. In the *Broadcom* article, we discuss the relevance of opinions of counsel to showing intent for inducement. For life sciences companies, the Federal Circuit's ruling in *Proveris* applies new guidance on infringement in the area of research tool patents. Finally, our recurring section on reexaminations discusses the protection

from patent infringement offered by intervening rights.

We hope you find this edition of the *IP Newsletter* informative. As always, we will continue to monitor the latest developments in IP law and make sure to keep our clients and readers updated with analysis of current events. ■

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Peter Davis, Managing Editor
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M. Andrew Woodmansee, Managing Editor

Amy Beckman, Contributing Editor
Jacqueline Charlesworth, Contributing Editor
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Jennifer Lee Taylor, Contributing Editor

Bidding for a Copyright Injunction After *eBay*

By Jacqueline Charlesworth

The Supreme Court's 2006 decision in *eBay Inc. v. MercExchange* addressed the standard for permanent injunctive relief to prevent future infringement of a business-method patent for an electronic marketplace. In *eBay*, the Court rejected the presumption in favor of granting a permanent injunction upon a finding of patent infringement and held that a court's decision whether to grant or deny such relief is "an act of equitable discretion." The Court then set forth a traditional four-factor test for courts to follow when considering permanent injunctive relief in the patent context, requiring a plaintiff to demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." Notably, in reaching its decision, the Court drew a parallel between the rights of a

patent owner and those of a copyright owner, observing that the Court has "consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed."

On remand, in ruling on *MercExchange's* renewed motion for permanent injunctive relief, the *eBay* district court interpreted the Supreme Court's directive as having significance beyond a mere equitable checklist. In the view of the district court, the Supreme Court's holding also meant that courts can no longer presume the critical factor of irreparable harm simply because there has been a determination of infringement. Accordingly, with respect to the irreparable harm prong of the *eBay* test, the district court determined that the burden was on the plaintiff to prove irreparable injury through "case-specific facts."

The effects of *eBay* are being felt in the copyright world. Following the *eBay* decision, the majority of courts

considering a motion for a permanent injunction upon a finding of copyright infringement have applied *eBay's* four-factor test to reject the assertion that a plaintiff is automatically entitled to injunctive relief upon a showing of infringement. Moreover, it appears that at least some courts are following the lead of the *eBay* district court in denying the presumption of irreparable harm that has typically governed in copyright cases when considering the question of permanent injunctive relief. Thus, plaintiffs seeking permanent injunctive relief for copyright infringement should be well prepared to demonstrate the four *eBay* factors, including how irreparable harm will result absent the requested relief.

Because *eBay* addressed the propriety of a permanent injunction, its relevance in the context of a motion for *preliminary* injunctive relief is less clear. Rather than adhering to the specific factors set forth in *eBay*, the majority of courts appear to be invoking the existing balancing test of their circuit when considering preliminary injunctions in copyright

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cases. This may be because existing preliminary injunction standards already incorporate equitable considerations, including, typically, consideration of irreparable injury, among other factors. Traditionally, the factor of irreparable harm has been presumed at the preliminary injunction stage based upon an initial showing of infringement. *eBay*, however, has caused some courts to question whether such a presumption still properly applies. *eBay* does not answer this question; as one court has noted, the issue remains to be “clarified.” Another court has suggested that *eBay* is inapposite in the preliminary relief context, opining that “[a] presumption temporarily removing the need to prove irreparable harm may serve the ends of equity.” In short, while a plaintiff seeking preliminary injunctive relief in a post-*eBay* copyright infringement action may still benefit from the traditional presumption, in light of the uncertainty surrounding the issue, he or she should be ready to make the case for irreparable harm. ■

New Law Expected to Add Teeth to Current Counterfeiting Laws

By Jennifer Lee Taylor and Ted Hasse

Recognizing that the increase in willful violations of U.S. counterfeiting laws pose a serious threat to the economy, both chambers of Congress finally passed the Prioritizing Resources and Organization for Intellectual Property Act (“the PRO IP Act”). The bill has had the strong support of IP owners from the beginning, but was not without criticism from those who have viewed it as pandering to the recording industry as it continues its efforts to stop peer to peer file sharing. Nevertheless, after several modifications, it passed with bipartisan support in both the House and the Senate, including a unanimous vote in the Senate. The bill will enhance remedies for willful trademark counterfeiting, enhance civil and criminal penalties for counterfeiters, provide more funding and personnel for federal and state enforcement, and establish a new cabinet-level IP enforcement coordinator who will report directly to the president and Congress. The bill was signed by President Bush on October 13, 2008.

The PRO IP Act has several components that should help brand owners as outlined below.

ENHANCED CIVIL AND CRIMINAL REMEDIES

Under the PRO IP Act, not only will counterfeiting be more dangerous, with the specter of 20 years in prison for certain instances of counterfeiting, it will also be more costly for those caught in run-of-the-mill counterfeiting of the types of items that one commonly finds sold on street corners, outside of sporting events, and over the Internet, such as fashion accessories, eyewear, personal care products, consumer electronics, software, and music.

First, when intentional trademark counterfeiting is established, actual damages will automatically be trebled, absent extenuating circumstances. This is in addition to recovering reasonable attorneys’ fees, as permitted under current law. For those trademark owners who elect to rely on statutory damages instead of actual damages, the PRO IP Act doubles the maximum statutory damages available for willful trademark counterfeiting

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from \$1 million to \$2 million, as well as for non-willful counterfeiting from \$100,000 to \$200,000. These increases in statutory damages is expected to result in more efforts by trademark owners to enforce their rights in civil actions, at least for those counterfeiters who have significant assets against which a judgment could be enforced.

Second, the PRO IP Act doubles the maximum period of imprisonment from ten years to twenty years for certain counterfeiting activities.

These activities include “trafficking” in counterfeit trademark goods and “knowingly or recklessly” causing bodily injury. If the counterfeit goods resulted in a death, the counterfeiter could face life in prison.

These enhanced remedies have been sorely needed to address the increasing numbers of counterfeit pharmaceutical products that are available over the Internet.

Third, criminal forfeiture laws against counterfeiters will be toughened. In addition to allowing for the confiscation and destruction of counterfeit and infringing goods,

the PRO IP Act will permit the confiscation and destruction of property used to “to commit or facilitate” such acts — a provision likely to be used to facilitate the seizure of computer systems and computer equipment that are being used to counterfeit products and digital content. These new forfeiture laws go further still, mirroring harsh penalties for drug dealing in the U.S., by allowing for seizure of property “derived from any proceeds” obtained through counterfeiting activities. That can mean the seizure of cash, investment assets, business property, real estate, homes, and even automobiles.

ENHANCED LAW ENFORCEMENT

Recognizing that there are a number of government agencies that have roles in protecting and enforcing IP rights, the PRO IP Act will establish the cabinet-level position of an Intellectual Property Enforcement Coordinator (“IPEC”), an IP Czar of sorts, a high-profile federal position. The IPEC will be appointed by the president, with Senate confirmation, and will report directly to the president and Congress. The IPEC will chair a new interagency IP enforcement committee comprised of Senate-confirmed representatives from a

number of departments and agencies including: The Department of Homeland Security, the Department of Justice, the Department of State, U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, the Food and Drug Administration, the U.S. Patent and Trademark Office, the U.S. Copyright Office, and a number of other federal agencies.

The primary function of this committee will be to develop a “joint strategic plan” to fight counterfeiting and piracy, with the joint strategic plan focusing on seven issues: (i) reducing domestic and international counterfeiting, (ii) streamlining enforcement, (iii) coordinating information sharing between agencies, (iv) taking down known counterfeiting networks, (v) assisting other nations in enforcing IP rights, (vi) working with other countries to establish international standards for protecting IP rights, and (vii) constructing processes for consulting with industry. It is hoped that if a process is developed for the federal government to partner with industry in fighting counterfeiting and piracy, the combined efforts will be more successful than under current law.

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The establishment of the IPEC position is the most controversial provision remaining in the PRO IP Act, and some commentators have speculated that it could draw a veto from President Bush. The administration does not object to increasing the protection of IP rights in the U.S.; instead, it objects to the creation of a cabinet-level position on the grounds that this would create an “unnecessary bureaucracy.” Given the overwhelming bi-partisan support enjoyed by the PRO-IP Act, it is thought that if the bill is vetoed by President Bush, Congress will be able to override the veto.

Moreover, the PRO IP Act will provide more money and personnel to federal agencies for criminal IP enforcement, including more FBI agents, more federal prosecutors, and a \$10,000,000 increase in funding for both the Department of Justice and the FBI. In addition to enhanced efforts at the federal level, the PRO IP Act also provides the Department of Justice with \$25 million a year to distribute in grants to state and local law enforcement agencies for

increased enforcement efforts against IP infringers.

EXPANDING THE FIGHT GLOBALLY

The PRO IP Act ambitiously looks beyond U.S. borders as well, to target IP issues internationally. In addition to the international enforcement efforts

The PRO IP Act ambitiously looks beyond U.S. borders as well, to target IP issues internationally.

assigned to the IPEC, the PRO IP Act calls for the United States Attorney General to establish an Organized Crime Task Force for investigating and prosecuting international IP crime syndicates. Congress states in the bill that “terrorists and organized crime utilize piracy, counterfeiting, and infringement to fund some of their activities,” and declares that “the Attorney General shall give priority to cases with a nexus to terrorism and organized crime.”

The United States is not alone in its fight. The changes in U.S. counterfeiting laws are mirrored, to some extent, by a new anti-

counterfeiting plan that is being launched in the European Union, following approval by the European Union ministers on September 26, 2008. The new EU anti-counterfeiting plan will improve coordination and information exchange between different agencies (from each of the 27 member countries), in an effort to reduce large and small-scale counterfeiting. With the increased focus on counterfeiting and piracy in both the U.S. and the EU, perhaps brand owners can look forward to a day when they are no longer required to spend substantial resources fighting to keep counterfeit products off the streets.

PREPARING FOR THE PRO IP ACT

The PRO IP Act can provide immediate benefits to brand owners, including the ability to seek up to two times the statutory damages that are available under current laws in civil actions. However, as under current laws, civil penalties for counterfeiting are only available for properly registered trademarks and copyrights. If they want to be in a position to take advantage of the enhanced penalties available under the PRO IP Act, IP owners should take a look at their IP portfolio now to make sure that their most important rights are properly registered and can be enforced. ■

Intervening Rights: Protection from Liability After Reexamination

By Robert Saltzberg and Amy Beckman

INTRODUCTION

In response to a request by either a patentee or another interested party, the USPTO will reexamine an issued patent in light of prior art that creates a “substantial new question of patentability” compared to issues considered during the original examination. Accused infringers in patent litigation are increasingly requesting reexaminations of asserted patents, recognizing reexamination as a relatively low-cost, potentially high-impact adjunct to a lawsuit. A similar procedure, “reissue,” allows a patentee to apply for a reissued patent based upon an error made during the original prosecution, including the patentee claiming more or less than he or she had a right to claim.

Reexamination may result in changes to the claims, but may not broaden claim scope. By contrast, a reissue allows the patentee to not only narrow claims (as in reexamination), but to broaden claims as well if the reissue application is filed within two years of the issue date of the original patent. Under either post-issuance procedure, a claim amendment¹ may impose an undue hardship on an infringer of the reexamined or reissued claim where the infringer relied upon the scope of the original claim in

attempting to avoid infringement of the original patent. To account for this hardship, “absolute” and “equitable” intervening rights are available to protect infringers from liability where claims are substantially changed during reexamination or reissue.²

ABSOLUTE INTERVENING RIGHTS: PROTECTION FROM PAST LIABILITY AND DAMAGES

“Absolute” intervening rights provide an accused infringer the right to *use or sell* a product that was *made, used, or purchased before* the grant of the reexamination certificate, as long as such activity did not infringe a claim of the reexamined patent that was in the original patent. *See* 35 U.S.C. §§ 252, 307(b). If a claim is amended during reexamination and the amendment substantively changed the claim, then absolute intervening rights apply. An absolute intervening right only protects products that have already been made when the reexamination certificate is granted, and does not extend to infringing processes or methods. Thus, an infringer may sell off existing inventory of a product that infringes the reexamined patent claims without incurring liability for past damages.

Of course, if the original claims survive reexamination intact, then a product

that infringes a reexamined patent claim necessarily infringed a claim of the original patent. In that event, damages are generally measured from the issue date of the original patent, with the infringer liable for damages incurred both before and after reexamination.

EQUITABLE INTERVENING RIGHTS: PROTECTION FROM FUTURE LIABILITY AND DAMAGES

Absolute intervening rights do not apply to infringing activity that occurs after the reexamination certificate is issued. However, “equitable” intervening rights may protect alleged infringers from liability for future infringing conduct.

Equitable intervening rights may provide for the continued manufacture, use, or sale of additional products covered by the reexamined patent when the defendant made, purchased, or used identical products, or made substantial preparations to make, use, or sell identical products, before the date of issuance of the reexamined claims. *See* 35 U.S.C. §§ 252, 307(b). Equitable intervening rights are potentially much broader than absolute intervening rights, but the former are discretionary. A court may provide for equitable intervening rights to protect

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Intervening Rights

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investments made before the grant of a reexamination certificate, including the continuation of infringing activity after such time.

The application of equitable intervening rights to reexamination and narrowing reissues is not clear. Equitable rights are more common in cases where claims have been broadened during reissue. In such cases, an infringer of the reissued claim may not have infringed the narrower original claim, leading to an unfair result if the infringer were held liable from the time of the original claim's issuance. The same inequity arguably does not arise when an amendment or added claim results in a *narrower* claim than in the original patent, as would be the case in reexamination.³ Thus, a court may be reluctant to grant equitable intervening rights for an activity that infringes reexamined claims.

Fashioning Equitable Remedies

In *Seattle Box*,⁴ a case involving a reissued patent, the Federal Circuit outlined three basic options that are available to fashion a remedy once the doctrine of equitable intervening rights has been raised. The court may (1) confine the infringer to the use of those infringing items already in existence; (2) permit the infringer to continue in

business under conditions that limit the amount, type, or geographical location of its activities; or (3) permit the infringer to continue in business unconditionally.

Generally, the goal of a court is to craft a remedy that would allow the infringing party to recoup its investment. As summarized in a district court decision,⁵ various factors may be considered in determining whether equitable intervening rights are appropriate, including whether:

1. Substantial preparation was made before the reissue;
2. The infringer continued manufacturing before reissue on advice of its patent counsel;
3. There were existing orders or contracts;
4. Noninfringing goods can be manufactured from the inventory used to manufacture the infringing product and the cost of conversion;
5. There was a long period of sales before the patent reissued for which damages cannot be assessed;
6. The infringer has made profits sufficient to cover its investment; and
7. The claims have been narrowed or broadened by amendment.

CONCLUSION

A patentee may amend claims or add new, narrower claims to avoid prior art raised during reexamination, yet still cover the accused product. Even

if reexamination does not result in invalidation of all infringed claims, intervening rights may provide at least some protection to an accused infringer with respect to added or amended claims. Moreover, even if equitable intervening rights do not apply, absolute intervening rights may be valuable, especially for cutting off past damages on a patent that is nearing expiration.

Any claim-narrowing must be supported by subject matter disclosed in the patent specification. With this in mind and an understanding of intervening rights, experienced patent counsel can consider potential amendments that might be made during reexamination, and assess whether and to what extent intervening rights may apply. ■

¹ This discussion of amended claims in reexamination also generally applies to new claims added during reexamination, which would be narrower in scope than any original claim. An amended or new claim is impermissibly broad if it covers any subject matter that would not have infringed the original patent (again noting the exception for broadening reissues filed within two years of a patent's issuance).

² Because of the similarities between reexamination and reissue proceedings, similar rules apply. While this article focuses on reexamination, the law of reissue will be referenced where that law is more well-defined.

³ However, one can imagine that even a narrowed claim may impose an undue hardship on an infringer. For example, the infringer could have manufactured a product that infringed the original patent in reliance upon an invalidity opinion finding the relatively broader claims of the original patent to be invalid over prior art; the narrowing during reexamination or reissue may avoid such prior art.

⁴ *Seattle Box Co. v. Industrial Crating & Packaging, Inc.*, 731 F.2d 818, 827-28 (Fed. Cir. 1984).

⁵ *Thayer v. Nydigger*, 1999 U.S. Dist. LEXIS 5886, at *34 (D. Or. Apr. 15, 1999).

Opinions of Counsel Ride Again: Federal Circuit Finds Opinions Relevant to Intent for Induced Infringement in *Broadcom v. Qualcomm*

By Elizabeth Richardson

As the Federal Circuit reaffirmed in *Seagate*,¹ opinions of counsel are not required to fend off allegations of willful infringement.² But in *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683 (Fed. Cir. 2008), the Federal Circuit recently held that such opinions *are* relevant to intent to induce infringement under 35 U.S.C. § 271(b).

Because inducement and willfulness both require intent, there is some overlap in relevant evidence as well as jurisprudence between these two issues. But in separate *en banc* opinions in the last couple of years, the Federal Circuit has adopted different quanta of intent necessary to establish inducement and willfulness. In *DSU*,³ the court required proof of “specific intent” to induce infringement, including knowledge of the patent; mere knowledge of another’s acts subsequently found to constitute direct infringement were deemed insufficient.⁴ Although the court noted that the alleged inducer in *DSU* had obtained non-infringement opinions as part of the evidence considered by the jury, which returned a verdict of no inducement, the Federal

Circuit did not directly discuss the role of opinion of counsel evidence in *DSU*.

In contrast, the *Seagate* court subsequently held that “proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness.”⁵ And the

that there is no affirmative obligation to obtain opinion of counsel.”⁷

Broadcom, a panel opinion by Judge Linn, was the first decision from the Federal Circuit to explore the potential implications of *Seagate* for inducement. In the *Broadcom* case, alleged

Although the court noted that the alleged inducer in *DSU* had obtained non-infringement opinions as part of the evidence considered by the jury, which returned a verdict of no inducement, the Federal Circuit did not directly discuss the role of opinion of counsel evidence in *DSU*.

Seagate court reiterated its holding from *Knorr-Bremse*⁶ that a failure to obtain an opinion of counsel, or invocation of the attorney-client privilege or work-product protection to avoid disclosure of such an opinion, does not create an adverse inference with respect to willfulness. According to the Federal Circuit in *Seagate*: “Because we abandon the affirmative duty of due care, we also reemphasize

inducer Qualcomm argued that *DSU*’s “specific intent” standard for inducement is “stricter” than *Seagate*’s “objective recklessness” requirement for willfulness. Qualcomm also argued that evidence (like opinions of counsel) that is not relevant for willfulness cannot be relevant for intent to induce. The *Broadcom* panel disagreed:

“Although Qualcomm is correct that there is no affirmative duty to

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seek opinion of counsel regarding infringement, and that it is improper to allow an ‘adverse inference or evidentiary presumption that such an opinion would have been unfavorable,’ *Knorr-Bremse*, 383 F.3d at 1346, it is incorrect in arguing that *Seagate* altered the state of mind requirement for inducement. Our *en banc* holding in *DSU* remains the relevant authority on that point. Despite Qualcomm’s assertion that the intent standard for inducement is higher than that for willful infringement, a lack of culpability for willful infringement does not compel a finding of non-infringement under an inducement theory.”⁸

Although this passage does not fully address the rationale for the tension between *DSU* and *Seagate* identified by Qualcomm, the court unequivocally decreed that *DSU*, not *Seagate*, establishes the parameters for assessing inducement. Discussing the admissibility of circumstantial evidence to establish intent to induce direct infringement, the *Broadcom* court concluded:

“Because opinion-of-counsel evidence, along with other factors, may reflect

whether the accused infringer ‘knew or should have known’ that its actions would cause another to directly infringe, we hold that such evidence

So while a jury may not draw an adverse inference as to willful infringement from the absence of an opinion of counsel, following *Broadcom* a jury may infer intent to induce infringement from the same gap in the evidence.

remains relevant to the second prong of the intent analysis.”⁹

“[T]he failure to procure such an opinion may be probative of intent in this context. It would be manifestly unfair to allow opinion-of-counsel evidence to serve an exculpatory function, as was the case in *DSU* itself, *see* 471 F.3d at 1307, and yet not permit patentees to identify failures to procure such

advice as circumstantial evidence of intent to infringe.”¹⁰

Like the alleged inducer in *DSU*, Qualcomm obtained opinions of counsel (though regarding invalidity rather than non-infringement). Unlike *DSU*, Qualcomm chose not to waive the attorney-client privilege as to those opinions, so they were unsurprisingly excluded from trial.¹¹ So while a jury may not draw an adverse inference as to willful infringement from the absence of an opinion of counsel, following *Broadcom* a jury may infer intent to induce infringement from the same gap in the evidence. Thus, in the post-*Seagate* world, opinions of counsel remain an important shield for those with potential exposure to allegations of induced infringement. ■

¹ *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

² *Id.* at 1371.

³ *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc in relevant part).

⁴ *See id.* at 1305-06.

⁵ *Seagate*, 497 F.3d at 1371.

⁶ *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-45 (Fed. Cir. 2004) (en banc).

⁷ *Seagate*, 497 F.3d at 1371.

⁸ *Broadcom*, 543 F.3d at 699.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *See id.* at 700.

Research Tool Patents: A Light At The End Of The Tunnel?

By Katherine Nolan-Stevaux, Ph.D.

In *Merck KGa v. Integra Life Sciences I, Ltd.*, the Supreme Court held that the safe harbor under 35 U.S.C. § 271(e) (1) extended to the use of patented compounds in pre-clinical studies, provided there is a reasonable belief that the experiments would provide information relevant for submission to the F.D.A.¹ However, the Court declined to reach the question of whether infringement of so-called “research tool” patents would also fall within this safe harbor. The Federal Circuit’s recent decision in *Proveris Scientific Corp. v. InnovaSystems, Inc.* suggests that life sciences companies holding research tool patents need not fear that competitors may infringe them with impunity.²

Research tools are reagents or methods that are useful in conducting experiments but are not diagnostic or therapeutic products or commercial scale production processes themselves. Common research tools may include cell lines, transgenic animals, particular DNA or protein sequences, libraries of chemicals, DNAs, or proteins, or even databases and software.

In *Proveris*, the Federal Circuit was faced with the question of whether an accused infringer’s activity fell within the 271(e)(1) safe harbor where the patent at issue concerned a device to test drugs for FDA regulatory submissions. Thus, unlike in *Merck*, where the patented item was used as a control in experiments submitted to the FDA, Innova manufactured the patented item for others to use to obtain data for FDA submissions. Innova’s product is a research tool as it was designed to help analyze other therapeutics.

In deciding *Proveris*, the Federal Circuit articulated a new, more stringent standard for determining when the safe harbor applies. The court anchored this standard in the relationship between the Federal Food, Drug, and Cosmetic Act (“FDCA”) and the Hatch-Waxman Act in which the safe harbor is found. According to the Federal Circuit, the Hatch-Waxman Act aimed to correct two distortions in the FDCA: First, FDA review of drugs precluded patentees from generating profits early in the patent term. Second, because of

The Federal Circuit’s recent decision in *Proveris Scientific Corp. v. InnovaSystems, Inc.* suggests that life sciences companies holding research tool patents need not fear that competitors may infringe them with impunity.²

FDA pre-market approval, the effective patent term was lengthened because competitors could only start obtaining FDA approval once the patent term was over. Section 156 of Hatch-Waxman provides for patent term extensions due regulatory delays, addressing the first distortion. Section 271(e)(1) sought to eliminate “de facto” patent term extension by

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immunizing competitors' activities "reasonably related" to FDA submissions to enable competitors to prepare for market entry upon expiry of the patent.

For the safe harbor provision, the key terms are "patented invention" and "reasonably related."³ The Supreme Court had already determined that "patented inventions" as used in Section 271(e)(1) were limited to drugs, medical devices, food additives, and color additives—i.e., substances for which FDA approval was necessary—and relied on the dual distortions of the FDCA in so ruling.⁴ This definition preserves the relationship between the two sections in rectifying the distortions of the FDCA. For "reasonably related," the Federal Circuit relied on the *Merck v. Integra* decision and the Federal Circuit's 2007 opinion on remand from the Supreme Court.⁵ The Supreme Court held that "reasonably related" encompassed activities where a party reasonably believed that a patented compound might work through a specific process to produce a specific result and used the compound in research that would be submitted to the FDA, if successful. On

remand, the Federal Circuit concluded that preclinical activities were reasonably related to FDA submissions.

In *Proveris*, Innova's activities did not qualify for the safe harbor because the patent was not a patented invention under sections 156 and 271(e)(1) and because use of the patented device was never subject to FDA approval and never qualified for patent term extension. Innova's device was not a drug, medical device, or a food or color additive. Further, it was never submitted to the FDA for approval and accordingly, the Federal Circuit found, is not eligible for safe-harbor relief.

For research tool patent holders, the key question is whether research tool patents that aren't "patented inventions" within sections 156 and 271(e)(1) may still be infringed by products that are subject to FDA approval and patent term extension. Because of the Federal Circuit's emphasis on how the two sections (156 and 271) work together to prevent distortions caused by regulatory review, the safe bet would say that if one component is missing, then the safe harbor doesn't exist. In other words, if the patent at issue is entitled to patent term extension, but the use of the patent is not reasonably related to FDA submissions, then the safe harbor will not apply. Similarly, if

On remand, the Federal Circuit concluded that preclinical activities were reasonably related to FDA submissions.

the patent is not eligible for term extension, but the accused products are submitted for FDA review, then the safe harbor should not apply either. Until this issue is actually before the Federal Circuit, life sciences companies should tread carefully during drug development. It may be a wiser approach to license a competitor's research tools than risk a finding that the safe harbor did not apply to your drug development activities once you've got a product ready to launch. ■

¹ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005).

² *Proveris Scientific Corp. v. InnovaSystems, Inc.*, -- F.3d --, No. 2007-1428, 2008 WL 29671000 (Fed. Cir. Aug. 5, 2008).

³ Section 271(e)(1) provides a shield for making, using, offering to sell, or selling in the U.S. "a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

⁴ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 672-674 (1990).

⁵ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1348 (Fed. Cir. 2007).

Intellectual Property Practice News

AWARDS AND ACCOLADES

Morrison & Foerster's Intellectual Property practice continues to garner awards and top rankings. In the most recent **Managing Intellectual Property** rankings of IP groups, Morrison & Foerster was ranked as having the fourth largest IP practice in the U.S., with 249 lawyers devoting at least 75% of their time to IP work.

GC California magazine honored our IP practice in a number of categories in its inaugural annual survey of in-house counsel. We ranked #1 in the categories of IP Transactions (Except Patent) and Licensing Transactions, and #2 in IP Litigation (Except Patent). The firm ranked highly in a number of other categories, including #2 rankings in Business Savvy and Bet-the-Company Litigation.

Fourteen lawyers from the IP practice's U.S. offices were named by their peers to the **2009 Best Lawyers in America Directory**. Best Lawyers in America listings represent 79 specialties in all 50 states and Washington, D.C., and are compiled through an exhaustive peer-review survey, in which thousands of the top lawyers in the United States anonymously evaluate their

professional peers. The 14 Morrison & Foerster IP lawyers are:

- Charles Barquist, Los Angeles
- Peng Chen, San Diego
- Thomas Ciotti, Palo Alto
- David Doyle, San Diego
- Paul Goldstein, San Francisco
- Michael Jacobs, San Francisco
- Rachel Krevans, San Francisco
- Jack Londen, San Francisco/Tokyo
- Harold McElhinny, San Francisco
- Gladys Monroy, Palo Alto
- Kate Murashige, San Diego
- James Pooley, Palo Alto
- Rory Radding, New York
- Mark Wicker, San Diego

FROM THE DOCKET

Our IP trial lawyers racked up resounding plaintiff and defense wins for several technology clients in recent months. Some of our biggest victories came in key venues, such as the Eastern District of Texas and the International Trade Commission.

Respondents Beat Tessera's Patent Infringement Claims in the ITC

Morrison & Foerster represents respondent Flash memory companies Spansion, Inc., and its affiliate in a closely watched ITC patent suit

filed by Tessera Technology, Inc. On December 1, after a full trial on the merits, the Administrative Law Judge presiding over the case issued an initial determination that Spansion and the other respondents did not violate Section 337 of the Tariff Act because Tessera's patents were not infringed. This tremendous victory for the respondents is the first decision that we know of that has been adverse to Tessera and the patents it has widely licensed and asserted against the semiconductor industry.

The Washington, D.C. team was led by partners **Alexander Hadjis** and **Kristen Yohannan**, with assistance from Of Counsel **Chip Terrill** and **Michael Maas**, and associates **Matthew Vlissides**, **Robert Giles**, **Yan Wang**, **Paul Kletzly**, **Nabila Isa-Odidi**, and **Alex Haliasos**.

Walt Disney Wins Summary Judgment and Sanction Awards

To win a patent case is great. To win and recover attorneys' fees is even better. That's what Morrison & Foerster did for Walt Disney Co. against Triune Star, Inc., which filed a patent infringement suit in 2007 against Disney and several other

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defendants in the Central District of Illinois. The case involved infrared camera technology for cell phones. In late November, Judge Michael Mihm of the Central District of Illinois granted summary judgment in favor of the defendants, finding Triune's assertions did not "pass the red face test" and that there was no literal infringement of Triune's patent. Referring to the plaintiff's case as "frivolous," Judge Mihm also granted the defendants' motion for Rule 11 sanctions, concluding that the plaintiff filed a case unwarranted in fact and law.

San Francisco partner **Michael Jacobs** and Of Counsel **Grant Kim** led the winning team for Disney.

East Texas Jury Awards Pioneer \$60 Million

Morrison & Foerster secured a major victory in October for Pioneer Corporation in a patent infringement suit against Samsung Electronics Co., Ltd., and its affiliates. After an eight-day trial, and only four hours of deliberation, a jury in the Eastern District of Texas decided three Samsung entities had willfully infringed the patents in

suit and awarded \$59.3 million in compensatory damages to Pioneer. We are now seeking enhanced damages due to the jury's conclusion that the infringement was willful. Filed in the fall of 2006, the suit asserted that plasma televisions manufactured by Samsung infringed two plasma display technology patents held by Pioneer.

In a press release announcing the outcome of the trial, Pioneer stated: "This significant decision in favor of Pioneer represents recognition of the strength of Pioneer's intellectual property rights in the field of plasma displays."

The winning team was led by **Harold McElhinny** (San Francisco office), **Karen Hagberg** (New York office), and **Andrew Monach** (San Francisco office) with assistance from partners **Peter Stern** (Tokyo office) and **Taro Isshiki** (Tokyo office), Of Counsel **Sherman Kahn** (New York office), and associate **Kyle Mooney** (New York office).

Victory for Funai in the ITC

In November, Morrison & Foerster secured a victory for Funai Electric Co., Ltd., and its affiliate, Funai Corporation, Inc. (collectively "Funai"), in a patent infringement case against 14 manufacturers and importers of digital televisions and other related products. An

Administrative Law Judge of the ITC issued an Initial Determination concluding that accused digital televisions of Vizio, TPV, Amtran, Proview, Syntax-Brilliant, and other respondents infringe asserted claims of one of Funai Electric's U.S. patents. The Administrative Law Judge has recommended the full ITC grant a limited exclusion order barring importation of the infringing products into the United States, as well as a cease and desist order to prevent sale or distribution of such infringing products in the United States.

The Morrison & Foerster winning team was led by partner **Karl Kramer** (Palo Alto office), with assistance from partners **Harold McElhinny** (San Francisco office), **Hector Gallegos** (Los Angeles office), **Brian Busey** (Washington, D.C. office), **Louise Stoupe** (Tokyo office), **Moto Araki** (Tokyo office), **Nicole Smith**, **Mark Danis** (Tokyo office), and **Anthony Press** (Los Angeles office).

Favorable Settlement Reached for Veeco in Nanotechnology Patent Dispute

In August, Morrison & Foerster client Veeco Instruments, Inc., announced it had settled the patent infringement case it had brought against Asylum Research Corporation in 2003. Veeco is the world leader in atomic force and scanning probe microscopy, with

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an installed base of more than 8,000 systems at university and research/nanotechnology centers worldwide.

In this lawsuit, Veeco alleged that the manufacture, use, and sale of Asylum's MFP-3D atomic force microscope constituted infringement of Veeco patents. As part of the terms of the settlement, Veeco and Asylum agreed to drop all pending claims against each other and to enter a five-year, worldwide cross-license of each company's patents and a mutual covenant not to sue on patents either party has a right to assert. Asylum will make a net payment plus an ongoing

royalty to Veeco for the five-year term of the cross license.

John R. Peeler, chief executive officer of Veeco, commented, "We are pleased to have reached this favorable settlement with Asylum that values our technology and validates our patents. Veeco has invested tens of millions of dollars in intellectual property and research and development for AFM technology, and this investment has helped us to bring the best AFM products to the marketplace. This settlement is a significant milestone for our employees, customers and shareholders, and we will continue to protect our valuable intellectual property, as necessary, in the future."

The winning team was led by partner **Charles Barquist** (Los Angeles office), along with partners **Eric Acker**

(San Diego office), **Mehran Arjomand** (Los Angeles office), and **Laurie Hane** (San Francisco office). ■

"This settlement is a significant milestone for our employees, customers and shareholders, and we will continue to protect our valuable intellectual property, as necessary, in the future."

About Morrison & Foerster's Intellectual Property Practice

Morrison & Foerster maintains one of the largest and most active intellectual property practices in the world. The IP practice provides the full spectrum of IP services, including litigation and alternative dispute resolution, representation in patent and trademark prosecution, and business and licensing transactions. Morrison & Foerster's IP practice has the distinguishing ability to efficiently and effectively handle issues of any complexity, in any venue, involving any technology. For more information about the IP practice, please visit www.mofo.com.

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