

The Federal Circuit has reaffirmed its decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, holding that 35 U.S.C. § 112 contains a requirement for separate and distinct written descriptions and enablement in patent applications.

Written description and enablement were identified by the Federal Circuit as separate and distinct requirements to patent applications in *Regents of the University of California v. Eli Lilly & Co.* in 1997. Until the *Ariad v. Eli Lilly* decision, however, there was some uncertainty of how generally applicable the *University of California v. Lilly* decision was in the eyes of the Federal Circuit.

Federal Circuit reaffirms separate enablement and written description requirements

Ariad v. Eli Lilly deals with a patent held by Ariad that relates to a method of inhibiting the activity of NF-kB, which is a naturally occurring protein involved in the regulation of immune responses. The patent is based on the discovery that interfering with this protein can reduce the symptoms of certain diseases; the patent was intended to cover methods (e.g., administering pharmaceuticals) that inhibit this protein.

In 2002, Ariad alleged that Evista® and Xigris®, two of Eli Lilly's pharmaceutical products, infringed on this patent. A jury ruled in favor of Ariad. On appeal however, the Federal Circuit reversed the jury's verdict, citing a lack of adequate written description in Ariad's patent. Ariad's request for a rehearing *en banc* was granted, during which the full court confirmed the panel decision that Ariad's patent claims were invalid for lack of written description, stating, "Every patent must describe an invention ... The

specification must then, of course, describe how to make and use the invention (e.g., enable it), but that is a different task."

"What the patent did not do is fulfill the written description requirement, which involves describing the specific invention with the same breadth that its claims cover," says John Conklin, a member in Leydig's Chicago office.

The panel stated that the case "illustrates the problem of generic claims," pointing out that Ariad's patent included claims on "methods encompassing a genus of materials achieving a stated useful result," but did not describe the species used to achieve that result.

"The court is attempting to discourage overly generic patents that lay claim to broad ideas – methods relating to whole families of chemical compounds, for example – but fail to describe specific inventions or ways to commercialize these ideas," says David Airan, a member in Leydig's Chicago office.

"The idea that enablement and a separate written description are required for a patent is nothing new," adds Conklin. "*Ariad v. Eli Lilly* serves as a reminder to patent holders, applicants, and those facing infringement suits that broad claims in well-written patent applications should include references to alternative embodiments, in addition to detailed descriptions of enabling embodiments. By routinely taking the extra step to reference alternative embodiments in your patent applications, you will create a higher-quality patent portfolio."

Considering this ruling in litigation situations is equally important.

"Clients who are initiating or facing patent infringement litigation must work with their attorneys to take a good look at the patents in question and ask whether the claims are fully supported by description and enablement," says Airan. "If not, patent holders may want to rethink litigation, and accused infringers may want to consider this as an element of their defense."

Federal Circuit's revision of *i4i v. Microsoft* decision readdresses finding of willfulness

The decision earlier this year by the U.S. Court of Appeals for the Federal Circuit in *i4i v. Microsoft Corp.* has provided clarification on issues related to evidentiary bases for findings of willful infringement and enhanced damages.

The Federal Circuit upheld an earlier judgment in the case, which awarded \$290 million in damages to *i4i* for a patent upon which a jury found Microsoft Corp. had infringed; the Federal Circuit issued a separate order, however, that allowed for panel rehearing, in which the panel readdressed issues of willfulness and enhanced damages in a revised decision.

In 2009, *i4i v. Microsoft* drew widespread attention, and some questioned whether the damage award was disproportionate to the usage of the patented technology and its contribution to the infringing

product. The patent in question was related to customization of extended markup language, or XML, “an obscure functionality” within Word software.

In its appeal, Microsoft questioned the rationale behind the enhanced damages award based on the finding of willfulness, not the jury’s willfulness verdict itself; the Federal Circuit argued that these are two distinct issues. The Federal Circuit therefore did not assess whether the jury’s finding of willful infringement was supported by evidence and instead only addressed whether the district court abused its discretion in awarding enhanced damages. The Federal Circuit affirmed the district court’s application of the nine factors set forth in *Read Corp. v. Portec, Inc.* in deciding whether to enhance damages once the finding of willfulness had been made.

In the revised panel decision, the Federal Circuit went on to say that even

if Microsoft’s appeal could be interpreted as an attack on the jury’s verdict, the original finding of willfulness would not be reversed, as “*i4i* presented sufficient evidence at trial to prove each prong of the *Seagate* standard for willfulness.” In *Re Seagate Technologies* established that a patentee must prove that the infringer “acted despite an objectively high likelihood that its actions constituted infringement,” and that the infringer knew or should have known of that infringement to establish willfulness.

“This case reinforces the two distinct standards related to willfulness: The nine factors set forth in *Read Corp. v. Portec, Inc.* should be used to enhance damages, while the jury must consider the *Seagate* standard when deciding on a willfulness verdict,” said Robert Wittmann, a member in Leydig’s Chicago office.

Federal judge raises the bar on e-discovery practices

Federal Judge Shira Scheindlin of the Southern District of New York has issued an amended order in the case of *The Pension Committee of the University of Montreal Pension Plan, et al. v. Banc of America Securities, LLC, et al.*, which sets strict standards for electronic discovery conduct.

Judge Scheindlin sanctioned the plaintiffs on the grounds of negligence and gross negligence due to failed preservation and search efforts for electronically stored information.

The judge’s original opinion covers two important points. First, “Failure to adhere to contemporary standards (of discovery duty) can be considered gross negligence.” A related opinion – *Zubulake* (2004) – established these duties as: issuing written litigation holds; identifying the key players and relevant

former employees and preserving their electronic and paper records; ceasing the deletion of e-mail; and preserving backup tapes when litigation is “reasonably anticipated.”

Second, the “pure heart, empty head” argument – long used by those accused of intentional misconduct – is not a viable defense as, “The standards (of acceptable conduct) have been set by years of judicial decisions.”

The judge’s amended order specifies that backup tapes need only be preserved “when they are the sole source of relevant information or when they relate to key players, if the relevant information maintained by those players is not obtainable from readily accessible sources.”

“This opinion recognizes that there are practical limits to e-discovery and

that parties will not be held to a standard of perfection,” says Michael Hartmann, a member of Leydig’s Chicago office.

“Still, given the ever-increasing volume of electronic documents, a litigant bears a heavy burden and must be very careful with the information.”

E-discovery has become an increasingly hot topic in recent years. The Northern District of Illinois created the Electronic Discovery Committee and Pilot Program to “incentivize the early and informal information exchange” and set standards for e-discovery conduct. Judges volunteered to implement the principles outlined in the program and the committee recently issued its report on phase one, which is now available online at www.7thcircuitbar.org.

Federal Circuit to review inequitable conduct doctrine through rehearing in *Therasense v. Becton*

The Federal Circuit recently granted an *en banc* rehearing in *Therasense, Inc. (Abbott) v. Becton, Dickinson and Co.*, through which many expect the court to perform a sweeping review of issues related to the law of inequitable conduct in the examination of patent applications.

The inequitable conduct issues in this case relate to a patent for glucose monitoring test strips owned by Abbott, which purchased Therasense in 2004. The district court found Abbott's patents unenforceable because the U.S. Patent and Trademark Office had not been informed of statements made to the European Patent Office during the examination of a related European patent that the court deemed to be material to the U.S. examination process.

On appeal, the Federal Circuit reaffirmed the district court's finding, with a dissenting opinion from Judge Richard Linn, who questioned the validity of the majority's rulings on intent and materiality. Abbott was granted a rehearing *en banc* based on its assertion that the inequitable conduct doctrine should be reformed to alleviate confusion on intent and materiality. The Federal Circuit has requested that the following considerations be addressed in new briefings:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the standard for unclean hands?
3. What is the proper standard for materiality? What role should the

United States Patent and Trademark Office'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 been 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 context.

As of press time, briefs have been filed and a decision from the court is expected within the next few months. Leydig will update its clients on this matter as new developments unfold.

Federal Circuit case deems photos not required for Web-based specimens

In its recent decision, *In Re Sones*, the Federal Circuit held that a picture of an identified product is not a mandatory requirement for a Web-based specimen of use in a trademark application.

Michael Sones originally filed a trademark application for the mark "ONE NATION UNDER GOD" used in connection with charity bracelets. As a specimen of use, Sones submitted a printout of a Web page that featured the trademark, a written description of the product, an "Add to cart" button, and a box that said, "Photo not available." The U.S. Patent and Trademark Office (PTO) rejected the specimen because it did not feature a picture of the product and denied Sones' application.

Sones appealed to the Trademark Trial and Appeal Board (TTAB), which sided with the PTO, citing the

decision in *Lands' End Inc. v. Manbeck*, interpreted by the PTO to mean that examining attorneys should accept a catalog or similar specimen provided that it includes a picture of the relevant goods, a mark sufficiently near the picture to associate the mark with the goods, and the information necessary to order the goods.

Sones appealed the TTAB decision to the Federal Circuit, which ruled that specimens of use taken from websites need *not* always contain pictures of goods because the *Lands' End* decision itself did not impose the three-part test set forth by the PTO, and the Lanham Act does not establish specific requirements for demonstrating the use of the mark. The Federal Circuit therefore held that the test for a website-based specimen, "just as any other specimen, is simply that it

must in some way evince that the mark is 'associated' with the goods and serves as an indicator of source."

The PTO will reconsider Sones' application, based on the court's decision, and is expected to accept the specimen of use and register the trademark.

"While this ruling grants some flexibility in regard to Web-based specimens, it remains to be seen how the somewhat-vague language of the decision will be interpreted," says Boris Umansky, an associate in Leydig's Chicago office.

Caroline Stevens, a member in Leydig's Seattle office, adds, "From a practical standpoint, we still recommend that a Web-based specimen include the mark, ordering information, and a picture of the goods to avoid the costs of responding to a refusal or preparing a substitute specimen."

Leydig announces

Leydig, Voit & Mayer has been recognized as the “Patent Prosecution Firm of the Year” in the Midwest by *Managing Intellectual Property*™ magazine. Accepting the award on behalf of the firm were members **John Belz** (Washington, D.C.) and **Xavier Pillai** (Chicago) on April 15, at the North American awards ceremony held at The Four Seasons Hotel in Washington, D.C.

“Leydig is honored to have been selected as the Patent Prosecution Firm of the Year in the Midwest,” says **H. Michael Hartmann**, president of the firm. “This recognition of the firm’s longstanding excellence in patent prosecution is particularly gratifying.”

Leydig, Voit & Mayer was recognized as one of the leading life sciences patent litigation law firms in Illinois in a survey published in the May/June 2010 issue of *Intellectual Asset Management (IAM)* magazine.

In addition, two of Leydig’s attorneys have been identified among the world’s leading life sciences patent litigators. **Robert F. Green** and **John Kilyk Jr.**, members in the firm’s Chicago office, were recognized in *Intellectual Asset Management (IAM)* magazine’s supplement, “IAM Life Sciences 250 – A Guide to the World’s Leading Life Sciences Patent Litigators,” published May 2010.

Contact us:

Chicago
Two Prudential Plaza
Suite 4900
Chicago, IL 60601
312/616-5600

Seattle
1420 Fifth Avenue
Suite 3670
Seattle, WA 98101
206/428-3100

Frankfurt am Main
Liebigstrasse 51
60323 Frankfurt am Main
Germany
+49 (0) 69 713 7798 0

Washington, D.C.
700 Thirteenth St. N.W.
Suite 300
Washington, D.C. 20005
202/737-6770

Rockford
6815 Weaver Road
Suite 300
Rockford, IL 61114
815/963-7661

Editors: Charles Mottier, John Augustyn,
Eley Thompson, Kevin Parks, Caroline Stevens

Editorial/Design: The Simons Group
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