KIRKLAND & ELLIS

INTELLECTUAL PROPERTY

BIOTECH IP UPDATE

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SPRING 2002

Festo II: Supreme Court Unanimously Rejects the Complete Bar Rule of Prosecution History Estoppel

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The Supreme Court, in its anxiously awaited decision in the Festo case, unanimously rejected the Federal Circuit's key holding below and thus largely restored the boundaries of prosecution history estoppel to pre-Festo status. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 122 S.Ct. 1831 (2002). The decision addressed two holdings from below:

- The Supreme Court agreed "that a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel," in contrast to only amendments made to avoid the prior art[1]; and
- The Supreme Court rejected the Federal Circuit's "controversial" holding that "[w]hen estoppel applies, it stands as a complete bar against any claim of equivalence for the element that was amended."[2] Instead, the Court reaffirmed the "flexible bar" approach that considers what scope of equivalents the patentee surrendered.

The Court further held "that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question."[3] Because it did not have a sufficient record to decide the issues in the Festo case itself, the Court vacated the Federal Circuit's judgment and remanded for further proceedings.

Festo marks the second time in five years that the Supreme Court has addressed prosecution history estoppel and the doctrine of equivalents. The doctrine of equivalents allows a patentee to argue that a process or composition which does not literally meet one or more claim limitations nonetheless infringes because it contains elements that differ only "insubstantially" from the claim. Prosecution history estoppel limits this expansion of the claims, precluding protection under the doctrine of equivalents for subject matter given up in the back and forth with the patent office in order to obtain issuance of the patent. As the Court explained:

> When the patentee responds to the rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent.[4]

The Supreme Court unanimously rejected the Federal Circuit's key holding below and thus largely restored the boundaries of prosecution history estoppel to pre-Festo status.

In its November 2000 en banc Festo ruling, the Federal Circuit held that the doctrine of equivalents was completely unavailable for any claim limitation whose scope had been narrowed by amendment for purposes of patentability. The Supreme Court unanimously rejected this holding. The Court cited with approval Judge Michel's dissenting opinion below that the Federal Circuit's "absolute bar" rule was contrary to eight Supreme Court decisions and more than 50 decisions of the Federal Circuit, and stated the Federal Circuit had "ignored the guidance" of the Supreme Court's

most recent doctrine of equivalents decision, Warner-Jenkinson v. Hilton Davis Chemical Co., 520 U.S. 17 (1997). Reiterating Warner-Jenkinson's recognition that "patent prosecution occurs in the light of our case law," the Court found the absolute bar rule unjustified because "[i]nventors who amended their claims under the previous regime had no reason to believe they were conceding all equivalents."[5] Furthermore, the Court reiterated its Warner-Jenkinson holding that the doctrine of equivalents is a "firmly entrenched part of the settled rights protected by the patent" and that if there is to be a significant change in the doctrine, Congress – not the courts – should make such a change.[6]

[The Supreme] Court reiterated that the doctrine of equivalents is a "firmly entrenched part of the settled rights protected by the patent" . . .

The Court, however, has placed several burdens of proof squarely on the patentee who claims equivalence to a narrowed claim limitation. First, unless the patentee proves that the amendment was not made for purposes of patentability, prosecution history estoppel presumptively applies to that limitation. Any reason relating to patentability creates an estoppel, regardless of whether the applicant intended to surrender the subject matter, so long as the amendment does, in fact, narrow the scope of the claim limitation. Second, to avoid the presumption of estoppel, the patentee must demonstrate that the amendment does not surrender the particular equivalent in question. In order to meet this burden, the "patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."[7] The Court specified three ways to show this:

> [1] The equivalent may have been unforeseeable at the time of the application; [2] the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or [3] there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.[8]

The Court emphasized that the imperfect nature of language necessitates the doctrine of equivalents, but "[p]rosecution history may rebut the inference that a thing not described was indescribable."[9]

While the patentee has the burden to show that there should be no estoppel, it seems that the analysis is still a matter for the court, not the jury. Nothing in Festo upsets the position that prosecution history estoppel is an issue of law to be determined by the court.

In the 18 months since the Federal Circuit decided Festo, the complete bar rule has played a role in numerous patent cases involving the doctrine of equivalents. The Supreme Court's Festo decision throws into question past rulings relying on the complete bar rule. Many such cases may have to be revisited in order to determine whether prosecution history estoppel applies in the absence of the short-lived complete bar rule now rejected by the Supreme Court.

Relying on Patent Opinions of Counsel – Waive the Privilege Goodbye?

Marcus E. Sernel

Defending against an allegation of willful patent infringement has always been a delicate problem for an accused infringer. To rebut the allegation, accused infringers often rely on an opinion of counsel in an attempt to show they had a good faith belief that they had "freedom to operate" despite the patentee's rights. But this reliance on an opinion of counsel is not without a price, as it effects a waiver of the attorney-client and work product privileges that otherwise shield the opinion and any underlying communications. The accused infringers thus face the choice between a rock and a hard place: they must either (1) rely on the opinion, and live with the privilege waiver that accompanies this reliance; or (2) not rely on the opinion, and have to otherwise disprove the willfulness of any infringement while facing an inference that any withheld opinion was inculpatory. Facing this dilemma, accused infringers have usually chosen to rely on their opinion of counsel and deal with the waiver of privilege that results. But the price of relying on an opinion of counsel may have just gone up.

A recent decision from the District of Delaware has established a new high-water mark for the breadth of the waiver that is associated with the reliance on an opinion of counsel. Judge Joseph Farnan's opinion in Novartis Pharmaceuticals Corp. v. Eon Labs Mfg., Inc., 206 F.R.D. 396 (D. Del. 2002), while acknowledging the prior range of case precedent, charts a new course for determining the

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scope of waiver, and demands the attention of in-house counsel and outside litigators alike. The Novartis decision holds that the waiver should be considered "absolute" and "unlimited" and extend to anything that the opinion counsel or his law firm considered on the subject matter of the opinion. But while the language of the opinion is attention-getting, prudent measures can be taken to avoid having a broad privilege waiver pierce the privileged communications of litigation counsel as well.

Judge Farnan suggests that a different starting point is appropriate, one that focuses on the infringer's decision to waive the attorney-client privilege in the first place.

Previous court holdings have varied in the scope of waiver, but have generally followed one of two schools of thought. The first line of cases has focused on the importance of the client's state of mind, finding a waiver only for those documents that have been communicated by the opinion counsel to the client.[1] A second line of cases has found a broader waiver, requiring production of documents that the opinion counsel considered in forming the opinion, whether these documents had been provided to the client or not.[2] Most courts have further extended the waiver to include other privileged documents on the same subject matter, requiring production of other opinions or communications relating to the subject (e.g., non-infringement or invalidity) of the opinion that is relied on.

Though the Novartis decision starts by discussing two District of Delaware cases that reflect the differing schools of thought on the scope-of-waiver issue, it ultimately turns away from their analysis and their focus on the infringer's state of mind as the starting point for assessing the scope of waiver. Instead, Judge Farnan suggests that a different starting point is appropriate, one that focuses on the infringer's decision to waive the attorney-client privilege in the first place. Noting that waiver is defined as "the voluntary, intentional relinquishment of a known right," Judge Farnan explains that the waiver should be considered "absolute" such that "**everything** with respect to the subject matter of counsel's advice is discoverable."[3] The opinion goes on to explain that it is not only the state of mind of the infringer, but also the mind of the infringer's lawyer, that can bear relevant evidence on the willful infringement question. Thus, Judge Farnan held that the waiver should be "considered unlimited" and "apply broadly to any and all materials available to the attorneys rendering the legal advice."[4]

The court found not only a waiver with respect to materials reviewed by the attorney preparing the opinion, but the waiver extended to **anyone associated with the preparing attorney's law firm**. Noting that the defendants had chosen "the unconventional and risky arrangement of having opinion and trial counsel from the same law firm," the court granted plaintiffs' motion for production to the extent it sought all legal advice received by the defendants from the opinion counsel's law firm regarding the subject matter of the opinion. The statement on this point is without qualification, and seemingly might require production of defense counsel's trial strategy and case assessment materials insofar as they relate to the subject matter of the opinion. While logically it seems that there must be some limit to the waiver — lest it obliterate the litigation privilege altogether — the opinion in Novartis does not draw the outer boundary.

Given the broad scope of the waiver he finds, Judge Farnan's opinion acknowledges that "an alleged infringer could incur undue prejudice as a result of the scope of discovery required" and indicates "the Court will consider separating the issues of willfulness and damages from the other patent issues."[5] While bifurcation might delay the dilemma that infringers face, it does not avoid the broad waiver that would ultimately be found under the reasoning in Novartis. Moreover, despite the Federal Circuit's invitation to consider bifurcating the infringement and willful infringement issues in a patent case,[6] most courts have been reluctant to do so because of concerns that it would be inefficient.[7]

. . . the defendants had chosen "the unconventional and risky arrangement of having opinion and trial counsel from the same law firm."

So now the real issue — how does the Novartis opinion change your handling of opinions of counsel and defenses to charges of willful infringement? Although most patent opinions never see the light of litigation, and it is still uncertain whether other courts will adopt the views of Judge Farnan in Novartis, prudent counsel should most assuredly have opinions prepared with the broad privilege waiver of Novartis in mind. At the very least, corporations should retain opinion counsel and trial counsel from separate firms, and should treat them as separate entities having separate functions. At bottom, the opinion counsel must be — and must be treated as — a truly independent evaluator and should not be included in privileged communications discussing litigation strategy. While the Novartis case should not drastically change the approach of the prudent corporation or its counsel regarding patent opinions and good-faith reliance on them, it is a threat to the unsuspecting litigant that does not separate the opinion counsel and trial counsel functions.

Written Description Doctrine of Eli Lilly Reaffirmed, Perhaps Extended

Kenneth H. Bridges

More than five years ago, the Federal Circuit expanded the written description inquiry for at least DNA-based inventions in Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997). There has since been appellate silence regarding the scope and impact of that holding. That silence was broken on April 2, 2002 by the split-panel decision in Enzo Biochem, Inc. v. Gen-Probe, Inc., 285 F.3d 1013 (Fed. Cir. 2002) (hereafter, "Enzo II"),[1] which reaffirmed, and perhaps extended, the Lilly holding. A heightened written description hurdle for at least some types of biotechnology patents may be here to stay.

Enzo sued several companies under a patent directed at nucleic acid probes for detecting the bacterium Neisseria gonorrhoeae. False positives were apparently a problem in prior tests for N. gonorrhoeae because another bacterium, Neisseria meningitidis, has between 80 and 93 percent genetic homology with N. gonorrhoeae. Enzo researchers created three different nucleic acid probes with much higher binding affinity for N. gonorrhoeae than N. meningitidis. Enzo's patent claimed selective hybridization probes in the language of differential hybridization:

> 1. A composition of matter that is specific for Neisseria gonorrhoeae comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater than about five ….

The specification of the patent did not contain sequence information for any of the three reported probes, although it stated that the probes were deposited at the American Type Culture Collection. The specification likewise gave no sequence information for any part of the genome of N. gonorrhoeae. However, the specification discussed the claimed probes and gave their approximate length, in addition to stating that they had been deposited in the ATCC.

The Enzo II majority decision reaffirms the decision in Eli Lilly, holding that a description in terms of function is not permissible . . .

Judge Lourie, author of the Eli Lilly decision, joined by Judge Prost, relied upon Lilly and held that the patent lacked a written description of the three asserted claims, thus invalidating all three. Judge Dyk filed a lengthy dissent.

The Enzo II majority decision reaffirms the decision in Eli Lilly, holding that a description in terms of function does not satisfy the written description requirement of the patent law: "A description of what the genetic material does, rather than of what it is, does not suffice."[2] In his dissent, Judge Dyk criticized this ruling, arguing that the description of the claimed probes in terms of hybridization affinities was not merely functional. He argued that a well-known rule informs one of the structure of a probe if one is told with what it does and does not hybridize: "The degree of hybridization between a probe and a target depends on the degree of complementarity [A-T and G-C pairing] between the chemical structure [of] the probe and the target."[3]

. . . biological deposits are not a part of the specification and thus do not count for written description purposes.

In the majority's view, however, without a disclosure of the sequence of the genomic DNA to which the probes hybridize, there could be no "calculation" of the sequence of the probes. It would thus appear that, to claim genetic material, it is necessary to provide information as to the sequence of the material to be claimed.

Despite language in prior opinions, the Court held that the written description requirement is not satisfied merely by informing one of ordinary skill in the art that the patentee was in possession of the invention. The Court held that an ipsis verbis recitation of the claimed subject matter in the specification is not necessarily sufficient. Because of the apparent position that DNA sequences cannot be described by anything less than their sequence, merely reciting "a DNA sequence coding for X" in the specification is not sufficient support for a claim to "a DNA sequence coding for X." Put simply, the written description requirement of Enzo II is a substantive inquiry for a description of the items in a claim. Written description may not be satisfied by merely finding terms in the specification parroting the claim language.

Enzo II further states that biological deposits are not a part of the specification and thus do not count for written description purposes.[4] While Enzo had reduced to practice and deposited three DNA probes – and said so in the specification – this was of no avail to the patentee. The

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court deemed it irrelevant to the written description analysis that it would require only routine work for one of ordinary skill to sequence the deposited probes. It was dispositive to the written description inquiry that the sequence was not set forth in the specification itself.[5] Standing alone, this is a significant holding. Deposit of biological materials may have previously seemed like a simple way to adequately describe a particular material. The examination guidelines set forth by the PTO might have been read to reinforce such a belief.[6] Under Enzo II, however, that is not the law. Only time will tell how many patents and patent applications filed prior to this decision have relied, at least in part, upon biological deposits in an attempt to satisfy the written description rquirement.[7]

Judge Dyk's dissent criticized the Eli Lilly decision as "imposing a unique written description requirement" and therefore being "open to serious question."[8] Even assuming Lilly applied, however, he argued that Lilly did not sanction the majority's decision. Judge Dyk would not demand sequence information when functionality sufficiently delineates the claimed probes.

Conclusion

Given the potential impact of Enzo II and the fact at least one judge (Dyk) thinks both Eli Lilly and Enzo II are flawed, it seems unlikely that the Enzo II majority will be the last word on written description or deposited materials. Only time will tell whether the Federal Circuit, or even the Supreme Court, will reverse, undermine or strengthen Enzo II. For now, however, Enzo II is the law. Patent drafters must include as much descriptive information as possible in a patent application in an attempt to support claims to some actual sequence information.

Caveat Emptor for the Patent Licensee and Sublicensee: Rhone-Poulenc, S.A. v. DeKalb Genetics Corp.

Kal K. Shah

The explosion of the biotech industry has been attributable in no small part to the availability of licenses to a wide range of basic technologies. The importance of thorough due diligence and appropriate contractual protections in such licenses, including adequate representations, warranties, and indemnification, was recently underscored by Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 284 F.3d 1323 (Fed. Cir. 2002). The Federal Circuit ruled that bona fide non-exclusive licensees and sublicensees of a patent are not shielded from infringement suits where their licensor fraudulently obtained the "right" to license.

In 1998, the Federal Circuit had ruled that a patent licensee could be protected as a bona fide purchaser for value. Heidelberg Harris, Inc. v. Loebach, 145 F.3d 1454 (Fed. Cir. 1998). Heidelberg was the exclusive patent licensee of the former employer of plaintiff Michael Loebach. But Loebach claimed that his former employer had fraudulently obtained assignment of the patent from him and, thus, the license to Heidelberg was invalid. Loebach therefore sued both his former employer and Heidelberg for patent infringement. The Federal Circuit first recognized the general equitable principle that:

> [O]ne who acquires an interest in a patent for valuable consideration from the legal title holder, without notice of an outstanding equitable claim or title is entitled to retain the purchased interest free of any equitable encumbrance.[1]

The Court then agreed with Heidelberg, represented by Kirkland & Ellis, and applied this rule to patent licensees. Because Heidelberg had no notice or knowledge of the fraud by Loebach's former employer, the Court found Heidelberg was a bona fide purchaser and therefore was entitled to retain its license even though the assignment to the licensor was invalid.[2]

. . . the Federal Circuit panel reversed its original decision and ruled that a non-exclusive licensee or sublicensee is not entitled to protection under the bona fide purchaser rule.

The facts of Rhone-Poulenc seemed to mirror those in Heidelberg. Rhone-Poulenc claimed that DeKalb's fraud in acquiring a license to Rhone-Poulenc's patented technology invalidated DeKalb's license as well as any sublicense issued by DeKalb. Rhone-Poulenc also alleged that the use of the technology by DeKalb, a licensee, and by Monsanto, a sublicensee, constituted patent infringement.

At trial, a jury found that DeKalb had indeed fraudulently obtained a license to the patent in suit. Monsanto moved for summary judgment claiming it qualified as a bona fide purchaser under Heidelberg. The

trial court agreed, finding that Monsanto had "paid value for the right to use the technology without knowledge of any wrongdoing by DeKalb." Relying on Heidelberg, the court granted summary judgment in favor of Monsanto.

On appeal, the Federal Circuit initially confirmed the existence of a general "bona fide licensee" rule. Holding fast to the Heidelberg decision, the Federal Circuit affirmed the grant of summary judgment for Monsanto. The Court held that the defense applied to a licensee irrespective of whether the license was granted by an assignee, as in Heidelberg, or granted as a sublicense by another licensee, as was the case here.[3]

A broad bona fide licensee defense was short-lived, however. In March 2002, the Federal Circuit ruled en banc, that Heidelberg, which involved an exclusive license, was not binding in this instance because of the "unique circumstances in that case."[4] Freed from the constraint of Heidelberg, the original three judge panel issued a new opinion reversing its earlier decision. Without disturbing Heidelberg, the Court held that the bona fide purchaser defense is **not available** to **non-exclusive** licensees.

The Court reasoned that neither the patent law nor general contract law supported the extension of a bona fide purchaser defense to non-exclusive licensees. First, the Court found that Congress had already created a bona fide purchaser defense in 35 U.S.C. § 261, which states that "[a]n assignment, grant or conveyance shall be void against any subsequent purchaser or mortgagee for valuable consideration, without notice . . . ."[5] Thus, had Congress intended for the defense to extend to licensees, it could have included licensees under section 261. Instead, Congress chose to limit the defense to assignments, grants or conveyances of a patent.

. . . a potential licensee should negotiate safeguards in a license to protect it from liability should the licensor lose its rights under the patent.

Second, the Court turned to modern contract law to determine that the bona fide purchaser defense is not applicable to mere contract rights, particularly in the context of intellectual property. The panel concluded that as a general matter, "obtaining or perfecting title is an essential element of the bona fide purchaser defense."[6] Because a non-exclusive license does not convey "all substantial rights" under a patent, it is not tantamount to an assignment under section 261 and therefore, a non-exclusive licensee is not deemed to have obtained or perfected title. Thus, the Federal Circuit panel reversed its original decision and ruled that a non-exclusive licensee or sublicensee is not entitled to protection under the bona fide purchaser rule.[7]

The Rhone-Poulenc decision further underscores the importance of negotiating safeguards in a license to protect licensees from liability should the licensor lose its rights under the patent. Thorough due diligence is of course critical, but it may be that no amount of due diligence will uncover a fraudulently procured "right" to license. Thus, representations, warranties, and appropriate indemnification by the licensor will provide some protection to a licensee where its licensor had fraudulently obtained the rights it purported to license.

Supreme Court Reaffirms the Broad Scope of Patentable Subject Matter

Dawn H. Dawson

In a recent 6-2 decision, the Supreme Court confirmed the broad patent protection available for "anything under the sun that is made by man" — in this case, plants. J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 122 S.Ct. 593, 596 (2001).[1] In Pioneer, the Court rejected arguments that patent protection for plants is more limited than the protection available for more "traditional" inventions. Instead, the Court held that newly-developed plant breeds are as eligible for full utility patent protection under the Patent Act as other inventions. In so doing, the Court refused to limit the protection afforded plants to two plant-specific statutes adopted by Congress.

The Court confirmed its prior decisions establishing that "the language of § 101 is extremely broad," and that § 101 is "a dynamic provision designed to encompass new and unforeseen inventions."

It was clear prior to Pioneer that **some** protection existed for new plants. Congress had specifically provided certain patent-like protections for plants through "plant patents" available under the Plant Patent Act of 1930[2] and "plant variety certificates" available under the Plant Variety Protection Act of 1970.[3] But the protections available for plants under these specific provisions are less extensive than those provided through conventional utility patents.

The Pioneer Court faced the question of whether the passage of these plant-specific statutes had carved plants out of the subject matter eligible for patent protection as new, useful, and non-obvious inventions. The Court reasoned that Congress did not express an intent, either expressly or impliedly, that either the Plant Patent Act or the Plant Variety Protection Act limited the availability of utility patent protection for plants under § 101.[4] To the contrary, the two plant-specific statutes are wholly consistent with the availability of utility patent protection under § 101.[5] If the strict requirements for obtaining a utility patent under § 101 can be met, an invention — even a plant — is entitled to the more significant protections afforded by a utility patent.

The Court confirmed its prior decisions establishing that "the language of § 101 is extremely broad,"[6] and that § 101 is "a dynamic provision designed to encompass new and unforeseen inventions."[7] A broad range of subject matter, including living organisms, as in Chakrabarty and Pioneer, and even methods of doing business, as in State Street Bank[8] and Excel,[9] are patentable under 35 U.S.C. § 101 where there has been no persuasive evidence that Congress clearly intended to exclude such subject matter.

NOTES

SUPREME COURT REAFFIRMS BROAD SCOPE (from this page)

[1] See also, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S.Rep.No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No. 1923, 82d Cong., 2d Sess., 6 (1952)).

[2] 35 U.S.C. §§ 161-64 (1994 ed. and Supp. V). The Plant Patent Act of 1930 provides limited patent protection only for asexually-reproduced plants.

[3] 7 U.S.C. §§ 2321-2582. The Plant Variety Protection Act of 1970 authorizes a certificate program administered by the Department of Agriculture that offers limited patent-like protection for certain sexually-reproduced plants.

[4] Pioneer, 122 S.Ct. at 599, 602-604.

[5] Id. at 605.

[6] Id. at 598.

[7] Id. at 600.

[8] State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

[9] AT&T Corp. v. Excel Communications, 172 F.3d 1352 (Fed. Cir. 1999), cert. denied, 528 U.S. 946 (1999).

Notes

FESTO DECIDED (from pages 1-2)

[1] 122 S.Ct. at 1839.

[2] Id. at 1836, 1840.

[3] Id. at 1842.

[4] Id. at 1835.

[5] Id. at 1841.

[6] Id. at 1838, 1841.

[7] Id. at 1842.

[8] Id.

[9] Id. at 1839.

PRIVILEGE WAIVER RE OPINIONS OF COUNSEL (from pages 2-3)

[1] E.g., Thorn EMI N. Am., Inc. v. Micron Technology, Inc., 837 F. Supp. 616, 622 (D. Del. 1993) (finding waiver of privilege for all documents related to the infringement opinion that were communicated to the client).

[2] E.g., Mosel Vitelic Corp. v. Micron Technology, Inc., 162 F. Supp.2d 307, 312-13 (D. Del. 2000) (rejecting Thorn and holding that the privilege waiver should extend to information considered by the opinion counsel but not communicated to the client).

[3] 206 F.R.D. at 398

[4] Id. at 399

[5] Id. at 398

[6] See Quantum Corp. v. Tandon Corp., 940 F.2d 642, 644 (Fed. Cir. 1991).

[7] See Donald L. Cox, Opinions of Counsel in Patent Litigation, in Patent Litigation 1996, at 207, 239-40 (PLI Pat. Litig. Course Handbook Series No. 457, 1996); but see Allergan Inc. v. Pharmacia Corp., 2002 WL 1268047 (D. Del. May 17, 2002) (recent decision following Judge Farnan's guidance in Novartis to bifurcate the willful infringement issue).

ELI LILLY REVISITED, REAFFIRMED (from pages 4-5)

[1] The case is referred to as Enzo II because another Federal Circuit patent decision is often referred to as "Enzo," Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999).

[2] 285 F.3d at 1018.

[3] Id. at 1026.

[4] Id. at 1023 ("A depository is not part of a patent specification"). Deposits do still count for purposes of enablement.

[5] Id. ("the invention must be described more than by stating that it exists in a depository").

[6] Id. at 1027-28 (Dyk, J., dissenting).

[7] Note that applications are also susceptible to this holding. Written description must be satisfied at the time of filing, at least if priority is to be maintained, and thus applications in prosecution may be defective.

[8] 285 F.3d at 1025.

PROTECTION FOR BONA FIDE LICENSEES? (from pages 5-6)

[1] Heidelberg Harris, 145 F.3d at 1458.

[2] Id. at 1459.

3 Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 271 F.3d 1081, 1083-84 (Fed. Cir. 2001).

[4] Rhone-Poulenc, 284 F.3d at 1334 (en banc).

[5] Id. at 1327; 35 U.S.C. § 261.

[6] Id. at 1331 (quoting U.C.C. § 2B-506(b) cmt. 3 (2000)).

[7] Id. at 1333-34.

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