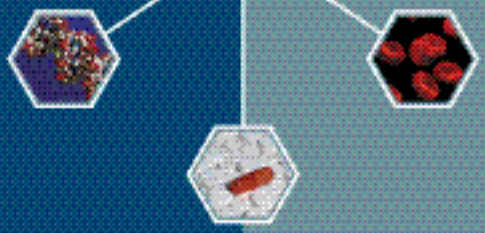
KIRKLAND & ELLIS

INTELLECTUAL PROPERTY

BIOTECH IP UPDATE



IN THIS ISSUE:

Editors:
Mark A. Pals
Kenneth H. Bridges

AUTUMN 2002

Kirkland to Open San Francisco Office

We are pleased to announce that Kirkland & Ellis will open a new office in San Francisco on January 2, 2003. The new office will initially focus on intellectual property (litigation and transactions) as well as general corporate matters. The office will benefit immediately from the contribution of specific biotechnology expertise from two senior IP partners. Stephen Johnson is moving from Kirkland's New York office to head the IP group in San Francisco. Stephen has a degree in genetics and has two decades of experience in strategic alliances and corporate transactions in the life sciences field, both in the U.S. and internationally. Mark Pals will divide his time between the San Francisco and Chicago offices. Mark has a Ph.D. in biophysics and an extensive biotech patent litigation practice, including his representation of Oxford Gene Technology in its jury trial victory over Affymetrix. We at Kirkland look forward to this new opportunity to enhance our service to our existing and prospective clients.

Supreme Court Rules That Not All Patent Claims Establish Federal Circuit Jurisdiction: Holmes Group v. Vornado

Lauren Hennessey Breit

The Supreme Court has pared back the appellate jurisdiction of the Federal Circuit – the federal appellate court generally thought of as handling all appeals of patent cases from U. S. district courts. The Supreme Court held in Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc. 535 U.S. 826, 122 S.Ct. 1889 (2002) that the Federal Circuit lacks appellate jurisdiction over a case in which the only patent law claim is asserted as a counterclaim. This decision confirms the primacy of the so-called "well-pleaded complaint" rule, and theoretically could lead to differences in the patent laws proliferated by the eleven regional appellate courts.

Vornado and Holmes Group manufacture fans and heaters. In late 1992, Vornado sued a third party, Duracraft Corporation, for trade dress infringement of its spiral grill design. The Tenth Circuit Court of Appeals held that Vornado had no protectible trade dress rights. See Vornado Air Circulation Systems, Inc. v. Duracraft Corp., 58 F.3d 1498 (1995) (Vornado I). Four years later, Vornado nevertheless filed a complaint with the U.S. International Trade Commission (ITC) against Holmes Group asserting the same trade dress infringement, and also asserting patent infringement. In response, Holmes Group sued Vornado in federal district court seeking, inter alia, a declaratory judgment that its fans did not infringe the alleged trade dress. Holmes Group did not, however, assert any cause of action under the patent law. Vornado answered and asserted a compulsory counterclaim for patent infringement.

The district court accorded collateral estoppel effect to the Tenth Circuit's ruling in Vornado I and entered judgment for Holmes Group.[1] Vornado appealed to the Federal Circuit instead of the Tenth Circuit. Although Holmes Group challenged the jurisdiction, the Federal Circuit heard the appeal and vacated the trial court's judgment.

The Supreme Court granted certiorari and held that the Federal Circuit does not have appellate jurisdiction where the complaint does not include any patent law claim, even where a patent law counterclaim is asserted. "[N]ot all cases involving a patent-law claim fall within the Federal Circuit's jurisdiction."[2] Under 28 U.S.C. § 1295(a)(1), the Federal Circuit has exclusive jurisdiction over an appeal from a final decision of a district court where jurisdiction is "based, in whole or in part" on 28 U.S.C. § 1338(a). Section 1338(a), in turn, gives district courts jurisdiction over patent claims, providing in relevant part "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents…." Because Section 1338(a) uses the same operative "arising under" language as 28 U.S.C. § 1331, the statue conferring general federal question jurisdiction, the well-pleaded complaint rule applies to both sections: whether a case "arises under" the patent laws is determined by what appears in the plaintiff's complaint and not by what is asserted in counterclaims.[3]

The Supreme Court rejected the argument that conferring appellate jurisdiction on the Federal Circuit in this case is necessary to effectuate Congress' goal of promoting uniformity in the patent law. "[O]ur task here is not to determine what would further Congress's goal of ensuring patent-law uniformity, but to determine what the words of the statute must fairly be understood to mean."[4]

Because Holmes Group's well-pleaded complaint asserted no claim arising under the patent law, the Federal Circuit erred in asserting jurisdiction over this appeal. The Supreme Court therefore vacated the judgment of the Federal Circuit and remanded with instructions to transfer the case to the Tenth Circuit.

The Supreme Court rejected the argument that conferring appellate jurisdiction on the Federal Circuit in this case is necessary to effectuate Congress' goal of promoting uniformity in the patent law.

Justice Ginsburg, joined by Justice O'Connor, concurred in the Court's judgment, but only because no patent claim was actually adjudicated (the patent issues had been stayed pending appeal of the trade dress claim[5]). Justice Ginsburg criticized the Court's holding as undermining Congress' intent: "Congress sought to eliminate forum shopping and to advance uniformity in the interpretation and application of federal patent law."[6]

Justice Stevens, on the other hand, seemed to welcome the potential for forum shopping. His concurrence noted with favor that "[a] plaintiff who has a legitimate interest in litigating in a circuit whose precedents support its theory of the case might omit a patent claim in order to avoid review in the Federal Circuit."[7] Justice Stevens also endorsed a role by other circuits in the development of patent law, writing that "occasional decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias."[8]

Impact

As a result of this decision, patent law counterclaims may be decided in appellate courts outside of the Federal Circuit. Indeed, pursuant to Holmes Group, the Federal Circuit has already transferred the appeal of an antitrust action with a patent infringement counterclaim to the appropriate regional circuit.[9]

With different appellate courts across the country deciding patent claims, regional differences could develop in the law because those courts are not forced to follow Federal Circuit precedent. It remains to be seen, however, to what extent the regional courts will in the end defer to Federal Circuit precedent. In a prior case, where the Federal Circuit had improperly adjudicated an appeal of a "patent-related" issue, the regional circuit that was charged with the appeal on remand from the Supreme Court wrote:

> Although we recognize that the Federal Circuit's decision does not bind us, the comprehensive nature of the decision, along with the recognition that Congress created the Federal Circuit with the goal of achieving uniformity and coherence in the patent laws, counsel us against straying far from the court's thorough analysis of the difficult issues presented by this case.[10]

Thus, the impact of regional circuit freedom to stray from the law of the Federal Circuit will be decided on a case-by-case basis in each court of appeals.

After Holmes Group, there may be an incentive to file certain claims first to ensure (or avoid) Federal Circuit review. Holmes Group avoided Federal Circuit review by filing a declaratory judgment action with no patent law claims. Had Vornado filed first in the district court asserting its patent law claim, the case would have been appealed to the Federal Circuit. If regional differences develop in the substantive patent law, filing decisions will take on even more strategic significance.

ENDNOTES FOR EACH ARTICLE APPEAR ON THE BACK PAGE

Enzo v. Gen-Probe Redux: Deposits May Support For Written Description

Kenneth H. Bridges

The last Biotech Update presaged that "it seems unlikely that the Enzo II majority will be the last word on written description or deposited materials."[1] After just three-and-a-half months, the original 2-1 panel decision of Enzo II has been replaced upon reconsideration by a unanimous opinion overturning the ruling that biological deposits cannot count toward satisfying the written description requirement. Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316 (Fed. Cir. 2002). The new Enzo decision also specifically adopted the PTO Guidelines for considering whether a functional description complies with the written description requirement, leaving open that possibility. Like the original decision, however, the reconsidered Enzo followed the trail blazed by Lilly[2] in applying a substantive written description requirement separate and apart from enablement, a ruling that provoked a spirited set of dissents from the petition for rehearing en banc (discussed in our next article).

[T]he original 2-1 panel decision of Enzo II has been replaced upon reconsideration by a unanimous opinion overturning the ruling that biological deposits cannot count toward satisfying the written description requirement.

From the outset, the reconsidered Enzo opinion adopted a softer line on functional descriptions. After acknowledging the decision in Lilly that "human insulin cDNA" was not a sufficient description, the court said, "[i]t is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement." 296 F.3d at 1324. The court then expressly adopted the PTO's Guidelines that:

> . . . the written description requirement can be met by showing that an invention is complete by disclosure of sufficient detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

296 F.3d at 1324 (emphasis original). Any notion that there is a hard-and-fast rule that DNA must be described by sequence has been dismissed. Thus, the reconsidered Enzo decision's treatment of Lilly appears better described as an acknowledgement rather than the full embrace of the earlier Enzo decision.

Turning to the question of biological deposits, the Enzo court again deferred to the PTO's Guidelines. Adopting the PTO's position, the court reversed its prior decision and held that biological deposits may count toward satisfying the written description requirement. 296 F.3d at 1326. The court's analysis on this point, though sparse, seems straightforward – deposits count for enablement, one part of section 112, and there is no reason that they should not count for the rest of section 112. It is notable, however, that the points made in the initial panel opinion in support of ignoring deposits were not rebutted, nor even addressed.

Indeed, the difference in style between the initial Enzo decision and its redux is stark. The written description issue pits "softer" arguments like practicality and reasonable reliance by patentees against cold, hard statutory and precedential interpretation. The earlier Enzo opinion largely brushed aside the softer arguments in favor of strict legalities. The reconsidered opinion, however, tries to place the realities of biotechnology patent practice above strict legal interpretations. There is an almost complete absence of statutory interpretation and resort to first principles in the reconsidered opinion. Rather, the practical advantages of allowing genetic sequences to be described by deposit and the desire not to upset patentees' historical reliance upon established PTO guidelines regarding deposits seem to have won the day.

The earlier Enzo opinion largely brushed aside the softer arguments in favor of strict legalities. The reconsidered opinion, however, tries to place the realities of biotechnology patent practice above strict legal interpretations.

Applying its rules to the case at hand, the court determined that factual issues precluded summary judgment and remanded the case to the trial court to assess compliance with the written description requirement in light of "the scope of the claims." 296 F.3d at 1327, 1328. Despite the presence of this language, it remains unclear (as the issue has never been vetted) whether the correct analysis is the same "full scope of the claims" analysis familiar to issues of enablement.

The original Enzo decision caused jitters in the biotechnology patenting community and prompted the PTO itself to file an amicus brief requesting rehearing en banc. Although the reconsidered opinion makes special accommodations for the biotechnology inventions involved there, it is clear that the intense litigation of written description questions will continue and that the law on this issue will continue to develop. The immediate pressures may have been relieved by softening the strict prohibition of functional descriptions of bio-molecules such as DNA, and allowing deposits to contribute to a sufficient written description. But the more fundamental issue remains – should a Lilly-type substantive written description doctrine exist at all? Following the revised panel decision, the full Federal Circuit denied Enzo's petition for rehearing en banc. Five different opinions signed by six judges weighing in on the en banc petition revealed deep fractures in the Court over Lilly-type written description. At least four judges seem to support discarding the Lilly written description doctrine altogether.[3] Even after the changes brought by Enzo, the safe bet remains that written description is by no means a settled issue.

Declining to Hear Enzo En Banc: Taking Sides on the Purpose and Applicability of the "Written Description" Requirement/Retrenching for the War on Lilly

Matthew R. Cohen

There is a clear divide among the judges of the Federal Circuit as to the purpose and applicability of the "written description" requirement of section 112. One camp views section 112 as setting forth a substantive written description requirement that, independent of the enablement requirement, requires a specific description of the subject matter claimed. Another camp sees enablement as the only true substantive requirement — written description is viewed as a mechanism to enforce the prohibition on the introduction of new matter during patent prosecution, thus assuring that patents accurately claim priority. The decision in Lilly,[1] criticized by the latter camp as creating a new doctrine of written description far beyond precedent, created the divide. But until the recent occasion to revisit the workings of Lilly in Enzo v. Gen-Probe, the issue was dormant. Now, after a controversial split panel decision was followed by a reconsidered opinion largely reversing the first and denial of a petition for rehearing en banc, the divisions in the court's thinking have been revealed in print. Enzo Biochem, Inc. v. Gen-Probe, Inc., 63 U.S.P.Q.2d 1618, 2002 WL 1592885 (Fed. Cir. 2002). As discussed in our prior article, although backing down from the original opinion in the case, the reconsidered Enzo opinion supported the Lilly decision in one crucial respect – both hold that compliance with the written description requirement is a substantive test independent from and in addition to the enablement requirement. This holding is the point of division in the court and was the subject of five opinions issued upon the denial of the petition for rehearing en banc.

The Dissents: Lilly Written Description Goes Too Far

As the dissents represent the affirmative arguments in favor of granting en banc review, we begin there. Judge Rader's dissent, joined by Judges Gajarsa and Linn, expressed his view that written description has no role to play outside of determining priority of invention. Judge Rader meticulously traced the origin and history of the written description requirement, and drew two conclusions. First, the written description requirement was traditionally (and should still be) only a means of enforcing the prohibition against adding new matter to the claims. Second, absent such priority issues, the only question of the sufficiency of a patent's disclosure should be one of enablement.

Judge Rader clearly regards Lilly and Enzo as contrary to precedent, and thus not controlling . . .

According to Judge Rader, the written description requirement originated and, with the exception of Lilly (and now Enzo), has always been applied as a means of policing the introduction of new matter in the claims. Judge Rader acknowledged the 1967 Court of Custom and Patent Appeals (C.C.P.A.) decision In re Ruschig,[2] as discussing a written description doctrine under section 112 as separate from the prohibition on new matter in section 132. However, Judge Rader asserted that until Lilly, the jurisprudence of both the C.C.P.A. and the Federal Circuit confirmed that written description rejections under

ENDNOTES FOR EACH ARTICLE APPEAR ON THE BACK PAGE

section 112 and new matter rejections under section 132 were interchangeable.

To Judge Rader, the Lilly decision was a significant deviation: "Two recent cases, however, this case [Enzo] and the 1997 Lilly case, have purported to create a new disclosure doctrine that supplants enablement."[3] He believes that this new doctrine "change[s] the application of the test and 'up[s] the ante' for disclosure . . . ."[4]

Judge Rader's dissent also indicated that the outcome of a particular appeal regarding written description may very well depend on the composition of the panel. Judge Rader clearly regards Lilly and Enzo as contrary to precedent, and thus not controlling:

> Lilly and this case really cannot depart from decades of established case law on § 112, ¶ 1. Even the court's decision to issue this improved version of Enzo … does not indicate any acceptance of written description as a general disclosure doctrine for all claims regardless of priority issues. Lilly and this case are panel cases and cannot override the statute that makes enablement the general disclosure doctrine and the vast body of prior case law limiting [written description] to is original purpose.[5]

The issue of written description seems far from decided.

Judge Linn emphasized the need for immediate en banc attention: "The issue is important, is ripe for us to consider, and deserves to be clarified, one way or the other."

Judge Linn joined Judge Rader's dissent, but also wrote separately (joined by Judges Rader and Gajarsa) to emphasize several points. First, Judge Linn fully concurred that Lilly was an unwarranted departure from precedent and that the written description requirement serves no purpose beyond "a convenient way to measure or test entitlement of later filed claims to an earlier priority date."[6] Second, as a consequence of the first, Judge Linn asserted that written description is satisfied by in ipsis verbis recitations of the claims in the specification or the original claims, and thus has no role to play in cases where that recitation is present. Third, Judge Linn emphasized the need for immediate en banc attention: "The issue is important, is ripe for us to consider, and deserves to be clarified, one way or the other."[7] In summary, three judges of the Federal Circuit have left little doubt that they stand against Lilly and welcome the opportunity to overturn it.

Judges Lourie and Newman: Written Description is a Separate Requirement

For Judge Lourie, author of both Lilly and the present Enzo decision, the denial of en banc rehearing was based upon the premise that, the "law is sound and does not need revision …"[8]

Judge Lourie, though he defended Lilly as consistent with precedent, seemed comfortable with the Lilly doctrine even if it was new law. Tackling Judge Rader's assertion that Lilly was such a departure, Judge Lourie stated that "[n]ew interpretations of old statutes in light of new fact situations occur all the time."[9] To Judge Lourie, although a holding that written description is a distinct requirement of a sufficient disclosure may not have been a feature of prior jurisprudence, such a holding was neither precluded by statute nor precedent and is a proper extension of the law. "Earlier cases also upheld a separate written description requirement, and the fact that they may have pertained to priority disputes does not vitiate their basic requirement to disclose one's invention."[10]

Judge Lourie stated that "[n]ew interpretations of old statutes in light of new fact situations occur all the time."

Judge Lourie argued that a separate written description requirement supports the public notice function of patents:

> "Interpretation of written description as this court has done furthers the goal of the law to have claims commensurate in scope with what has been disclosed to the public."[11]

He seemed to view the separate written description as an important check on the scope of patent claims in an era when such claims are "being asserted to cover what was not reasonably described in the patent."[12] In addition, Judge Lourie asserted that biotechnology subject matter perhaps poses a unique problem, where describing an invention and enabling one to make and use it are not one-and-the-same.[13]

The Other Opinions

Judge Newman, who joined Judge Lourie's opinion, also wrote separately to emphasize her disagreement with the dissenters' position that the written description requirement is only relevant in cases in which priority is at issue. She criticized their views as a "dramatic innovation in the theory and practice of patents."[14]

Judge Dyk's position in all of this is particularly interesting. As the dissenter from the original panel opinion, Judge Dyk questioned the validity of the Lilly decision. He was willing, however, to join the reconsidered Enzo opinion despite its consistency with Lilly in treating written description as a separate doctrine. Judge Dyk then voted against rehearing en banc because he believed the issues raised were not yet ripe for en banc review. Although Judge Dyk believed that now was not the time to bring the issues to a head, he still expressed doubts about Lilly and foreshadowed a future confrontation on the issue. He noted that the four other opinions "raise important and interesting questions, including questions concerning the correctness of our earlier decision in [Lilly]."[15]

Conclusion

Anyone searching for clarity in the law of written description will find little comfort in the Enzo decisions – particularly as the doctrine applies to biotechnology. It is clear, however, that the Federal Circuit continues to grapple with the challenges presented in fitting biotechnology inventions into the general patent law. The apparent disagreement at the Federal Circuit on the nature and scope of a written description requirement will undoubtedly produce further contentious outcomes.

Shielding Research Uses From Infringement Liability: The "Experimental Use" and Section 271(e)(1) Defenses

Christopher R. Liro

The issue of whether use of patented technology for "experimental" reasons constitutes infringement has been a persistent question in patent law. The Federal Circuit recently clarified this doctrine and soon will address new questions in the related topic of the section 271(e)(1) statutory exemption for activity related to the submission of data to a regulatory agency.

The "traditional" experimental use defense

The Federal Circuit recently affirmed the continued existence of a judge-made "experimental use" defense to patent infringement, but limited its role to only the most extreme cases. Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002). In a dispute between Dr. John Madey and Duke University, the court ruled that even non-commercial, university research does not qualify as "experimental use." The defense only applies to acts performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." In the late 1980s, Dr. Madey accepted a tenured position at Duke and established a free electron laser research laboratory at the university. Some of the specialized equipment in the laboratory practiced two patents owned by Madey. By 1997, the relationship between Madey and Duke had soured – the university removed Madey as the director of the laboratory, and he later resigned from the university. Madey then sued Duke for infringing his two patents by continuing to operate the laboratory equipment.

The trial court reasoned that the patent law recognized a non-infringement defense for uses "solely for research, academic or experimental purposes." The trial court found that use of the laboratory equipment by Duke was for an "experimental, non-profit purpose," based in part on the university's mission statement and non-profit status, and thus granted summary judgment of non-infringement for Duke.

The Federal Circuit reversed. Relying on precedent including Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343 (Fed. Cir. 2000), the court confirmed the theoretical existence of the experimental use defense, but concluded that the trial court had adopted an overly broad view of the defense. The court held that a use is not protected under the exception or defense if it has any "definite, cognizable, and not insubstantial commercial purpose," or if the use is "in keeping with the legitimate business of the alleged infringer."[1] The defense shields only acts performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[2]

While Duke's use was arguably non-commercial, and therefore different from that in previous cases, the court emphasized that whether use was non-commercial was not the complete inquiry. Conduct in keeping with the alleged infringer's legitimate business is not immunized, regardless of the commercial implications. Major research universities, such as Duke, often sanction and fund research projects

with no commercial applications whatsoever, but such projects "unmistakably further the institution's legitimate business objectives," including educating and enlightening students and faculty, increasing the status of the institution, and luring grants, students, and faculty.[3] Moreover, the profit or non-profit status of the user is not determinative.

Section 271(e)(1) exemption

In contrast to the very limited protection provided by the experimental use defense, the statutory exemption provided by 35 U.S.C. § 271(e)(1) continues to be a strong, though hotly litigated, provision of the patent law. Section 271(e)(1) generally exempts from liability otherwise infringing uses related to the development and submission of information under Federal law regulating drugs and medical devices. But section 271(e)(1) creates its own uncertainties. Recent cases have tested whether section 271(e)(1) provides a safe harbor for any patented invention used in the course of research that might ultimately lead to the submission of data to a regulatory agency. Does it, for example, protect the use of a patented screening tool used in the hope of identifying a candidate drug for subsequent pre-clinical and clinical study? A trial court recently held that section 271(e)(1) shielded Bristol-Myers Squibb's ("BMS") use of a patented intermediary compound to screen other candidate drugs to identify the "best drugs" for further study. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001). That ruling has been appealed to the Federal Circuit.[4]

Following that success, BMS similarly has invoked section 271(e)(1) in seeking summary judgment of non-infringement in Housey Pharmaceuticals, Inc. v. Abbott Pharmaceutical Corp., Civ. No. 01-401 SLR (D. Del.). BMS is accused of infringement for its use of patented cell-based assay technology to identify candidate drugs. BMS has argued that the use of the assay at issue was "reasonably related to the development of information for submission to the FDA, in that it either directly yields information that the FDA would find relevant in its approval process or yields information that facilitates the development of other information directly relevant to the FDA approval process."[5] Housey has responded that this interpretation is flawed because the uses are not "solely" related to the submission of information, as required by the statute, and because such an interpretation "would work to nullify the value of any research tool patent."[6] A ruling on BMS's motion for summary judgment is pending.

A trial court recently held that section 271(e)(1) shielded Bristol-Myers Squibb's ("BMS") use of a patented intermediary compound to screen other candidate drugs to identify the "best drugs" for further study.

While the "experimental use" defense remains a part of the patent law, the Federal Circuit has continued to limit the cases to which it will apply. Meanwhile, the scope of protection afforded under section 271(e)(1) continues to be hotly litigated, particularly as courts confront the question of whether research tools can be used without liability. The Federal Circuit's decision in the BMS case, currently on appeal, should be expected to make news regardless of how it is decided.

NOTES

EXPERIMENTAL DEFENSES TO INFRINGEMENT (from this page)

1 307 F.3d at 1362.

2 Id.

3 Id.

4 The appeal was docketed on September 6, 2002. The parties are still briefing the issue. Thus, a decision is not likely for at least several months.

5 Def. Bristol-Myers Squibb Co.'s Opening Br. in Supp. of its Mot. for Summ. J. of Non-infringement Under 35 U.S.C. § 271(e)(1), Docket 194, at 2.

6 Pl. Housey Pharms., Inc.'s Resp. Br. to Bristol-Myers' Mot. for Summ. J. Under 35 U.S.C. § 271(e)(1), Docket 220, at 7.

For more information visit
www.kirkland.com or contact:

Chicago
Mark A. Pals
Tel: 312-861-2450
mpals@kirkland.com

London
Pierre-André Dubois
Tel: +44 (0)20 7816 8830
pdubois@kirkland.com

Los Angeles
Robert G. Krupka, P.C.
Tel: 213-680-8456
rkrupka@kirkland.com

New York
Lisa A. Samenfeld
Tel: 212-446-4968
lsamenfeld@kirkland.com

San Francisco
Stephen P. H. Johnson
Tel: 415-439-1439
sjohnson@kirkland.com

Washington, D.C.
Edward C. Donovan
Tel: 202-879-5289
edonovan@kirkland.com

Notes

FEDERAL CIRCUIT JURISDICTION PARED BACK (from pages 1-2)

1 93 F. Supp. 2d 1140 (D. Kan. 2000).

2 122 S.Ct. at 1895.

3 Id. at 1893. See also, Christianson v. Colt Industries Operating Corp., 486 U.S. 800 (1988).

4 Holmes Group, 122 S. Ct. at 1895.

5 The Court addressed this argument in a footnote, clarifying that its decision would apply even if the patent law counterclaim were fully adjudicated in the court below. Id. at 1894 n.3.

6 Id. at 1898 (Ginsburg, J., concurring).

7 Id. at 1897 (Stevens, J., concurring). One commentator has suggested that there may be a real incentive to avoid Federal Circuit review in the area of antitrust, where the Federal Circuit has (in his view) proved to be hostile to certain antitrust claims. Lewis Clayton, "Justices Initiate Review of Fed. Circuit Cases," 3 Pat. Strategy & Mgmt. 4 (July 2002).

8 Holmes Group, 122 S. Ct. at 1897 (Stevens, J., concurring).

9 Telcomm Technical Services, Inc. v. Siemens Rolm Communications, Inc., 295 F.3d 1249 (Fed. Cir. 2002)

10 Christianson v. Colt Industries Operating Corp., 870 F.2d 1292, 1298-99 (7th Cir. 1989) (internal citation omitted).

ENZO ALREADY OVERTURNED (from pages 3-4)

1 See "Written Description Doctrine of Eli Lilly Reaffirmed, Perhaps Extended," Biotech Update, Spring 2002, pp. 4-5, available at www.kirkland.com/db30/cgi-bin/pubs/BioTech%20Spring%20Issue.pdf.

2 Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

3 Judges Rader, Linn and Gajarsa clearly support discarding Lilly in their dissents from the denial of rehearing en banc, 2002 WL 1592885, 6-7, and in his dissent from the original panel opinion Judge Dyk wrote that the "unique written description requirement" of Lilly was "open to serious question." 285 F.3d at 1025.

THE ONGOING BATTLE OVER LILLY (from pages 4-6)

1 Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

2 379 F.2d 990, 154 U.S.P.Q. 118 (C.C.P.A. 1967).

3 2002 WL 1592885 at 14.

4 Id. at 12.

5 2002 WL 1592885 at 13.

6 2002 WL 1592885 at 19.

7 Id. at 20.

8 2002 WL 1592885 at 1 (joined by Newman, J.).

9 Id. at 2.

10 Id. at 3.

11 Id. at 2.

12 Id.

13 Id. at 5

14 2002 WL 1592885 at 6.

15 Id.