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The Primary Source for Claim Construction: Dictionary or Specification?

Introduction

Claim interpretation is a pivotal aspect of almost every patent case. In fact, a court's determination regarding an entire infringement or invalidity case often turns on its construction of a single claim term. Due to a split within the Court of Appeals for the Federal Circuit, however, there is a high degree of uncertainty as to the appropriate *method* for construing the claims. The issue is of great importance because the different methods employed by different panels of the Federal Circuit can yield entirely different results.

The issue dividing the court focuses on which sources deserve primacy in interpreting claim terms—the specification and the intrinsic record on the one hand or dictionaries and technical treatises on the other. The dissents in two recent, particularly intriguing cases highlight the difference between the two methods, and taken in concert suggest that the manner in which a patent's claims will be construed by the Federal Circuit may depend on the panel of judges arbitrarily selected for the case. Fortunately, the Federal Circuit

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Legislative Update: Joint Research Agreements May Protect Patent Rights

Introduction

On December 10, 2004, President Bush signed into law the Cooperative Research and Technology Enhancement (“CREATE”) Act. CREATE amends 35 U.S.C. § 103(c) of the Patent Act in an attempt to promote cooperative research, such as between a university and a start-up company. The main thrust of the new law is to exclude certain prior art from obviousness consideration under 35 U.S.C. § 103(a), if the prior art was developed by a party subject to a joint research agreement with the assignee of the application. The USPTO has adopted interim rules without notice or public comment in order to allow applicants to take immediate advantage of the Act. 70 Fed. Reg. 1818-24 (to be codified at 37 C.F.R. pts. 1 and 3). The following is a discussion of the Act and its implications.

35 U.S.C. § 103(c)

Even before the amendment, section 103(c) rendered certain jointly researched prior art exempt from consideration under 35 U.S.C. §§ 102(e), (f), or (g) as obviousness-type prior art. However, the old rule required that the prior art be owned by or subject to an obligation of assignment to the same person or company as the pending application.

Now, under the newly amended section 103(c), prior art developed by a person at one company cannot be used as section 102(e), (f), or (g) obviousness-type prior art against an application disclosing an invention made by a person at another company, provided that both persons or companies are parties to a joint research agreement.

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Legislative Update: Joint Research Agreements May Protect Patent Rights

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Naturally, the joint research agreement must have been in effect before the claimed invention was made. However, the statute does not require that the excluded prior art be developed after the signing of the joint research agreement. Importantly, to qualify under the Act, the claimed invention must also be within the scope of the field of technology as described by the joint research agreement.

Joint Research Agreements

In order to take advantage of the new law, a joint research agreement should be created whenever inter-agency collaborative research is taking place. The agreement should include at least the names of the parties to the agreement, the date the agreement was executed, and a concise statement of the field(s) of technology to which the joint research applies. A redacted portion of the agreement containing this information may eventually need to be submitted to the PTO in order to overcome a rejection.

One area of concern is the “field(s) of technology” or “field of the claimed invention” identified in the research agreement. Generally, the field of technology listed in the research agreement must correlate to the claimed invention. However, because these terms have not yet been construed, research agreements should include multiple fields that are both broadly and narrowly written. Current joint research agreements should be revised to include the technology field descriptions.

In drafting and revising joint research agreements, the parties should know that collaborations may enter unanticipated

fields. Thus, the field description should be crafted to embrace fields other than those specifically contemplated from the onset.

Applications That Benefit from the Act

The Act applies to patents granted on or after December 10, 2004 and to pending and reissue patent applications. However, the Act will have no impact on claims in reissue applications of patents granted before December 10, 2004 that had been amended or canceled during the prosecution of the patent applications.

Further, the Act does not affect any final decision of a court or the USPTO that was rendered before December 10, 2004. The Act also does not affect the right of any party in any action that was pending before the USPTO or a court on December 10, 2004.

Only inventions made after the start of a joint research agreement are covered by the Act. Thus, the Act requires that the inventions be made after the execution of a joint research agreement whether or not the agreement was executed before or after December 10, 2004.

Overcoming a 35 U.S.C. § 103(a) Rejection

The applicant carries the burden to avoid an obviousness rejection based on prior art via section 102(e), (f) or (g). To satisfy that burden, the applicant should provide a statement that the prior art and the claimed invention were made by or on behalf of parties to a joint research agreement, and that the claimed invention was made as a result of activities within the scope of the agreement. The statement must begin on a separate sheet and not be directed to other matters. The statement must be signed either by the

The logo for 'snippets' features the word in a lowercase, sans-serif font. The letter 'i' is stylized with a square dot, and the letter 'p' has a square loop at its base.

In order to take advantage of the new law, a joint research agreement should be created whenever inter-agency collaborative research is taking place.

applicant or by the assignee of the entire interest.

In addition, the applicant must also amend the specification to disclose the names of the parties to the joint research agreement, disclose the date of execution of the agreement, and provide a concise statement of the field of the claimed invention. Alternatively, the date and field information can be provided by specifying where this information is recorded in the assignment records of the USPTO.

Moreover, an examiner may enter a double patenting rejection if the Act is invoked to avoid a section 103(a) rejection because the prior art and the claimed invention will be treated as commonly owned. Further, an examiner may refuse to enter any amendments in applications under final rejection if the amendments are not accompanied by appropriate terminal disclaimers. Amendments may be entered but this may require reopening prosecution and entry of double patenting rejections, which may be made final. However, the USPTO has yet to provide the type of terminal disclaimers necessary to overcome such a double patenting rejection.

Amending Applications

In order to invoke the act, applications currently pending before the USPTO that are covered by the Act must be amended to disclose the names of the parties to a joint research agreement, the date the agreement or amended agreement was executed, and a concise statement of the field of the claimed invention. Applications filed after December 10, 2004 resulting from a joint research agreement can be filed with a section in the specification that includes the names of the parties to the agreement, the date the agree-

ment or amended agreement was executed, and a concise statement of the field of the claimed invention.

Amendments must be accompanied by a processing fee if not filed (a) within three months of the filing date of a national application or the date of entry of a national stage application; (b) before the mailing of a first office action on the merits; or (c) before the mailing of a first office action after the filing of a request for continuing examination. An amendment filed after the date the issue fee is paid must also be accompanied by the processing fee.

To claim the benefit of the Act in a patent granted on or after December 10, 2004, a patentee may submit a certificate of correction. The filing of reissue or reexamination applications is, therefore, not necessary.

Conclusion

If you are collaborating on a project with another company, you should create a joint research agreement. In addition, any current joint research agreements should be revised to ensure that these agreements contain field of technology descriptions. Such precautionary measures may be the difference between receiving a notice of allowance or a final rejection.

Dennis Crouch's practice is focused on patent prosecution, litigation and counseling in the areas of mechanical and electrical engineering, software, and business methods. Mr. Crouch is also the editor of the popular patent law blog "Patently-O."

crouch@mbhb.com

Dr. Baltazar Gomez's practice includes providing technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the areas of biology, chemistry, biochemistry, and cellular and molecular biology. Dr. Gomez's doctoral research concerned bioenergetics and membrane biochemistry.

gomez@mbhb.com

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recently heard one of these cases *en banc* in hopes of resolving the dispute.

Judge Dyk's Argument to Follow the "Dictionary Definition" in *Phillips*

On April 8 of last year, in a calculated dissent in *Phillips v. AWH Corp.*, Judge Dyk complained of the majority's attempt "to work a major and unfortunate change in our recent claim construction jurisprudence." 363 F.3d 1207, 1216 (Fed. Cir. 2004) (Dyk, J., dissenting), *rehearing granted en banc*, 376 F.3d 1382 (Fed. Cir. 2004). According to Judge Dyk, the majority had improperly imposed an additional structural limitation on a relevant claim term ("baffles") that was contrary to the "plain meaning" of the term and that (at least in the perception of Judge Dyk) was not suggested by the specification. *Id.* at 1216-18. Instead, Judge Dyk preferred the "general purpose dictionary definition" of the term, and found no grounds to divert from this definition. *Id.* at 1218 (emphasis added).

Judge Newman's Emphasis on the "Written Description" in *Housey*

Then, on May 7, 2004, in opposing the majority position in *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, Judge Newman followed the very analysis rejected by Judge Dyk. 366 F.3d 1348, 1356-60 (Fed. Cir. 2004). Specifically, Judge Newman argued that although "[t]he written description . . . is the primary resource in understanding the claims," the *Housey* majority had neglected to give proper emphasis to the context of the contested phrase, "inhibitor or activator of a protein," as used in the written description. *Id.* at 1358 (emphasis added). Instead, according to Judge Newman, the majority had curiously "announce[d] a 'heavy presumption' that the meaning of

a term in a patent claim is unencumbered by the specification," and had placed "a 'heavy burden' on overcoming that presumption." *Id.* at 1357.

Judge Newman further countered that "[t]he rule is that claims are viewed and understood in light of the specification," and that "[t]he role of the dictionaries and treatises is to educate the non-technical judge in understanding what the inventor and the examiner understood, not to impose a new evidentiary presumption and not to enlarge the patented invention beyond that set forth by the inventor." *Id.* at 1358. Strikingly reminiscent of Judge Dyk's dissent in *Phillips*, Judge Newman accused the *Housey* majority of basing its claim construction "on confusing recent pronouncements of [the Federal Circuit], contravening earlier statements of precedent, [and] thus adding to the confusion." *Id.* at 1356. In exasperation, Judge Newman called for restoration of the law of claim construction to "a more apt wisdom and more usable simplicity." *Id.*

These cases were decided less than one month apart. Both dissenting judges took opposite positions regarding the proper method of construing a claim. While it is not entirely uncommon for judges to disagree on how to come to a particular legal result, what is particularly notable about these dissents is that they not only took a fundamentally opposing position, they accused the majority of subverting the whole precedent on the critical issue of claim construction.

The Significance of the Difference

At first blush, the difference between the two models might seem unimportant, in part because it would seem likely that a patent specification would be written

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using terms just as they are depicted in any relevant dictionary. But things frequently are not that simple. Many cases turn on which method is used or, at least, emphasized. The decision in *Merck & Co. v. Teva Pharms. USA Inc.*, 347 F.3d 1367 (Fed. Cir. 2003) is illustrative.

Writing for the *Merck* majority, Judge Newman (with Judge Prost joining) affirmed a district court holding that Merck's claim to a method of treating osteoporosis with alendronic *acid* encompassed the use of the corresponding *salt* form of the compound as well as the acid form. *Id.* at 1369. Judge Newman turned first to the specification, noting that "throughout the specification the inventors described the acid active agent as encompassing the acid and its salt forms," *id.* at 1371, relying on instances in which the specification exemplified formulations and use of alendronic acid in terms of the salt form. Judge Newman also relied on testimony of pharmacologists that "[one] of ordinary skill in the field would understand that the active agent is [alendronic] acid, and that the method of treatment of bone disorders includes use of the active agent in the form of the salt" and technical publications that referred to the acid and salt forms in much the same way as the specification. *Id.* at 1370-71. Judge Newman discounted the testimony of chemists relative to pharmacologists, asserting that chemists were not of ordinary skill in the art of the invention (*i.e.*, treating osteoporosis). *Id.* at 1371-72.

Writing in dissent and acknowledging that in a few instances alendronic acid is recited in the specification when actually referring to the salt, Judge Mayer read the specification as recognizing a distinction between the acid and salt

forms. *Id.* at 1374. Accordingly, Judge Mayer reasoned that there could not be literal infringement of the claims because the salt form was not the acid recited in the claims, and there could be no infringement under the doctrine of equivalents because, following *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002), the use of the salt form was a disclosed but unclaimed embodiment. 347 F.3d at 1374.

While there were differences among the judges on the *Merck* panel as to whether the specification equated salts and acids, the result may have come out differently had technical dictionaries or treatises been consulted first to determine the meaning of the term "acid." Under that approach, the court likely would have found that an acid and its corresponding salt are structurally different molecular entities. The court would have then turned to the specification and would have likely determined that it failed to manifest a clear intent to deviate from the dictionary definition.

While the Federal Circuit is clearly fractured with regard to claim construction, it seems clear they all agree on at least one thing—claim construction jurisprudence is unclear. On July 21, 2004, the Federal Circuit opted to rehear *Phillips en banc* in an attempt to decide this and other related issues. 376 F.3d 1382. However, review of Federal Circuit claim construction cases demonstrates general judicial trends (with certain exceptions) that may lead to a split court in the *Phillips* rehearing. In particular, certain judges, including Judges Dyk, Linn, and Mayer, seem to prefer a dictionary-based model in which the dictionary meaning of a term is the primary claim interpretation source.

Other judges, such as Judges Newman and Lourie, seem to favor a specification-focused model, effectively allowing the specification to limit the scope of the claim language.

Conclusions

In deciding upon the fundamental method of claim construction in its *en banc* review of *Phillips*, the Federal Circuit will be attempting to resolve fundamental disputes between some of its judges. In particular, the parties and over thirty *amici* have filed briefs addressing the following questions:

1. Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee's use of the term in the specification? If both sources are to be consulted, in what order?
2. If dictionaries should serve as the primary source for claim interpretation, should the specification limit the full scope of claim language (as defined by the dictionaries) only when the patentee has acted as his own lexicographer or when the specification reflects a clear disclaimer of claim scope? If so, what language in the specification will satisfy those conditions? What use should be made of general as opposed to technical dictionaries? How does the concept of ordinary meaning apply if there are multiple dictionary definitions of the same term? If the dictionary provides multiple potentially applicable definitions for a term, is it appropriate to look to the

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specification to determine what definition or definitions should apply?

3. If the primary source for claim construction should be the specification, what use should be made of dictionaries? Should the range of the ordinary meaning of claim language be limited to the scope of the invention disclosed in the specification, for example, when only a single embodiment is disclosed and no other indications of breadth are disclosed?

4. Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?

5. When, if ever, should claim language be narrowly construed for the sole purpose of avoiding invalidity under, e.g., 35 U.S.C. §§ 102, 103, and 112?

6. What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?

7. Consistent with the Supreme Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), and our *en banc* decision in *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998), is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what

aspects, in what circumstances, and to what extent?

376 F.3d at 1383. From the foregoing, it should be apparent that how the court answers these questions will have a significant impact on patent prosecution and litigation. The Federal Circuit reheard *Phillips en banc* on February 8, 2005, and an opinion is expected later this year.

Dr. Michael S. Greenfield's practice primarily comprises patent procurement, interference practice, and client counseling on matters of patent prosecution strategy, validity, infringement, and freedom-to-operate, all with special emphasis in the chemical and biotechnology arts. Dr. Greenfield's work has appeared in several articles in leading legal and scientific journals.

greenfield@mbhb.com

Jennifer M. Pope's practice primarily concentrates on obtaining patent protection for clients in the areas of biotechnology, pharmaceuticals, and chemistry.

pope@mbhb.com

Dennis Crouch's practice is focused on patent prosecution, litigation and counseling in the areas of mechanical and electrical engineering, software, and business methods. Mr. Crouch is also the editor of the popular patent law blog "Patently-O."

crouch@mbhb.com

Dr. Y. Elaine Chang's practice includes preparing and prosecuting patent applications, conducting legal research, and providing technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the area of biotechnology. Dr. Chang is currently a student at DePaul University School of Law.

chang@mbhb.com

Recent Trends in E-Discovery, Part I: New Local Rules and Recent Judicial Opinions

Introduction

This is the first part in a series of articles examining recent developments in electronic discovery (“e-discovery”). Part I highlights emerging trends for non-compliance with discovery orders, especially when digital information is normally archived or stored on back-up tapes; Part II will discuss who should bear the costs of preservation, production, and restoration of electronic evidence. Thereafter, subsequent articles will discuss practical guidelines for reducing costs and managing production of documents and reviewing electronic evidence produced by the opposing party, as well as in-house counsel’s best bet for implementing safeguards to avoid e-discovery disasters. The Judicial Conference of the United States, the principal policy making body concerned with the administration of the United States Courts, is actively considering changes to the Federal Rules of Civil Procedure in order to deal with electronic discovery, and these considerations will also be dealt with in future articles. Many jurisdictions, not waiting for amendment of the Federal Rules of Civil Procedure, have already begun enacting local rules to control electronic discovery. See Ark. L.R. 26.1; Cal. Code Civ. P. § 2017; Sup. Ct. Miss. R. 26; N.J.L.R. 26.1(d); Wyo. L. Civ. R. 26.1(d).

Who Is Responsible for This Game of Blind Man’s Bluff?

Faced with the decision of whether to produce or request electronic documents, most parties preparing for litigation tend to avoid the complexities and colossal price tag of conducting e-discovery. Until recently, e-discovery was mostly used as a bluffing technique, but now the sands are shifting as a national standard is developing. Counsel and their clients should be aware of recent decisions and new

local rules making it unambiguously clear that counsel has a heightened duty to monitor a client’s compliance with document retention policies and discovery orders. When determining what information must be disclosed, local rules may require counsel to thoroughly review the client’s information management systems as well as the client’s “historical, archival, back-up, and legacy computer files.” See N.J.L.R. 26.1(d); Wyo. L. Civ. R. 26.1(d). The rules may also require counsel to decide in advance whether back-up data will be necessary and which media or format will be used. See, e.g., N.J.L.R. 26.1(d).

Recent Opinions

Now, more than ever before, courts are hearing discovery disputes involving relevant discoverable email and electronic files (oftentimes deleted by the opposing party). Almost inevitably, the requesting party contends that missing documents likely contained “the smoking gun.” In the leading current case, U.S. District Judge Scheindlin has written five opinions relating to a discovery battle between Laura Zubulake and USB Warburg over missing and deleted email. (The most recent opinion is *Zubulake v. USB Warburg, LLC.*, No. 02 Civ. 1243 (SAS), 2004 U.S. Dist. LEXIS 13574 (S.D.N.Y. July 20, 2004) (*Zubulake V*)). Discovery has dragged on for more than two years in what started out as a “relatively routine employment discrimination” lawsuit. See *id.* at *2. The latest opinion clearly establishes counsel’s heightened responsibility “to ensure that relevant information is preserved by giving clear instructions to the client to preserve such information.” *Id.* According to Judge Scheindlin, once the duty to preserve attaches:

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Recent Trends in E-Discovery, Part I: New Local Rules and Recent Judicial Opinions

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[C]ounsel must identify sources of discoverable information. This will usually entail speaking directly with the key players in the litigation, as well as the client's information technology personnel. In addition . . . counsel must put in place a litigation hold and make that known to all relevant employees by communicating with them directly. The litigation hold instructions must be reiterated regularly and compliance must be monitored. Counsel must also call for employees to produce copies of relevant electronic evidence, and must arrange for the segregation and safeguarding of any archival media (e.g., backup tapes) that the party has a duty to preserve.

Id. at *15.

On a motion to reconsider in a different case, the Southern District of New York reiterated that sanctions are appropriate for a “wholesale abdication of responsibility by all defense counsel.” *Metropolitan Opera Assoc., Inc. v. Local 100*, No. 00 Civ. 3613 (LAP), 2004 WL 19430099, at *4 (S.D.N.Y. Aug. 27, 2004). U.S. District Judge Preska emphasized that counsel did not “address deficiencies in the client’s retention and production of electronic documents . . . including contacting *all* the [client’s] ISPs to attempt to retrieve deleted documents.” *Id.* at *10. Arguing that the documents were irrelevant did not pass muster. *Id.*

In another recent case, *United States v. Phillip Morris, USA, Inc.*, there was “no question that a significant number of emails have been lost and that Philip Morris employees were not following the company’s own internal procedures for

document preservation,” but what was most troubling to the court was that the “employees who failed to follow the appropriate procedures . . . held some of the highest, most responsible positions in the company.” 327 F. Supp. 2d 21, 24 (D.D.C. July 21, 2004). Because the emails were “irretrievably lost,” U.S. District Judge Kessler granted a sanction wherein those employees were precluded from testifying as a fact or expert witness at trial. *Id.* at 25. Furthermore, the court ordered a monetary sanction of \$2,750,000, as a deterrent so that “the corporate and legal communit[ies] understand that such conduct will not be tolerated.” *Id.* at 26.

Forensic Specialists

Today, emerging computer forensic specialists and discovery support services, such as Fios (www.fiosinc.com); Applied Discovery (www.appliedDISCOVERY.com); Online Security Inc. (www.onlinesecurity.com); Jerry Saperstein (jerry@telocity.com); and Competitive Advantage Solutions (www.casglobal.com), provide litigation teams with access to digital data, making it possible to recover metadata or other valuable information otherwise unavailable. Yet the question still remains—who should pay for e-discovery? In the next article, we will discuss factors to consider in light of the cost-shifting analyses developed by the courts.

Daniel A. Boehnen is a founding partner of MBHB. His extensive litigation experience encompasses numerous high-technology industries in all federal courts, including district and appeals courts, International Trade Commission actions, and Court of Claims. Mr. Boehnen’s practice focuses on the formulation and execution of successful strategies for trials, oppositions, and appellate proceedings. Mr. Boehnen has been involved in numerous notable and precedent-setting cases, including *Plas-Tool, Inc. v. Philips Container Corporation*, *Amgen Inc. v. Elanex Pharmaceuticals*, *Emerson Electric v. Davoil* and *Amgen v. Chugai Pharmaceuticals and Genetics Institute*.

boehnen@mbhb.com

Dr. Deana C. Larkin’s practice primarily comprises assisting in patent litigation and patent prosecution; conducting legal research; and providing technological advice in support of validity, infringement, and patentability analyses related to biochemistry, chemistry, molecular biology, and biotechnology. Dr. Larkin’s research experience encompasses RNA-protein interactions during protein biosynthesis, as well as on unlocking the origins of translational machinery and early ribosomal mechanisms using truncated RNA molecules, small peptides, and inorganic molecules.

larkin@mbhb.com

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The Continued Confusion Over Written Description

Introduction

The written description requirement embodied in 35 U.S.C. § 112, first paragraph, is at present a quagmire for patent applicants and a trap for unwary patent litigants, particularly for biotechnology inventions. This is the case because the judges of the CAFC have divergent views of the scope and nature of the requirement and its relationship with the enablement requirement of the statute, particularly with regard to biotechnology inventions. Understanding this aspect of patent law, how the Patent Office and the courts have and are applying it, and what the future may hold may be the most critical mission confronting clients and their patent attorneys, because the ability to obtain and enforce patents on biotechnology inventions is likely to depend on it.

The “Priority Policeman”

The Federal Circuit’s predecessor court, the CCPA, first recognized the written description requirement as a separate component of the disclosure requirements in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). In *Ruschig*, the CCPA used the requirement to ensure that a later-filed claim was entitled to its asserted priority date. The court reviewed the specification to determine whether the invention as claimed had been described, thus establishing that the applicants were in possession of the invention when the application was filed. Importantly, this analysis of whether a specification satisfies the written description requirement did not delve deeply into a substantive determination of the extent of the disclosure. For example, an originally filed claim fulfilled this requirement by definition because claims are a part of the patent disclosure *ab initio*. See *In re Gardner*, 480 F.2d 879 (C.C.P.A. 1973). Following *Ruschig*, the courts used the

written description requirement exclusively in this context, as a “priority policeman” to prevent an applicant from enjoying the benefits of a priority date without disclosing the invention in the corresponding priority application. See *In re Wertheim*, 541 F.2d 257, 261-65 (C.C.P.A. 1976).

The Nucleic Acid Trilogy

Courts constrained the written description requirement to these boundaries until the 1990s, when three Federal Circuit cases illustrated a new use: *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993); and *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (“*Eli Lilly*”). In these cases, the court established the use of the written description requirement to “police” the sufficiency of disclosure in applications claiming nucleic acids. This use of the written description requirement was qualitatively different because the court conducted a substantive examination of the extent of the disclosure, rather than merely reviewing the specification to find a description (*i.e.*, the words) of the invention.

The Federal Circuit first clearly explicated this standard for nucleic acid claims in the seminal *Eli Lilly* case. In *Eli Lilly*, the Court reasoned that a claim to a specific nucleic acid (in this case encoding human insulin) must contain a description of the DNA itself, as a chemical compound. Using this analysis, the Court held that “[a] written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” 119 F.3d at 1568



In practice, the extent of the disclosure required to support a claim is directly proportional to the complexity and inversely proportional to the predictability of the claimed invention. These relationships pose a particular problem for biotechnology inventions, which are at the same time the most complex and least predictable technologies examined by the Patent Office.

(citing *Fiers*, 984 F.2d at 1171). Courts have subsequently interpreted *Eli Lilly* to require disclosure of a nucleotide sequence for inventions that involve nucleic acids.

Although the Federal Circuit has since expanded the focus of this enhanced written description requirement outside biotechnology inventions, see *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159-60 (Fed. Cir. 1998); and *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998), the Court's increased stringency of review has had the biggest impact on biotechnology patents. Patent applicants have felt this impact during patent procurement before the Patent Office, and likewise patent holders have felt this impact during enforcement of patents in the courts.

Patent Office Written Description Guidelines

The Patent Office now reviews applications under a set of written description guidelines. See Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) ("the Guidelines"). The standard for satisfying the written description requirement, according to the Guidelines, embodies both the traditional and revised approaches. A specification satisfies the written description requirement if one of ordinary skill in the art would understand that the inventors had possession of the invention at the time the application was filed (the priority policeman aspect) and the ordinarily skilled worker would accept that the written description was "adequate" (the substantive aspect introduced by *Eli Lilly*). The Guidelines provide that claims as originally filed are presumed to satisfy the requirement, but

an Examiner can rebut that presumption by showing that one of ordinary skill would not believe that the inventors either possessed or adequately described their invention.

In practice, the extent of the disclosure required to support a claim is directly proportional to the complexity and inversely proportional to the predictability of the claimed invention. These relationships pose a particular problem for biotechnology inventions, which are at the same time the most complex and least predictable technologies examined by the Patent Office.

The more rigid application of the written description requirement under the Guidelines renders the issue of sequence variants problematic for inventions that involve nucleic acids. Although a change of a single nucleotide or amino acid in a claimed nucleic acid or protein can alter (typically, reduce or abolish) its function, the majority of changes will have no effect. Such sequence variants are in every way equivalent to the originally deduced sequence. The Patent Office, however, has interpreted the Guidelines as treating variants as species members of a genus, thereby requiring disclosure of a "representative number" of common structural features sufficient to define the genus adequately. The vast number of combinations and permutations of a sequence possible from any given nucleotide or amino acid sequence render this a practical impossibility. Claims to such variants are important, however, because otherwise one could make a trivial sequence change in a nucleotide or amino acid sequence that does not affect function, and thereby practice an invention that embodies the sequences while avoiding literal infringement of a claim protect-

ing them. Thus, the Patent Office's appraisal of these types of biotechnology claims under the Guidelines has made it more difficult to obtain adequate protection of these inventions, and has reduced the number of patents granted in this area. Stacy Lawrence, *Patent Drop Reveals Pressures on Industry*, 22 Nature Biotech. 930 (2004).

Federal Circuit Written Description Jurisprudence After *Eli Lilly*

Meanwhile, the Federal Circuit has continued to rule in this area. Although, in some respects, these cases have modulated the rigid disclosure rules enunciated in *Eli Lilly*, they have also provided the occasion, in both concurrent and dissenting opinions, for Federal Circuit judges to reveal a deep division in the Court over the application of the *Eli Lilly* holding to biotechnology patent claims.

Three cases are informative. In *Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 99 Civ. 4548 (AKH), 2001 U.S. Dist. LEXIS 23791 (S.D.N.Y. Apr. 4, 2001), the district court found invalid generic claims to nucleic acid probes specific for a disease-causing bacterial strain, as well as species claims reciting nucleic acids deposited in a patent repository recognized under the terms of the Budapest Convention. The Federal Circuit initially affirmed, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002), but after a firestorm of controversy the Court retreated to its traditional position that a deposit of a nucleic acid satisfies the written description requirement. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002). The Court's published refusal to hear the case *en banc* and remand it to the original panel

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The Continued Confusion Over Written Description

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for reconsideration, however, was as informative as the substantive decision. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d (BNA) 1618 (Fed. Cir. 2002). This decision contained three concurring opinions and two dissenting opinions, written or joined by six of the twelve judges, with each opining on the direction of the Court's written description jurisprudence since *Eli Lilly* or on the opinions of the other judges on the question.

Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003), illustrates procedural limitations to the application of the increased stringency of the written description requirement. This case involved the issue of the extent of disclosure necessary to support a claim limitation for human erythropoietin made by "mammalian cells in culture." The specification disclosed two examples (Chinese Hamster Ovary cells and COS-1 (monkey) cells), while the accused infringer used human cells. The Federal Circuit affirmed the district court's determination that disclosure of the two exemplary cell types provided adequate written description support for the broadly recited "mammalian cells in culture." Both the district court and the Federal Circuit, however, evinced some discomfort in their ruling, and the Federal Circuit explicitly based its affirmance on the fact that the patentees claimed the pharmaceutical composition and not the cells themselves. *Amgen Inc.*, 314 F.3d at 1333 (basing its decisions on the fact that "what was claimed was not the cells themselves but recombinant erythropoietin made by the cells"); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 136 F. Supp. 2d 69, 148-49 (D. Mass. 2001) (making its decision "af-

ter much reflection and despite some hesitancy").

The most clear-cut application of the written description requirement under current Federal Circuit jurisprudence is *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). In this case, the University sued several drug manufacturers making drugs (Vioxx®, Celebrex®) that are specific inhibitors of a human protein, COX-2. The inventors had isolated nucleic acids encoding this protein, expressed the protein *in vitro*, and showed that the protein was expressed *in vivo* consistent with its role in mediating pain. The claims at issue recited methods of specifically inhibiting COX-2 in an animal by administering a compound that was a COX-2-specific inhibitor; the patent specification, however, did not disclose such an inhibitor. The district court found, and its finding was affirmed by the Federal Circuit, that the failure to disclose any compound capable of specifically inhibiting COX-2 constituted a failure to satisfy the written description requirement for these method claims, even though the claims did not protect the undescribed inhibitors themselves.

Of course, there is one countervailing case. In *Noelle v. Lederman*, which was an appeal from an interference proceeding, the Federal Circuit upheld the Board of Patent Appeals and Interferences' determination that Noelle's claims were invalid for failure to satisfy the written description requirement. 355 F.3d 1343 (Fed. Cir. 2004). The interference involved claims directed to human antibodies against a specific human antigen, but the specification disclosed only mouse antibodies to the corresponding mouse antigen. Although holding that failure to disclose human antibodies was a failure

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The prudent client and her patent attorney would be wise to craft their disclosure to comply with the heightened requirements, particularly in biotechnology-related patent applications. Generally, increasing the amount of disclosure, including functional data, expression pattern data, or data from transgenic animals, will increase the scope of patent claiming available to a biotechnology applicant.

to satisfy the written description requirement, the Court in dicta tantalizingly opined that a claim to a human antibody against the human antigen would be patentable, even *without disclosure* of such an antibody, if the *antigen* was “fully characterized.” *Id.* at 1349. More remarkable was that the Federal Circuit used as persuasive authority the Guidelines, *id.* (noting that the court in *Enzo Biochem* also treated the Guidelines as persuasive), a stark departure from the Court’s usual resistance to crediting Patent Office practices in its own jurisprudence. See, e.g., *In re Recreative Techs. Corp.*, 83 F.3d 1394 (Fed. Cir. 1996) (noting that the courts must reject administrative statutory constructions that are inconsistent with their statutory mandates).

Quo Vadis Written Description?

Despite the *Noelle* case, a majority of the Federal Circuit judges believe either that the Court’s written description jurisprudence is correct or that the issue is not ripe for *en banc* review. *Enzo v. Gen Probe*, 63 U.S.P.Q.2d (BNA) 1618 (Fed. Cir. 2002). For example, Judge Dyk believes the Court would “benefit from further percolation of these issues.” *Id.* at 1622 (Dyk, J., concurring). Under these circumstances, it is unlikely that the current state of the law will change in the near future.

The level of uncertainty over the future contours of the written description requirement, due to disagreement among Federal Circuit judges, creates difficulties in determining strategies today that can be asserted with any confidence to satisfy the requirement tomorrow. The prudent client and her patent attorney would be wise to craft their disclosure to comply with the heightened requirements, particularly in biotechnology-related

patent applications. Generally, increasing the amount of disclosure, including functional data, expression pattern data, or data from transgenic animals, will increase the scope of patent claiming available to a biotechnology applicant. A patent applicant can limit claim scope as another strategy, for example, by reciting conservative amino acid substitution variants (rather than all sequence variants). In instances where the specification discloses a genus of amino acid sequences comprising several (i.e., greater than two) species, sequence comparisons can form the basis for hypothetical sequences, or can identify invariant residues and the identities of variable residues at specific positions in the sequence. Finally, although of more limited usefulness, a patent applicant can use product-by-process claims to capture products of a synthetic or discovery method that are otherwise undefined by amino acid or nucleotide sequence. See, e.g., U.S. Patent No. 6,541,603 (issued Apr. 1, 2003); U.S. Patent No. 6,376,241 (issued Apr. 23, 2002); U.S. Patent No. 6,326,488 (issued Dec. 4, 2001); U.S. Patent No. 6,281,011 (issued Aug. 28, 2001); U.S. Patent No. 6,083,746 (issued July 4, 2000); U.S. Patent No. 6,083,745 (issued July 4, 2000); U.S. Patent No. 6,043,340 (issued Mar. 28, 2000).

In litigation, biotechnology patents will frequently be at a disadvantage because the Patent Office will have examined and granted the patent before the Federal Circuit signaled its change in the stringency of its application of the written description requirement. This may mean that a patent holder may need to assert narrower claims that are squarely within the explicit disclosure of the specification. Of course, because of the narrower claim scope, this may require alleging

infringement by the doctrine of equivalents instead of literal infringement. On the other hand, such a stringent written description requirement will provide a safe haven from patents with claims broad enough to cover nucleotide or amino acid sequences not disclosed in the specification, especially when the accused infringer obtained the sequence in question independently without reference to patent holder’s disclosure.

Dr. Kevin E. Noonan has extensive experience in biotechnology and the chemical arts. Dr. Noonan brings over 10 years’ experience as a molecular biologist working on high-technology problems to his legal work. Dr. Noonan has wide experience in all aspects of patent prosecution and client counseling on validity, infringement, and patenting strategy matters. He represents pharmaceutical and biotechnology companies both large and small, and he is particularly experienced in representing university clients in both patent prosecution and licensing to outside investors.

noonan@mbhb.com

mbhb News: Congratulations Partners, Welcome Associates

McDonnell Boehnen Hulbert & Berghoff LLP (“MBHB”) has elected five new partners effective January 1, 2005:

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- o Paul W. Churilla
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MBHB also welcomes the following associates, who joined in 2004:

- o Deana C. Larkin, Ph.D.
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With more than 60 attorneys, the firm has been one of the fastest growing in the country. Based in Chicago with a west coast office in the Seattle area, MBHB has broad experience in litigation and prosecution of patents, trademarks and copyrights. Most of MBHB’s professionals have Ph.D.s or other advanced technical degrees and practical experience working in high-tech fields ranging from biotechnology, pharmaceuticals, and medical diagnostics to telecommunications, computers, and electrical engineering.

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300 South Wacker Drive
Chicago, Illinois 60606

312 913 0001 phone
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www.mbhb.com
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