2008-1248

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, AND
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY & COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in Case No. 02-CV-11280, Judge Rya W. Zobel

BRIEF OF AMICUS CURIAE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION ON *EN BANC* REHEARING IN SUPPORT OF NEITHER PARTY

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CERTIFICATE OF INTEREST

Counsel of record for amicus curiae New York Intellectual Property Law Association certifies the following:

1. The full name of every party or amicus represented by me is: New York Intellectual Property Law Association.

2. The party represented by me as amicus curiae is the real party in interest.

3. The parent companies, subsidiaries (except wholly owned subsidiaries), and affiliates that have issued shares to the public, of the party or amicus represented by me are: None.

4. The names of all law firms and partners or associates that appeared for the parties now represented by me in the trial court or agency or are expected to appear in this court are:

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

U.S. Cases

Statutes

Foreign Authorities

Other Authorities

STATEMENT OF INTEREST OF AMICUS CURIAE

The New York Intellectual Property Law Association ("NYIPLA" or "the Association") is a bar association of more than 1,600 attorneys whose professional interests and practices lie principally in the areas of patents, copyrights, trademarks, trade secrets and other forms of intellectual property. Since its founding in 1922, NYIPLA has committed to maintaining the integrity of the U.S. patent law and to the proper application of that law and the related bodies of contract and trade regulation law to commercial transactions involving patents.

The NYIPLA and its undersigned counsel represent that they have authored this brief, that no party or counsel for a party in this proceeding authored any part of the brief, and that no person other than the NYIPLA, its members or its counsel, including any party or counsel for a party, made any monetary contribution intended to fund the preparation or submission of the brief.

The arguments set forth in this brief were approved on or about October 14, 2009, by an absolute majority of the total number of officers and members of the Board of Directors (including those who did not vote for any reason, including recusal), but may not necessarily reflect the views of a majority of the members of the NYIPLA or of the organizations with which those members are affiliated. After reasonable investigation, the NYIPLA believes that no person who voted in favor of the brief, no attorney in the firms or companies with which

such persons are associated, and no attorney who aided in preparation of this brief represents a party in this litigation. Some such persons may represent entities that have an interest in other matters which may be affected by the outcome of this proceeding.

INTRODUCTION AND SUMMARY OF ARGUMENT

Written description and enablement are separate and distinct requirements of 35 U.S.C. § 112 ¶ 1. The codification of a written description requirement predates the requirement of claims, and goes back at least as far as the 1793 Act and probably to the original 1790 Act, which required that the "description" must be "in writing." By the time of the O'Reilly v. Morse decision in 1853, 56 U.S. (15 How.) 62, it was understood that attempting to dominate an entire field by generic functional claiming was prohibited when the applicant had invented and disclosed only limited techniques or apparatus to carry out such function. Though phrased differently, this doctrine has continuing vitality and is today most closely embodied in the requirement that the specification enable the full scope of the claimed invention. Written description survives as a separate requirement with a narrower but vitally important purpose.

Specifically, the modern written description requirement limits claim amendments and polices entitlement to priority. This purpose is prosaic but important: without it, applicants would be able to broaden or otherwise amend their claims during prosecution to embrace subject matter they did not invent (typically, in order to read their claims on later-discovered activities taking place in the market). The enablement requirement is not adequate by itself to stop this, because such amended claims might be enabled even if the inventor had never

contemplated their new subject matter (due to the gap-filling standard of enablement that permits resort to the knowledge of those of ordinary skill in the art).

The enablement requirement serves a different purpose: to ensure that the scope of patent protection is reasonably commensurate with the applicants' technical contribution. In alliance with the requirements of novelty and nonobviousness, the enablement requirement polices the quid pro quo at the heart of the patent system, ensuring that the subject matter put off-limits to the public by virtue of the patent grant is commensurate in scope with the public's enrichment by the specification's teaching (and the invention's advance over the prior art).

To be sure, written description plays a role here too. By (i) preventing applicants from later claiming more than they actually invented (as shown by the content of the application as filed), and (ii) making sure that unwarranted priority claims do not negate the claims-restricting effect of intervening prior art, written description also has a hand in preventing claims that are not reasonably commensurate with the applicants' actual invention. But written description does it in a (usually) simpler, easier to apply way. The intellectual heavy lifting—the policy debate and judgment calls about the "right" scope of claims for pioneering inventions or new technologies—is done by enablement. Vigorous application of the requirement that the specification enable the full scope of the claims, coupled

with the rule that applicants cannot rely on the hypothetical knowledge of those skilled in the art to save a specification that lacks the basic enabling disclosure central to the claimed invention, suffices to prevent applicants from claiming beyond their true contribution. See infra at 24-25.

In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), the Court invoked principles seen in the Morse line of cases to invalidate for lack of written description claims with ipsis verbis support in the original application. Controversy followed as to both (i) the correctness of the result (should the claims have been held invalid?) and (ii) use of written description to reach this result (if the claims were invalid, under what principle of patent law?). As to the latter point, this brief submits that the written description requirement, while it exists, was not the proper legal ground to reach the result.

With respect to the former point, which concerns the correct way to police covetous claiming that seeks to dominate an entire field of endeavor although the applicants' contribution is limited to one (or a few) embodiments, this brief submits that vigorous application of the full-scope enablement requirement is (i) sufficient to address this concern and (ii) provides a more rigorous doctrinal and evidentiary platform than the written description analysis articulated and applied in Regents v. Eli Lilly and its progeny.

NYIPLA takes no position concerning the validity of Ariad's claims.

I. SECTION 112 CONTAINS A SEPARATE WRITTEN DESCRIPTION REQUIREMENT THAT FINDS SUPPORT IN SUPREME COURT CASE LAW DATING BACK TO 1853

The existence of a written description requirement separate from enablement has been a feature of patent law for decades, and is well understood by the innovation community—including patent attorneys, courts, and industry—as ensuring that the entirety of what is eventually claimed was indeed part of the applicant's invention as originally disclosed in the relevant priority application. The recent and ongoing controversy regarding the application of the written description requirement as a substantive regulator of claim scope and a determinant of the patentability of original claims (or claims that are textually supported by the application as filed), especially in the fields of biotechnology and pharmaceuticals, should be resolved on its own merit. This controversy should not call into doubt the long-existing and well-established role of the written description requirement to govern claim amendments and police priority.

A. Whether Called "Written Description" or Not, the Substance of This Requirement Has Long Been Recognized in Section 112 and Its Predecessors

The delineation of a distinct written description requirement (separate from enablement) is commonly traced to Judge Rich's opinion in In re Ruschig, 379 F.2d 990 (CCPA 1967). See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 977-78 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing

en banc) ("Ruschig . . . created for the first time a new WD doctrine to enforce priority."). However, a search of available contemporaneous literature failed to uncover any academic or practitioner commentary on the Ruschig decision, suggesting that it was not recognized at the time as creating any new standard.

Ruschig's lack of a splash at the time may be explained by the fact that the legal standards applied in that case had been established and applied well before 1967, even if Ruschig articulated them differently. For example, In re Ruscetta, 255 F.2d 687 (CCPA 1958), affirmed the Board's rejection of claims that were not described in the parent application by using the intervening publication of the applicant's own U.K. application as a statutory bar. The original U.S. application (and its published U.K. counterpart) disclosed a method of electrolytically etching tantalum. More than a year after this disclosure published (in the U.K. application), the applicant filed a CIP with claims to etching similar metals and alloys. There was no reason why the original application's disclosure of the method with tantalum would not enable it to be used on similar metals, but the claim to priority was still rejected (making the published U.K. application § 102(b) prior art):

> Appellants have been given the benefit of the filing date of their parent application as to what it discloses, and of course they are "entitled" to it to that extent, and the method claims 4-18 specific to the etching of tantalum stand allowed. The claims on appeal, however, being either specific to metals first disclosed in the [CIP] or generic to those metals and tantalum,

> find no support in the earlier applications and it is for this reason that the British specification is cited against them.

Id. at 689. Ruscetta, in turn, relied on In re Steenbock, 83 F.2d 912 (CCPA 1936), which it characterized as "an exact parallel." 255 F.2d at 690.

In Steenbock, the court affirmed the Board's rejection of claims to a method of irradiation fungus to make an anti-rickets product when the parent application disclosed only yeast. 83 F.2d at 913 ("there was no disclosure in [the parent] application of the involved process as applied to fungus material generally—the process there disclosed being limited, so far as fungus material is concerned, to yeast"). Without the benefit of priority, the appealed fungus claims were anticipated by two intervening references. Again, the result is readily understood as applying a description requirement to determine (and reject) the applicant's entitlement to priority.

Thus, even though it may not have been called "written description" (and of course Steenbock predated the current formulation of Section 112 in the 1952 Patent Act), the doctrine that applicants are not permitted to expand the scope of their claims beyond what they described in their applications is not a new or controversial feature of the patent laws. Its purpose was well summarized by the Third Circuit as ensuring that the entirety of what is eventually claimed was indeed part of the applicant's invention:

> Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.

Rengo Co. Ltd. v. Molins Machine Co., 657 F.2d 535, 551 (3d Cir. 1981).

B. A Similar Doctrine, Aimed at Preventing Amendments to Claims That Are Not Supported by the Specification and Controlling Claims to Priority, Can Also Be Found in the Patent Laws of Other Jurisdictions

The prohibition against amending claims in ways that exceed or diverge from the original application is not a peculiarity of the U.S. patent laws.[1] For example, Article 123(2) of the European Patent Convention ("EPC")[2] stipulates that an application or patent "may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed." Article 87(1) provides that an application will enjoy a right of priority "in respect of the same invention" disclosed in an application filed up to twelve months earlier. In explaining the concept of "the same invention," the EPO's Enlarged Board of Appeal held that:

> The requirement for claiming priority of "the same invention" referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent

[1] Foreign authority does not control the interpretation of the Patent Act but, given the general similarity of Western patent law, may be useful to show that the existence of a separate written description requirement of the scope urged herein is neither illogical nor unreasonable.

[2] Convention on the Grant of European Patents, Oct. 5 1973, 1065 U.N.T.S. 255, 13 I.L.M. 270, as amended (available at http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html; last accessed October 14, 2009).

> application . . . is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.

Decision G0002/98 at 25-26 (May 31, 2001). This standard is not dissimilar to that applied in U.S. law.[3] It is also consistent with the rules of priority in Article 4 of the Paris Convention[4] (to which the U.S. is a signatory), a matter of concern to the Enlarged Board because the EPC is "clearly intended not to contravene the basic principles concerning priority laid down in the Paris Convention." Id. at 12.

The U.K. patent statute also embodies separate written description and enablement requirements. Section 14(2) of the Patents Act requires a patent application to contain "a description of the invention," while section 14(3) requires that the application "disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."[5]

And in Canada, section 27(3)(a) of the Patent Act requires that the specification "correctly and fully describe the invention and its operation or use as contemplated by the inventor," while section 27(3)(b) separately requires the

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[3] See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("[O]ne skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims."); Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002) ("[O]ne skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue in the claims.").

[4] Paris Convention for the Protection of Industrial Property, 21 U.S.T. 1583.

[5] Patents Act 1977 (as amended), c. 37, § 14 (available at http://www.ipo.gov.uk/patentsact1977.pdf; last accessed October 14, 2009).

specification to set out clearly the various steps in making or using the invention "in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains" to make or use it.[6]

C. A Mixed Doctrine of Enablement, Description, and Definiteness That Predated the 1952 Patent Act Restricted Generally Claiming the Solution to a Problem or Using Functional Language at the Exact Point of Novelty

The use of written description as a substantive limitation on the scope of patent claims (as developed in the line of cases beginning with Regents v. Eli Lilly in 1997 and leading to the case at bar) is not required because the remedy for claims that are not commensurate in scope with the applicants' contribution (as judged by the application as filed) can be found in the full-scope enablement requirement. In different terms, this restraint on over-claiming can be found in an old line of cases that limited so-called "functional" claiming. The statutory origin (if there was one) of the rules applied in those cases is often unclear, combining elements of what we would today call definiteness, enablement, and written description (in its Regents v. Eli Lilly form) but the existence of the restraint as a feature of U.S. patent law for well over 100 years is clear. As shown below, this doctrine applied to invalidate claims that were not commensurate in scope with the applicants' disclosures, typically because the claims embraced all methods of

[6] Patent Act § 27(3), R.S.C., ch. P 4 (1985) (available at http://laws.justice.gc.ca/en/P-4/index.html; last accessed October 14, 2009).

obtaining a desired result (or all compositions exhibiting the desired properties) even though the specification enabled only limited ways to achieve the claimed goal. The language is different, and the need to determine as a predicate if claims were "wholly functional" may have been abandoned as largely unworkable in practice, but the overriding concept—that claims must be commensurate in scope with the disclosure—is doctrinally sound and fits comfortably within our current statute and precedent that requires the full-scope of claims to be enabled by the specification.

In Morse, the Supreme Court invalidated Morse's general claim to the function of using electromagnetism to print characters at a distance based on his description of a single process for such printing characters at a distance. The Court held that Morse was not entitled to a patent for an effect produced by the use of electromagnetism, as distinct from the process or machinery necessary to produce that effect. 56 U.S. (15 How.) at 120. Cf. In re Hyatt, 708 F.2d 712, 714-15 (Fed. Cir. 1983) (citing Morse and concluding that proper basis for rejection of single-means claim is lack of full-scope enablement).

Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928), relied on Morse to invalidate claims to starch-based glues that functioned similarly to animal glue but, unlike other plant-derived glues, did not require large amounts of water. The Court held that the description of a particular starch glue that

functioned like animal glue did not justify claims to all starch glues with those desirable properties, explaining that a person attempting to use (or avoid) the invention as claimed could do so only after elaborate experimentation. 277 U.S. at 256-57.

The claims in General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364 (1938), recited electric light bulb filaments composed of comparatively large tungsten grains of such size and contour as to prevent substantial sagging and offsetting. Noting that the patent failed to distinguish the claimed invention from a tungsten filament in the prior art that had large grains but was still subject to offsetting, the Court identified the problem of functional claiming as arising when applicants use "conveniently functional" language at the "exact point of novelty," writing:

> The claim uses indeterminate adjectives which describe the function of the grains to the exclusion of any structural definition, and thus falls within the condemnation of the doctrine that a patentee may not broaden his product claims by describing the product in terms of function. "As a description of the invention it is insufficient and if allowed would extend the monopoly beyond the invention." [citing Holland Furniture] The Court of Appeals for the Ninth Circuit relied on the fact that the description in the claims is not "wholly" functional. 80 F.2d 958, 963. But the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but also when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty.

304 U.S. at 371.[7] The Court explained that a primary vice of such "functional" claiming is the tendency to transform a statement of a problem in the art into a claim to a solution that hasn't actually been found:

> A limited use of terms of effect or result, which accurately define the essential qualities of a product to one of skilled in the art, may in some instances be permissible and even desirable, but a characteristic essential to novelty may not be distinguished from the old art solely by its tendency to remedy the problems in the art met by the patent.

Id. at 371-72. Stated differently, it does not suffice to state in the form of a patent claim the alleged solution to a problem that has not actually been solved. This is "an attempt to preempt the future before it has arrived." Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993); cf. Univ. of Rochester v. G.D. Searle & Co., 358

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[7] The issue faced by the Supreme Court in GE v. Wabash calls to mind the issue confronted by this court in 1997 when in Regents v. Eli Lilly it faced claims to a known human gene that had not yet been isolated:

> A definition by function . . . is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

119 F.3d at 1568 (citations omitted). It is also, however, the problem addressed on enablement grounds in Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir 1997), which invalidated for lack of enablement a claim purporting to solve what was set out in the specification as the very problem sought to be avoided. Infra at 24-25.

F.3d 916, 926 (Fed. Cir. 2004) (claiming method for selectively inhibiting COX-2 activity with a nonsteroidal compound without having any such compound that actually does this).

The difficulty of applying the rules of the old cases against "functional" claiming, and the lack of clear statutory grounding in our current Patent Act, may explain why they are today rarely cited or applied. And their lack of objectivity and difficulties of application are suggested by the largely incomprehensible synthesis of a long-ago commentator:

> No new invention can generically transcend the physical conditions inherent in the group of its paramount factors belonging to the organization by which it has been concretely exemplified; nor can the presence of that invention be evidenced by any novel utility other than that which is identified with the direct resultant of the functions conjointly performed by these paramount factors.

1 George L. Roberts, Patentability of Inventions and the Interpretation of Patents 250 (1927).[8] See also William Macomber, The Fixed Law of Patents § 426 at 385 (1909) ("It has been perfectly well settled ever since the time of Corning v. Burden, [56 U.S. (15 How.) 252 (1853)] that a function is not patentable, but to determine whether a claim is so far functional in character as to be invalid is a

[8] Mr. Roberts presciently wrote that his treatise was motivated by his conclusion that the "accumulated and digested patent law of this country lacked precise definition in certain fundamentals, chief among them which was the question: What is a patentable invention?" Id. at vii.

constantly recurring problem."). But the idea behind those rules is part of our current enablement law.

Thus, as discussed below, it is NYIPLA's position that the permissible breadth of claims should be commensurate with, and mainly limited by, the degree of enablement provided in the disclosure of the application. A rigorous application of enablement law should be sufficient to police the scope of claims, while also providing doctrinal clarity and objective standards.

II. THE CORRECT SCOPE AND PURPOSE OF THE WRITTEN DESCRIPTION REQUIREMENT ARE TO GOVERN CLAIM AMENDMENTS AND POLICE ENTITLEMENT TO PRIORITY

The written description requirement operates to ensure that the claimed subject matter does not exceed the applicant's originally disclosed invention via two mechanisms: (i) circumscribing the breadth of permissible claim amendments during prosecution; and (ii) regulating entitlement to the priority date of an earlier application. In both applications, its purpose is as noted above, i.e., to ensure that the subject matter ultimately claimed in a patent application is actually part of the applicant's invention.

A. Application of the Written Description Requirement Ensures That Amendments to Claimed Subject Matter Do Not Exceed the Application's Original Disclosure

Inevitably, there arise situations where an applicant discloses an invention A that enables the practice of a related invention B, but fails to describe

invention B in her original application in a way that shows she regarded it as her own and actually conceived it. In such a situation, the written description requirement prevents her from amending the claims during prosecution to recite invention B (typically in an effort to ensnare products or actions of competitors that are not encompassed by invention A, or sometimes to assert priority of inventorship in an interference). See, e.g., In re Barker, 559 F.2d 588, 593 (CCPA 1977) (application as originally filed disclosed method of making shingle panels having a repetitive series of 8 or 16 shingles as to width; claim amended to recite method of making prefabricated shingle panels having a width of "at least six shingles" failed to comply with description requirement though disclosure clearly enabled manufacture of such panels); In re Wright, 866 F.2d 422, 424 (Fed. Cir. 1989) ("When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of § 112, first paragraph." (emphasis in original)); Purdue Pharma, 230 F.3d at 1320; Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158-60 (Fed. Cir. 1998); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1478-79 (Fed. Cir. 1998); Ruscetta, 255 F.2d at 689-90.

The question of compliance with the written description requirement often arises in connection with an applicant's claim to the priority date of an earlier application. See, e.g., Tronzo, 156 F.3d at 1158; Ruscetta, 255 F.2d at 689; Steenbock, 83 F.2d at 912-13. Entitlement to priority depends, in effect, on whether an amended or added claim, i.e., a claim in a daughter application that was not in the originally filed parent application, is supported by the disclosure of the parent. Here, application of the written description requirement is a special case of its role in limiting the scope of amendments during prosecution of a single application.

In evaluating the permissibility of claim amendments, the written description requirement has a restrictive effect that is analogous to the prohibition of 35 U.S.C. § 132(a) against introducing "new matter" into the specification. In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981) ("a rejection of an amended claim under § 132 is equivalent to a rejection under § 112, first paragraph"). However, because Sections 119 and 120 refer to Section 112 for determining entitlement to priority, it is not sufficient to rely on Section 132(a) for this purpose and abandon the written description requirement of Section 112.

Nor is it sufficient to rely solely on the enablement requirement without causing a profound and unwarranted change to the types of amendments that are permitted, because a specification can enable more than it describes. In re

Barker, 559 F.2d 588, 591 (CCPA 1977). In mechanical inventions, enablement is rarely at issue: there is little doubt that disclosure of the conical cup for the artificial hip joint in Tronzo enabled those of ordinary skill in the art of hip prosthetics to make a hemispherical cup (which was well-known in the art), or that disclosure of the recliner controls on the console in Gentry Gallery enabled ordinarily skilled designers of motion furniture to put them elsewhere. And in the chemical arts, the substitution of related but undisclosed moieties in a chemical structure, a change in reaction conditions, or use of a different synthetic route would often be a matter of absolute routine to graduate chemists or skilled technicians. The written description requirement stops applicants from making up new "inventions" on the fly and after the fact based on what might have been (but wasn't) in their applications.[9]

B. There Is No Need To Use the Written Description Requirement As a Substantive Restraint on Claim Breadth To Augment the Enablement Requirement, Which Itself Can Carry This Weight

Apart from its function in limiting the amendment of claims, the written description requirement does not impose any substantive restraint on the breadth of original claims. This much is clear from the long-established rule that

[9] Indeed, the scope of amendments allowed under U.S. practice even with the current written description requirement is far more permissive than in some other jurisdictions. See, e.g., Andrew Rudge, Guide to European Patents 197, 245 (2009) (explaining for U.S. patent lawyers comparatively strict standards for amendments in EPO practice).

an original claim inherently provides its own description. See, e.g., In re Smith, 481 F.2d 910, 914 (CCPA 1973) ("Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."); McBride v. Teeple, 109 F.2d 789, 796 (CCPA 1940) ("It is elementary in patent law that claims contained in an application as originally filed may be considered as a part of the disclosure of the application.").

A complaint that an original claim is "too broad" is properly directed to the limitations imposed by 35 U.S.C. §§ 102 and 103, and especially the enablement requirement of § 112 which mandates that the specification enable the full scope of the claim. See AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (enabling full scope of each claim is "part of the quid pro quo of the patent bargain"); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) ("The scope of the claims must be less than or equal to the scope of the enablement" to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims."); Auto. Techs. Int'l., Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007); Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008).

Sections 102, 103, and 112 (enablement) set forth express requirements of the statute, with well-established and objective criteria for application. This does not mean that these statutory provisions are always easy to apply, or that claims that might now be invalidated on sight will get to summary judgment proceedings, trial, JMOL, or appeal.[10] But the wealth of precedent in these areas of the patent law permits a rigorous application that can be tested by expert testimony and cross-examination, in contrast to the arguably ad hoc approach that could be said to characterize application of written description as a "super-enablement" doctrine in the fields of biotechnology and pharmaceuticals.

C. Application of the Enablement Requirement Should Be the Main Constraint on Claim Breadth

The present controversy regarding the scope and purpose of the written description requirement can be traced in large part to the holding in Regents v. Eli Lilly that a claim directed to human insulin cDNA was invalid for lack of written description, even though the specification disclosed the amino acid sequence of human insulin and showed how to make cDNA for rat insulin, 119 F.3d at 1562, 1567, without regard to whether this information and technique also enabled isolation of cDNA for human insulin, id. at 1567. However, that decision

[10] Cf. Biogen Inc. v. Medeva PLC, [1996] UKHL 18 ¶ 46, [1997] RPC 1 ¶ 46 (Hoffman, L.) (cautioning that judges would be "well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth" even though it can be "tempting to take an axe to the problem by dismissing the claim without inquiring too closely into which of the conditions [for patentability] has not been satisfied").

can be understood as a necessary corollary to the then-recent decision of In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995), that claims to DNA sequences encoding known proteins were not obvious even when the methods of make such DNAs were in the prior art.

Specifically, the holding of Deuel made possible a potential land-rush of claims to useful DNAs by putative "inventors" who had done nothing more than write down the standard techniques to make a cDNA sequence by reverse transcription from the mRNA for a desired (and known) protein. Because the fact that every protein was coded for by a corresponding gene was known even by educated laymen, the act of naming the gene for a known protein without having it in hand would neither distinguish the applicant's knowledge from that in the art nor enrich the public. The use of the written description requirement to curb this, and keep open the possibility of patents for those who did the hard work of actually isolating and sequencing important DNAs, had much to commend it on policy grounds. But it should be recognized as a significant change in the legal landscape that has now taken on a life of its own, to the extent that it threatens to trump the central role of the enablement requirement in the field of biotechnology and pharmaceuticals.

In the case at bar, for example, the work done by the inventors of the patent-in-suit was of great scientific and technical merit: they did not just write

down a hoped-for solution to a known problem, but seemingly opened the doors to a new class of important drugs. If the question is whether they went far enough beyond elucidation of a scientific principle to merit the rewards of a patent, the answer is properly found in the enablement requirement. Cf. Genentech, 108 F.3d at 1366-67 (rejecting as contrary to the essence of the enablement requirement patentee's argument that knowledge of those skilled in the art made up for specification's lack of disclosure of necessary materials and techniques in the specification, and noting that patents are granted "in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable"). And even the specific problem addressed by the first Regents v. Eli Lilly case has been solved by the de facto overruling of Deuel by In re Kubin, 561 F.3d 1351, 1358-61 (Fed. Cir. 2009), which affirmed the Board's rejection as obvious of claims to a DNA sequence encoding a known protein when the amino acid sequence of that protein, while not published, could be determined by standard techniques.

D. There Is No Reason To Extend Application of the Written Description Requirement Beyond Priority Disputes and Amendment Practice Because the Principle of Full Scope Enablement Is Sufficient for That Purpose

The enablement requirement of patentability has long been recognized as the basis of the quid pro quo between the patentee and the public, i.e., that the patentee is granted a limited monopoly right for his invention in exchange for a

description of the invention that is complete enough to enable the public, upon expiration of the patent monopoly, to make and practice the invention, thereby benefiting from its technological advance, as well as using it as a springboard for further technological development.

The adequacy of enablement to serve this purpose is illustrated by Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997), in which Genentech's patent was directed to a method of producing human growth hormone ("hGH") by recombinantly expressing a longer protein (with a "leader sequence") and then using enzymes to cleave off the excess ("cleavable fusion"). However, the specification did not disclose any enzymes suitable for this purpose, and indeed the bulk of disclosure was directed toward expressing hGH that lacked the leader sequence in the first place. The court rejected Genentech's resort to the knowledge of hypothetical persons of ordinary skill in the art, and on appeal from a preliminary injunction entered in favor of Genentech held the claim invalid for lack of enablement without the need for a remand:

> Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to

> enable members of the public to understand and carry out the invention. . . .
>
> It is true, as Genentech argues, that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

108 F.3d at 1366 (citations omitted).

This rationale and analysis applies across technical fields and is firmly grounded in conventional enablement law. It is the proper basis for substantively policing claim scope and sufficient for this purpose.

The proper balance between competing theories about whether broad claims spur innovation or stifle it is a matter of profound and legitimate dispute. See, e.g., Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839 (1990). The ongoing debate (present in the case at bar) about the permissible scope of biotechnology claims should be resolved on its own merit in a way that does not subvert the long-established and

well-defined role of the written description requirement in limiting amendments and policing priority.

CONCLUSION

For the foregoing reasons, amicus curiae New York Intellectual Property Law Association respectfully submits that (i) 35 U.S.C. § 112 ¶ 1 contains a written description requirement that exists apart from the enablement requirement, and (ii) the scope and purpose of the written description requirement is to regulate amendments to claims (corresponding to the "new matter" prohibition of § 132(a)) and police the right to priority. Apart from the restraints imposed by operation of these rules, the written description requirement does not impose any substantive restraint on the breadth of claims not broadened by amendment, which is appropriately fulfilled by the novelty requirement of § 102, the nonobviousness requirement of § 103, and the full-scope enablement requirement of § 112 ¶ 1.

Respectfully submitted,

NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION

By: 

CHARLES A. WEISS
Chair, Amicus Committee

DATED: October 15, 2009

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Ariad Pharmaceutical v. Eli Lilly, 2008-1248

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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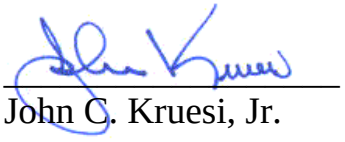

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