

No. 2008-1248

IN THE 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 AND 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* WILLIAM MITCHELL COLLEGE OF LAW
INTELLECTUAL PROPERTY INSTITUTE ON *EN BANC* REHEARING
IN SUPPORT OF ELI LILLY AND COMPANY.**

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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 v. Eli Lilly & Co.

No. 2008-1248

CERTIFICATE OF INTEREST

Counsel for the Amicus Curiae certifies the following (use "None" if applicable; use extra sheets if necessary):

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William Mitchell College of Law Intellectual Property Institute

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

(none)

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

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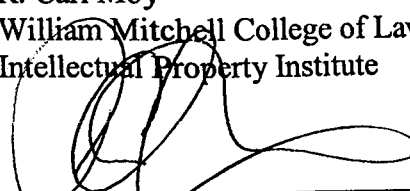
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November 19, 2009

Date

R. Carl Moy
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Intellectual Property Institute



Signature of Counsel

R. Carl Moy

Printed name of Counsel

STATEMENT OF INTEREST

The Intellectual Property Institute (“Institute”) is an entity within William Mitchell College of Law. The mission of the Institute is to foster and protect innovation through education, research, and service initiatives. Among its activities, the Institute advocates for the responsible development and reform of intellectual property law, including patent laws and the patent system of the United States. A purpose of the Institute is to raise issues and arguments in light of the public interest and the best interests of the patent system as a whole. The Institute has no financial interest in any of the parties to the current action.

In accordance with Federal Rule of Appellate Procedure 29(a), the Institute is filing this amicus brief under the authority of the Federal Circuit *en banc* order dated August 21, 2009, inviting *amicus curiae* briefs in this matter. *See* 2009 WL 2573004 (C.A.Fed.).

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I. SUMMARY OF ARGUMENT

The substantive legal issues in this case are largely the result of United States patent system's adherence to the principle of peripheral claim interpretation. That principle assigns a technological scope to the patent claim without any necessary connection to the technological scope of the disclosure in the associated patent specification.

This is problematic because, as result, the patent applicant can choose to present a patent claim whose technological scope exceeds by far that of the specification. In particular, it is possible for the patent applicant to seek rights over an entire genus, when only only an insufficient number of species is disclosed. In fact, it is possible for the applicant to claim broad generic rights even though the specification does not teach any workable embodiment at all.

This appeal presents exactly these difficulties. The claims cover a broad genus, and yet the specification does not teach one of skill to practice even a single embodiment. Because of this, the claimed invention is far from being enabled, and the claims should therefore be held invalid.

Whether any of the rules of disclosure that are involved in this determination are denominated as part of a "description requirement" is largely a

matter of nomenclature. The Institute recommends that the term “description requirement” be reserved solely for use in connection with situations where the applicant has impermissibly shifted the claims of the application by amendment. Therefore, neither of the grounds on which the instant claims are invalid would fall under that name.

II. ARGUMENT

A. The Issues in this Appeal Arise as a Result of Peripheral Claim Interpretation

As has been noted in some authorities, the United States defines the technological scope of a patent right through the paradigm of peripheral claiming.¹

¹*See, e.g.,* N.J. Brumbaugh, *History and Purpose of Claims in United States Patent Law*, pts. I and II, 14 JPOS 273, 426 (1932); Karl B. Lutz, *Evolution of the Claims of U.S. Patents*, 20 JPOS 134 (1938); 1 Anthony W. Deller, *Patent Claims* §§ 7, 11 (2nd ed. 1971).

See, e.g., Ex Parte Fressola, 27 USPQ2d 1608 (Bd. Pat. App. & Interferences 1993), *aff'd.*, 17 F.3d 1442 (Fed. Cir. 1993).

See generally also, e.g., Merrill v. Yeomans, 94 U.S. 568 (1876); *Keystone Bridge Co v. Phoenix Iron Co*, 95 U.S. 274 (1877); *Union Water-Meter Co. v.*

Under that paradigm, the language of the patent claim is read much like that of a contract or statute.² Peripheral claim interpretation thus involves assigning a proper meaning to each word in the patent claim, and then aggregating those meanings together under the rules of grammar and syntax.³

This paradigm exists as an alternative to central claiming.⁴ Unlike

Desper,

101 U.S. 332, 337 (1879) (Bradley, J.); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378-83 (1996).

See generally 1 Moy, *Walker on Patents*, §§ 4:2 - 4:9.

²*See generally, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

³*See generally, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996); *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111 (Fed. Cir. 2004); *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

⁴*See generally, e.g., Toshiko Takenaka, Interpreting Patent Claims: The United States, Germany & Japan*, 17 IIC Studies 1 (1995); 1 Anthony W. Deller, *Patent Claims* § 5 (2nd ed. 1971).

See generally also 1 Moy, *Walker on Patents* § 4:8 (4th ed. 2008).

peripheral claiming, central claiming views the patent claim primarily as a device that points out that portion of the patent specification in which the patented invention has been set out. The technological scope of the patent right is defined directly as the scope of the teaching in that part of the specification.⁵

This distinction is key to understanding the issues in the present case.

Unlike central claim interpretation, there is no guarantee that the technological scope of a peripherally interpreted patent claim will bear any relationship to the technological information in the associated patent specification.⁶ Instead, systems that use peripheral claiming are inherently vulnerable to being misused: it is easy

⁵*See generally, e.g.*, Toshiko Takenaka, *Interpreting Patent Claims: The United States, Germany & Japan*, 17 *IIC Studies* 3 (1995); Mark D. Janis, *Who's Afraid of Functional Claims? Reforming the Patent Law's § 112, ¶ 6 Jurisprudence*, 15 *Santa Clara Comp. & High Tech. L.J.* 231, 251 (1999); David L. Cohen, *Article 69 and European Patent Integration*, 92 *Nw. U. L. Rev.* 1082, 1111 (1998); Klaus Grabinski, *Can and May Determination of the Extent of Protection Conferred by a European Patent in Different Countries Lead to Different Results?*, 30 *IIC* 855 (1999).

⁶*See, e.g.*, Emerson Stringham, *Wirth-Irsay Theory of Patent Interpretation*, 16 *JPOS* 614 (1934).

for the patent applicant to present a claim whose technological scope exceeds his or her actual contribution to the art.⁷ In fact, it is possible for the presented claim to exceed the contribution even by amounts that are fantastically large.

The present case deals with this basic weakness. Over time, applicants are certain to explore zealously how far the technological scope of their patent claims can exceed their actual work. Therefore, once one has decided to interpret claims peripherally, one must adopt a variety of legal rules to police this certainty. Doing so is essential; if the system refuses to invalidate the offending claims it will not operate in good order.

The primary task in deciding this appeal, therefore, is determining whether the asserted patent claims violate any of the legal rules by which this connection

⁷This position is potentially at odds with the dissent's assertion, in *In re Jones*, 10 Fed. Appx. 822 (2001), that "[w]ith the advent of peripheral claiming," "the sufficiency of a written description no longer had relevance to claim scope or validity, except to enlighten the meaning of claim terms." While the written description may no longer be primarily relevant to determining the scope of the claims that the applicant has presented, it remains very important in the determination of whether those claims are valid.

See generally 1 Moy, Walker on Patents § 4:9 (4th ed. 2008).

between the claims and the specification is enforced. Whether any of these rules is part of a “description” requirement is secondary. Clarity and good order probably require that each of the rules be given a separate name. But in the end, this is only a question of nomenclature, and not substance. These nomenclature issues should not control how the appeal is decided.

B. The Technological Scope of a Patent Disclosure Can be Inadequate in at Least Three Ways

There are at least three situations in which the technological scope of an individual patent claim so exceeds the scope of the associated patent specification, that the patent claim is invalid. The first of these is where the specification contains no teaching of any specific embodiment by which the invention can be put into practice.⁸ The second is where the specification does not teach a range of embodiments that is representative of a claimed genus.⁹ The third of these is where the claims of the application are amended to encompass subject matter that the applicant did not originally appreciate.¹⁰

⁸See part II.B.1., *infra*.

⁹See part II.B.2., *infra*.

¹⁰See part II.B.3., *infra*.

The immediately following sections discuss the details of each of these situations.

1. The Patent Specification Must Teach At Least One Specific Embodiment

The first paragraph of section 112 requires that the patent specification be “enabling.”¹¹ The applicant’s most basic duty under this requirement is to teach a skilled reader at least one embodiment of the invention. To do this, the specification must teach three things about the particular embodiment: (i) how it is configured; (ii) how it can be made; and (iii) how it can be used.¹² The authorities agree that these teachings must be such that one of skill in the art can put the embodiment into practice without undue experimentation.

¹¹35 U.S.C. § 112, ¶ 1.

¹²*See, e.g.*, 35 U.S.C.A. § 112, ¶ 1 (“The specification shall contain a written description of the invention, and of the manner and process of making and using it”); 2 William C. Robinson, *The Law of Patents for Inventions* § 484 (1890) (“According to the statutes, the Description must contain full explanation of three different subjects: the invention itself; the manner of making it; and the mode of putting it to practical use”); *In re Honn*, 364 F.2d 454 (1966).

Therefore, where the specification fails to teach the configuration of even one specific embodiment, the associated patent claim is invalid.¹³ An invention can only be practiced in one or more specific forms; it cannot be practiced generically. Accordingly, where the specification does not teach even one specific embodiment, no one in the art can put the invention into practice, and the social justification for patenting is unmet.

This sort of failing occurs much more commonly in the chemical arts than in the mechanical and electrical arts. In these latter two fields, a specific embodiment is usually set out at least in the drawings required by section 113.¹⁴

¹³*See, e.g., In re Hay*, 534 F.2d 917 (CCPA 1976); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993); *University Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004).

¹⁴35 U.S.C. § 113 (“The applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented.”).

See, e.g., In re Gay, 309 F.2d 769 (CCPA 1962) (electro-mechanical apparatus; alleged failure to disclose particular numerical value within claimed range) (“One final point remains to be discussed – the Patent Office requirement based on Rule 71(b) that a ‘specific embodiment’ of appellant’s invention be described in the specification. . . . The term ‘specification’ must be taken to

In the chemical arts, in contrast, the applicant may refer to the invention solely in generic terms. When this happens there is a risk that the specification does not teach any embodiment specifically.¹⁵

There are at least two scenarios in which this sort of failure can occur. In the 1940's and 1950's for example, it appears that some inventors purposefully supplied only generic statements of their inventions, in an effort to both obtain broad patent rights, and still retain the details of their specific embodiments as trade secrets.¹⁶ To combat this, the Patent Office promulgated its Rule 71(b), which required each application to set out at least one specific embodiment of the

include the drawings which are a part of it.”).

¹⁵*See, e.g., Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993); *University Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004).

¹⁶*See generally, e.g., Ex parte Lawsberg*, 124 USPQ 49, 50 (Pat. Off. Bd. App. 1959) (noting that appellant knew of a specific embodiment and did not disclose in specification); *Ex parte Bickell*, 122 USPQ 27 (Pat. Off. Bd. App. 1957) (noting applicant’s offer of evidence at Board hearing of specific embodiments); *Ex parte Hill*, 116 USPQ 457 (Pat. Off. Bd. App. 1957) (noting offer on appeal of evidence, not disclosed in specification, to prove knowledge of person of skill in the art).

invention:

It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.¹⁷

The provision is now section 1.71(b) of Title 37 of the Code of Federal Regulations.¹⁸

Alternatively, the specification may not teach a specific embodiment because the applicant does not actually know of one. This can occur, for example when the applicant has learned to understand the technology or scientific explanation for what has been occurring naturally, but has not yet found any way to alter the natural world into something new and useful. Stated frankly, if one agrees that invention is the act of actually altering the world, situations of this second sort are ones in which the applicant has not yet made an invention. The specification sets forth no invention because the applicant has no invention to disclose.

¹⁷Patent Office Rule 71(b) (1949). Rule 71 was first published in the MPEP in 1949. *See* MPEP ¶ 608.01 (1st ed. 1949).

¹⁸The provision was codified into the Code of Federal Regulations, at 37 C.F.R. § 1.71(b), in 1959. *See* 24 Fed. Reg. 10332 (1959).

Decided cases that fall into this second alternative appear to be mostly recent. Examples include *Fiers v. Revel*¹⁹ and *University of Rochester v. G.D. Searle & Co., Inc.*²⁰ Both stand for the proposition that the discovery of scientific knowledge, even when coupled with a conviction that specific embodiments will eventually be made by someone, does not adequately enable patent rights at the moment.

In terms of specific legal rule, the Court of Customs and Patent Appeals eventually held that, while the specification need not disclose a specific embodiment of the claimed invention *in haec verba*, the specification nevertheless must enable a typical reader to arrive at a specific embodiment relatively quickly – that is to say, without any experimentation that is “undue.” This occurred as early as 1962, in *In re Gay*,²¹ where the court overturned a lack-of-enablement rejection because the specification allowed one “to make and use [the claimed] invention without undue experimentation.”²² Other decisions followed suit.²³ The line of

¹⁹*Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

²⁰*University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004).

²¹*In re Gay*, 309 F.2d 769 (CCPA 1962).

²²*In re Gay*, 309 F.2d 769, 774 (CCPA 1962) (“[W]e feel that one skilled in

cases extends to decisions of this Court.²⁴

This explains why the appellants' reliance on *In re Borkowski*²⁵ is incorrect. *Borkowski* is one of the CCPA decisions that followed *In re Gay*.²⁶ While it does

the art would be enabled to make and use appellant's invention without undue experimentation.”).

²³See, e.g., *In re Fuetterer*, 319 F.2d 259, 262 (CCPA 1963); *In re Long*, 368 F.2d 892, 895 (CCPA 1966) (“If by ‘specific embodiment’ is meant a working example, then the same is not required where sufficient working procedure has been set forth showing that one skilled in the art may prepare the claimed article without undue experimentation.”); *In re Stephens*, 529 F.2d 1343, 1345 (CCPA 1976) (“The test is whether there is sufficient working procedure for one skilled in the art to practice the claimed invention without undue experimentation.”).

²⁴See, e.g., *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990) (citing *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)); *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004).

²⁵*In re Borkowski*, 422 F.2d 904 (CCPA 1970).

²⁶See, e.g., *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970) (citing *In re Long*, 368 F.2d 892 (CCPA 1966) (citing *In re Gay*, 309 F.2d 769 (CCPA 1962))).

stand for the proposition that the specification need not disclose a specific embodiment *expressly*, the opinion goes on to repeat the usual formulation:

[A] specification need not contain a working example *if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.*²⁷

There, the required experimentation was not undue because it could be completed in a few hours.²⁸

2. The Specification Must Disclose a Range of Specific Embodiments That is “Representative”

Under peripheral claiming the patent applicant can present a claim that characterizes his work generically. This possibility exists even if the applicant’s actual accomplishments, and thus his disclosure, are not generic at all.

Accordingly, there is a risk that the patent applicant will be over-compensated, in the sense that he may gain control over much more technology than he has actually invented. Essentially, the risk is that the applicant will dominate too many

²⁷*In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970) (emphasis added).

²⁸*In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970) (“The ‘few hours’ experimentation mentioned by the examiner certainly would not seem to be an undue amount of time considering the nature of the claimed invention.”).

inventions that are yet to be made.

For this reason, a patent system that uses peripheral claiming must contain rules that police these attempts to obtain generic rights prematurely.²⁹ Historically, in fact, controversies over the limits on generic claiming appear to have arisen almost simultaneously with the change to peripheral claiming, in the United States, in the late 1860's and 1870's.³⁰

²⁹For example, the European Patent Convention, which is based largely on central-claiming precedents of Germany, lacks express provisions that call for claims to be invalidated if they are overly broad in relation to the patent disclosure. This has caused considerable difficulty in the UK, which continues to employ peripheral claiming after standardizing the language of its patent statute on the EPC, but now potentially lacks authority to police claims to “free beer.” See, e.g., Mark D. Janis, *On Courts Herding Cats: Contending with the Written Description Requirement (And Other Unruly Patent Disclosure Doctrines)*, 2 Wash. U.J.L. & Pol'y. 55, 102–06 (2000).

³⁰See, e.g., *In re Arkell*, 1871 C.D. 263 (Comm'r. Pat.); *Ex parte Wilson*, 1879 C.D. 108 (Comm'r. Pat.); *Ex Parte Morrison*, 1897 C.D. 169 (Comm'r. Pat.); *Ex parte Smith*, 1879 C.D. 216 (Comm'r. Pat.); *Ex parte Beavis*, 1879 C.D. 231 (Comm'r. Pat.); *Walsh v. Shinn*, 1879 C.D. 279 (Comm'r. Pat.); *Slade v. Blair*,

United States patent law regulates this problem through an overall requirement that the technological scope of the specification be “commensurate”³¹

1880 C.D. 25 (Comm’r. Pat.); *Ex Parte Ewart*, 1880 C.D. 78 (Comm’r. Pat.); *Ex Parte Kent*, 1880 C.D. 115 (Comm’r. Pat.).

“Generic claims” is first set out as a separate heading in the subject-matter index to volume 1879 of the Commissioner’s Decisions.

³¹*See, e.g., In re Moore*, 439 F.2d 1232, 1236 (CCPA 1971); *In re Hogan*, 559 F.2d 595, 605–06 (CCPA 1977) (“Rejections under § 112, first paragraph, on the ground that the scope of enablement is not commensurate with the scope of the claims, orbit about the more fundamental question: To what scope of protection is the applicant’s particular contribution to the art entitled?”); *In re Hyatt*, 708 F.2d 712, 714–15 (Fed. Cir. 1983) (“The proper statutory basis for the rejection of a single means claim is the requirement of the first paragraph of § 112 that the enabling disclosure of the specification be commensurate in scope with the claim under consideration.”); *In re Wands*, 858 F.2d 731, 741 (Fed. Cir. 1988) (“[T]he claims must be commensurate with the inventor’s contribution.”); *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (“[W]hat is necessary is that he [the applicant] provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his

or “reasonably correlated”³² with the scope of the claim. The requirement deals with the chemical arts rather strictly. There, the specification must disclose enough different species so that the disclosed group is “representative” of the genus being claimed. This occurs when each claimed specie can be expected to operate analogously to one of the species disclosed.³³

claims.”); *National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*, 166 F.3d 1190, 1195–96 (Fed. Cir. 1999) (“The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.”).

³²See, e.g., *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (“[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”); *In re Bowen*, 492 F.2d 859, 861–64 (CCPA 1974); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (“There is no reasonable correlation between the narrow disclosure in appellants’ specification and the broad scope of protection sought in the claims”); *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 786 (Fed. Cir. 1988).

³³See, e.g., *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997), *reh’g. denied, in banc suggestion declined*, (Oct. 24, 1997) (representative number of species); *Enzo Biochem, Inc. v. Calgene*,

The failure to satisfy this condition renders the generic patent claim invalid. Modern decisions of this Court that apply this rule include *In re Wright*,³⁴ *Regents of the University of California v. Eli Lilly & Co.*,³⁵ and *Enzo Biochem, Inc. v. Gen-Probe Inc.*³⁶

Inc., 188 F.3d 1362, 1374, (Fed. Cir. 1999), *reh'g. and reh'g. en banc denied*, (Dec. 1, 1999) (disclosure sufficient to allow practice of genus); *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352 (Fed. Cir. 2007), *cert. dismissed*, (U.S. 2008); *Pharmaceutical Resources, Inc. v. Roxane Laboratories, Inc.*, 253 Fed. Appx. 26 (Fed. Cir. 2007).

³⁴*In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

³⁵*Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), *reh'g. denied, in banc suggestion declined*, (Oct. 24, 1997) (disclosure of technology using insulin-encoding cDNA from rats claimed in terms of mammals and vertebrate animals)

³⁶*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002) (disclosure of four amino-acid probes claimed in terms of all probes able to satisfy sought-after function).

3. The Application May be Amended to Claim Subject Matter That the Applicant Did Not Originally Appreciate

The claims in a patent application are not static, but instead can be amended by the applicant during prosecution as a matter of right.³⁷ Consequently, prosecution carries a risk that the applicant will introduce by amendment claims to subject matter that he invented only after the application was originally filed. This is obviously improper; various rules of substantive patent law assume that the subject matter claimed in a patent application was invented, and that the patenting transaction began, no later than the original filing date.³⁸

Whether situations of this sort in the chemical arts need to be controlled through a rule beyond the standard law of enablement is frankly obscure, and the decided cases need to be read very carefully to understand the exact points on which they rest.³⁹

In the mechanical and electrical arts, however, the need for such an additional rule is absolutely clear. There, the legal rule regarding the disclosure

³⁷35 U.S.C. § 132(a).

³⁸*See, e.g.*, 35 U.S.C. §§ 102(a), (b), (e).

³⁹*See, e.g., In re Ruschig*, 379 F.2d 990 (CCPA 1967); *In re McLamore*, 379 F.2d 985 (CCPA 1967); *In re Wertheim*, 541 F.2d 257 (CCPA 1976).

required to enable a genus is notoriously lax.⁴⁰ As a consequence, it is possible that a later-introduced claim – particularly one to a genus – will be considered enabled by the original disclosure, even though the surrounding facts make it clear that the applicant had no thought of the generic invention at the time the application was originally filed.

A recurring example of this is where the applicant files an application that discloses and claims only first specie A, and thereafter learns that someone else has introduced a competing specie B. In these circumstances the applicant has been known to amend the pending application to claim a genus that encompasses both species A and B.⁴¹

This new genus claim is clearly improper, because the applicant did not actually invent the generic form of his work until *after* the original date of filing,

⁴⁰*See, e.g., Beale v. Schuman*, 212 USPQ 291 (Pat. & Trademark Off. Bd. App. 1980); *Ex parte Branham*, 67 USPQ 52 (Pat. Off. Bd. App. 1944); *Ex parte Sundstrand*, 48 USPQ 482 (Pat. Off. Bd. App. 1940).

See also In re Moore, 439 F.2d 1232 (CCPA 1971); *In re Vickers*, 141 F.2d 522 (CCPA 1944).

⁴¹*See, e.g., In re Barker*, 559 F.2d 588 (CCPA 1977); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998)

when it was already anticipated by another's invention of specie B. Yet, it is fairly clear that the legal rules regarding enablement to a genus do not, and cannot, police sufficiently this type of abuse in the mechanical and electrical arts. Accordingly, a different legal rule must be interposed; failure to do so will leave the system vulnerable to being abused.

Modern cases applying this requirement in the mechanical and electrical arts include *In re Barker*,⁴² and *Gentry Gallery, Inc. v. Berkline Corp.*⁴³

The present appeal seems not to present any question as to the proper application of this third requirement. Accordingly, there is no occasion to address its merits in deciding the case. It is discussed here solely to provide background for the nomenclature discussion set out in part II.D., *infra*.

C. The Specification in This Case Does Not Teach Any Specific Embodiment

The foregoing discussion demonstrates that the patent claims asserted by the appellee are invalid. In this case, the applicants filed the relevant specification on April 21, 1989. That specification discusses the pathway by which the nuclear

⁴²*In re Barker*, 559 F.2d 588 (CCPA 1977).

⁴³*Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

factor NF-kB generates inflammatory or immune responses to outside stimuli.

This discussion sets out the operation of pathways that occur naturally. Speaking generally, the discussion is extensive.

The same specification, however, apparently contains little or no discussion of specifically how this pathway can be altered to reduce inflammation or immune responses. Instead, it speculates broadly on the general mechanisms by which such alterations might be accomplished. In particular, it does not teach any specific embodiment by which this alteration can be actually practiced without undue experimentation.

Accordingly, the specification fails to support the asserted patent claims. The claims are directed to methods by which a reduction in NF-kB activity might be achieved. Because the specification fails to teach at least one specific embodiment by which this can be done, the claimed invention is not enabled, for reasons analogous to *Fiers v. Revel*⁴⁴ and *University of Rochester v. G.D. Searle & Co., Inc.*,⁴⁵ as explained in part II.B.1, *supra*.

In addition, the asserted claims are generic. They control the reduction of

⁴⁴*Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

⁴⁵*University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004).

NF-kB activity by essentially any method whatsoever. The art in which the invention resides, moreover, is both chemical and especially unpredictable. Accordingly, the governing law requires the specification to disclose multiple species by which the invention can be actually practiced, such that those species are representative of all the species within the claimed genus.

Because the specification does not teach even one specie by which the invention can be practiced, it necessarily fails this more stringent requirement of supporting a claim to the genus. The generic claims are therefore invalid, because of a lack of adequate support in the specification, analogous to the reasoning in *In re Wright*,⁴⁶ *Regents of the University of California v. Eli Lilly & Co.*,⁴⁷ and *Enzo Biochem, Inc. v. Gen-Probe Inc.*,⁴⁸ as explained in part II.B.2, *supra*.

⁴⁶*In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

⁴⁷*Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), *reh'g. denied, in banc suggestion declined*, (Oct. 24, 1997) (disclosure of technology using insulin-encoding cDNA from rats claimed in terms of mammals and vertebrate animals)

⁴⁸*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002) (disclosure of four amino-acid probes claimed in terms of all probes able to satisfy sought-after function).

D. Are Any of These Three Requirements Properly Referred to as a “Description Requirement”?

The preceding sections of this brief, parts II.B.1 – II.B.3, have explained how the disclosure in the specification of a patent can fall short of supporting a claimed invention in at least three ways. Beginning in about the 1960's, and continuing until the fairly recent past, the term “description requirement” was used only to refer to the third of these situations, where claims introduced by amendment were directed to an invention not recognized initially.⁴⁹

⁴⁹*See, e.g., In re Ruschig*, 379 F.2d 990 (CCPA 1967); *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976); *In re Barker*, 559 F.2d 588, 591 (CCPA 1977); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (“[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.”) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)); *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996) (“The purpose of the adequate written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed.”); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), reh'g denied, in banc suggestion declined, (Apr. 3, 1998).

More recently, at least some decisions from this Court have expanded the use of the term “description requirement,” to include other situations as well. Some of these have used the term where the the specification fails to teach even a single embodiment, and where the range of embodiments taught in the specification is not representative of a claimed genus.⁵⁰

These decisions have violated the basic operating principle that distinct items should be assigned distinct names. It is therefore not surprising that a considerable amount of confusion and disagreement has arisen.

It would improve matters if the law were to return to the state that existed roughly prior to the mid-1990's, in which the term “description requirement” was reserved to situations where offending claims had been introduced into the application by amendment. Violations of the other two types could be addressed

⁵⁰*See, e.g., Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), *reh'g. denied, in banc suggestion declined*, (Oct. 24, 1997); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002); *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004); *University Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004).

The earlier panel decision in the present case is another example of a decision in this category.

as aspects of the enablement requirement.

Even this development, however, would likely leave at least one complication. The term “description” was probably inserted into the statute originally to ensure that patent specification would teach at least one specific embodiment.⁵¹ Until very recently, violations of this sort were very rare. Thus, in the 1960's the statutory term “description” was largely unused and open for appropriation by a mainly new body of law.⁵²

As the present case exemplifies, however, the state of the chemical arts now has progressed to the point where cases presenting the type of defect originally targeted by the term “description” can occur regularly. Improving the law in this area therefore will likely involve distinguishing between this older, more basic requirement, and more modern one centered on improper amended claims.

⁵¹*See generally, e.g.,* Willard Phillips, *The Law of Patents For Inventions* 233 (1837); 2 William C. Robinson, *The Law of Patents for Inventions* § 484, at 73 (1890).

See generally also In re Barker, 559 F.2d 588 (CCPA 1977).

⁵²*See generally*, 1 Moy, *Walker on Patents* § 7:7 (4th ed. 2008).

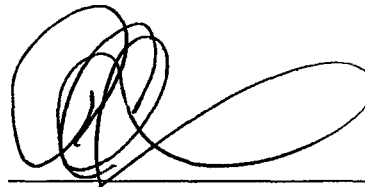
III. CONCLUSION

For the foregoing reasons, the Institute respectfully submits that the decision of the lower court in this matter was incorrect, and that the asserted claims should be held invalid.

Respectfully Submitted,

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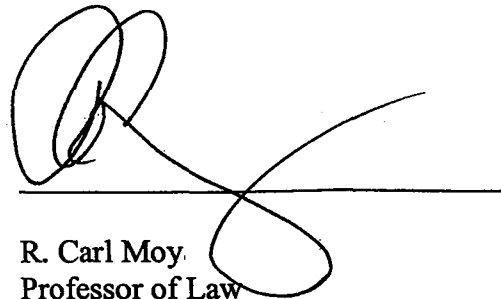
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