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 NOVOZYMES A/S ON *EN BANC* REHEARING IN SUPPORT OF NEITHER PARTY

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CERTIFICATE OF INTEREST

Counsel for amicus Novozymes A/S certifies the following:

1. The full name of every party or amicus represented by me is:

Novozymes A/S

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:

Novozymes A/S

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:

None

4. [X] There is no such corporation as listed in paragraph 3.

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

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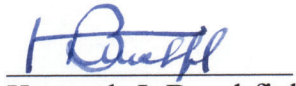

Kenneth J. Burchfiel

October 13, 2009

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INTEREST OF THE AMICUS CURIAE

Novozymes A/S is a world leader in bioinnovation, specializing in the discovery and production of enzymes used in industrial processes, in areas as diverse as removing trans-fats in food and advancing biofuels. With over 700 products used in 130 countries, and over 6,000 patents in the United States and abroad, Novozymes recognizes the critical role of patents in fostering and rewarding bioinnovation.

Broad patent coverage is essential to provide adequate protection against "designing around" by competitors who are easily able to make insubstantial changes in patented biomolecules, avoiding the scope of narrow claims while obtaining the benefit of valuable biotechnology inventions which are clearly enabled by the specification. The written description doctrine developed under *University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) imposes a severe burden on biotechnology innovators, because it frequently limits claim scope that can be obtained in the United States to specific protein and gene sequences, and affords little protection against design around by competitors.

For these reasons, Novozymes urges the Court to overrule *Lilly* and restore the written description requirement to its proper and limited scope, which is to ensure support of claimed subject matter in the original specification.

RESPONSE TO EN BANC QUESTIONS

This Court's en banc order asked the following two questions which Amicus answers as follows:

(1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

Answer: Yes, § 112, first paragraph contains a written description requirement separate from the enablement requirement.

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

Answer: The statute imposes a separate requirement for identification in an original application of subject matter that is first claimed after the original filing or benefit date.

SUMMARY OF THE ARGUMENT

Following *Lilly*, the Court has applied a nonstatutory, heightened requirement of disclosure which far exceeds the traditional written description specified in 35 U.S.C. § 112, first paragraph. Under *Lilly*, biotechnology innovators have been required to provide a description of their inventions that includes a "precise definition" of a biomolecule, which generally requires a specific sequence listing, and to provide a "representative number" of such specific examples to support generic claim scope. *Lilly* has also prevented biotechnology innovators from defining the scope of their inventions using functional definitions, even where functional descriptions precisely and uniquely identify a class of compounds that is enabled by the disclosure.

In fashioning an additional written description requirement that is more stringent in its application to biotechnology inventions, *Lilly* departed from a half-century of precedent recognizing a limited "written description" requirement, which required that claims added to an application after its original filing or benefit date be supported by the original disclosure. This traditional doctrine imposed no requirement of additional disclosure, by examples or otherwise, to provide a "written description" of broad generic claims that were literally set forth in the

original disclosure. Nor did the traditional doctrine proscribe defining or claiming a molecule by its function.

Amicus urges this Court to restore the written description requirement to its traditional original scope, as illustrated by *In re Ruschig*, 379 F.2d 990 (CCPA 1967) and *In re Robins*, 429 F.2d 452 (CCPA 1967), which was uniformly followed until "written description" was cut loose from its statutory moorings in *Lilly*.

ARGUMENT

The issues raised by the present case are of critical importance to biotechnology innovators, such as Novozymes, who are subjected to a stringent "written description" requirement, following the decision in *University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The additional written description requirement developed under *Lilly* has disadvantaged biotechnology applicants and patentees, by restricting the scope of biotechnology claims to an extent that is tantamount to forfeiture of the broader invention that is actually disclosed and enabled by the specification. It is this misapplication of the statutory requirements of § 112, first paragraph which Amicus requests that this Court now rectify by overruling *Lilly*.

A. The Written Description Requirement Is Satisfied Where Claimed Subject Matter Is Supported By The Disclosure Or The Original Claims

The traditional written description standard, which requires disclosure of later-claimed subject matter in the originally-filed specification, is set forth in CCPA and Federal Circuit cases prior and subsequent to *Lilly*. Applying this traditional standard, "the essence of the description requirement of section 112, first paragraph [is] whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the 'later' claimed invention in the specification as filed." *Texas Instruments, Inc. v. International Trade Comm'n*, 871 F.2d 1054, 1062 (Fed. Cir. 1989). *See also*, *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'") (quoting *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)); *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) (quoting *Amgen*); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the

amendment process to update their disclosures (claims or specifications) during their pendency before the patent office."); *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983) ("The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.") (citations omitted).

The traditional written description requirement comes into play in the following circumstances: 1) when an applicant presents a claim which is not present in the application as filed; 2) when an applicant claims the benefit of the filing date of an earlier-filed foreign or United States application for claims in a later-filed application; and 3) when an applicant presents a claim corresponding to an interference count. *Vas-Cath,* 935 F.2d at 1560.

In this limited context, the traditional written description doctrine only requires that the original disclosure "support" later-claimed subject matter by specifically identifying it. *See, e.g., In re Ruschig*, 379 F.2d 990, 996 (CCPA 1967) ("The issue here is in no wise a question of its compliance with section 112, it is a question of fact: Is the compound of claim 13 described therein? Does the specification convey clearly to those skilled in the art, to whom it is addressed, in

any way, the information that appellants invented that specific compound?"); *In re Sus*, 306 F.2d 494, 497 (CCPA 1962) ("While the term 'aryl and substituted aryl radicals' is a broad term, it is not objectionable for this reason alone, if the term is (1) supported by the specification, and (2) if it properly defines the novel subject matter described in the specification."); *In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973) ("But we see no need for either additional representative examples or more definite language to satisfy the description requirement. Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed. Nothing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. 112.") (citation omitted), *reh'g denied*, 480 F.2d 879 (CCPA 1973); *In re Robins*, 429 F.2d 452, 456 (CCPA 1967) (specification satisfies § 112, first paragraph if it "contains a statement of appellant's invention which is as broad as appellant's broadest claims"); *In re Mattison*, 509 F.3d 563, 565 (CCPA 1975) (specification satisfies the written description requirement of § 112, first paragraph, where it contains language that is "as broad as that used in appellants' broadest claims") (citing *Robins*); *In re Smythe*, 480 F.2d 1376, 1382-83 (CCPA 1973) (sufficient disclosure conveyed the information that applicants invented an inert fluid medium, where this generic term

was broader than the specifically disclosed embodiments); *In re Grimme*, 274 F.2d 949, 952 (CCPA 1960) (sufficient disclosure supported a later-claimed subgeneric invention where the subgenus "formed a definite part of appellants' generic invention" disclosed in an earlier application); *In re Wohnsiedler*, 315 F.2d 934, 937 (CCPA 1963) (support for a copied claim must be provided by the applicant's disclosure as a whole) (citing *Gardner*).

Under the traditional standard, it is well settled that an original claim itself satisfies the written description requirement, regardless of its scope, because the underlying concept of ensuring disclosure as of the application filing date is satisfied. *See In re In re Gardner*, 475 F.2d 1389, 1391, *reh'g denied*, 480 F.2d 879, 879-80 (CCPA 1973) ("Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention."); *In re Koller*, 613 F.2d 819, 823-24 (CCPA 1980) ("[O]riginal claims constitute their own description. Later added claims of similar scope and wording are described thereby") (citing *Gardner*); *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971) (originally filed claims, which are part of the disclosure, provided a written description of generic subject matter broader than the disclosure of the specification); *In re Wertheim*, 541 F.2d 257, 264 (CCPA 1976) (an originally filed claim is its own written description).

The CCPA consistently rejected any suggestion that broad claims require written description beyond enablement, provided that the specification or an original claim expressly disclosed an invention of the same scope. *See Robins*, 429 F.2d at 456-57; *Mattison*, 509 F.3d at 565 (written description rejection is improper where language appearing in the written description is as broad as that used in the broadest generic claims); *In re Kamal*, 398 F.2d 867, 870 (CCPA 1968) ("there can be no question that the claims are 'too broad"' where the original disclosure of the invention in the specification indicated the breadth of invention); *Gardner*, 475 F.2d at 1391 (where an original claim constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter claimed, "[n]othing more is necessary for compliance with the description requirement of the first paragraph of 35 USC 112.").

These principles, which were consistently followed until *Lilly*, set forth the correct standard for the written description requirement. The sufficiency of "written description" for original claims, or for claim scope expressly disclosed in the specification, does not depend on the disclosure of specific working examples, or a representative number of species to "justify" broad claim scope. *Robins*, 429 F.2d at 456-57; *Gardner*, 475 F.2d at 1391. Instead, the written description

analysis properly applies only to later-added claims which are not literally identified and thus not "supported" by the original disclosure.

B. The Lilly Written Description Requirement Is Improper Under § 112, First Paragraph

The heightened written description requirement announced in *Lilly* was an abrupt and radical departure from this Court's precedent uniformly followed for the previous half century, and finds no basis in § 112, first paragraph. Amicus considers that *Lilly* and its progeny should be squarely rejected, as imposing a nonstatutory requirement for disclosure that uniquely disadvantages biotechnology innovators, and continues to generate unpredictability in the most dynamic fields of developing technology.

1. The Cases Cited In Lilly Do Not Support An "Additional" Written Description Requirement

The additional written description requirement first fashioned by the *Lilly* panel is neither required nor supported by precedent, and conflicts with the traditional written description doctrine. The heightened standard for biotechnology inventions applied in *Lilly* was based on an amalgam of cases, none of which supports the creation of a written description requirement independent from enablement under § 112, first paragraph. The *Lilly* panel erred in three principal respects: (1) requiring that molecules such as cDNAs be described by "a precise

definition, such as by structure, formula, chemical name, or physical properties" provided by specific sequence information (119 F.3d at 1566, 1568-69); (2) requiring that a genus of cDNAs be supported by "a representative number of cDNAs, defined by nucleotide sequence" (*id.* at 1569); and (3) holding that a definition of a cDNA by function "does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is" (*id.* at 1568).

a) Written Description Does Not Require A Precise Structural Definition Of Biomolecules

The *Lilly* panel held that "[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566, quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). *Fiers*, however, does not require a specific, structural definition of the sequence of a biological molecule to provide a written description under § 112, first paragraph.

The issue in *Fiers* was whether the parties in an interference had shown a conception or constructive reduction to practice of a species within the scope of a count broadly reciting "[a] DNA which consists essentially of a DNA which codes

for a human fibroblast interferon-beta polypeptide." 984 F.3d at 1166. The count thus recited a full-length DNA molecule including the entire coding sequence. Fiers did not disclose the complete nucleotide sequence of the DNA coding for this protein, but only disclosed a method for isolating the DNA of the count. *Id.* at 1168. The Court held that this disclosure did not establish a conception of the compound *per se* recited in the count, without "conception of its structure, name, formula, or definitive chemical or physical properties." *Id.* at 1169. Revel's earliest priority application similarly failed to disclose "the nucleotide sequence or 'an intact complete gene.'" *Id.* at 1170. In the absence of the disclosure of the structure of a complete DNA species within the generic count, Revel was not entitled to benefit of its priority application.

Nothing in *Fiers* suggests that § 112, first paragraph requires that a claimed generic cDNA be further described by a precise structural definition of the DNA, or by disclosure of a number of species within the genus. "Support" for interference counts is not required by either party, and disclosure of a single species entitles a party to benefit with respect to the subject matter of the entire count. *See In re Zletz*, 893 F.2d 319, 323 (Fed. Cir. 1989). In an interference, the requirement for a complete conception or reduction to practice of a single species meeting each limitation of a count led to a heightened standard for priority proofs,

surpassing the description required by § 112, first paragraph. *See, e.g.*, *Wetmore v. Quick*, 536 F.2d 937, 941 (CCPA 1976) (party's disclosure "might describe the invention embodied in the count and enable one skilled in the art to practice the same" but nonetheless be insufficient to establish an actual reduction to practice of the count). Interference cases such as *Fiers*, which relate to conception or reduction to practice of species within the scope of a generic interference count, are of little relevance to the issue of written description support for generic claims under § 112, first paragraph. To the extent that *Fiers* suggests that § 112, first paragraph may more generally require a "precise definition" by sequence information to adequately describe a generic DNA or other biomolecule, this dictum should be rejected for the same reasons as the heightened *Lilly* written description requirement.

The *Lilly* panel similarly relied on *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997), for its holding that "an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" 119 F.3d at 1566. *Lockwood* did not impose a new written description standard, requiring disclosure of specific structures to

support claims of generic scope, but instead related to the issue of benefit where the later-claimed invention was not described in an earlier application.

The issue in *Lockwood* was whether a prior application supported a claim in a later filed application, *i.e.*, whether the earlier application complied with the written description requirement. Because the earlier application did not include specific disclosure of all of the limitations of the claims in the later application, the Court followed the traditional written description doctrine, explaining that "[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." 107 F.3d at 1572.

In contrast, in *Lilly* there was no dispute that the generic scope of the claims, including "vertebrate insulin cDNA" and "mammalian insulin cDNA", was literally disclosed in the specification. Thus, under the traditional written description requirement of *Robins* and *Ruschig* there should have been no issue regarding compliance with the written description requirement, and the *Lilly* panel incorrectly disregarded the generic disclosure of the specification as filed. By extrapolating *Lockwood* – and written description – outside its context of benefit

for a later-added generic claim, the *Lilly* panel departed radically from this Court's precedent. *Lilly*, 119 F.3d at 1566.

The *Lilly* panel further stated that "a description that does *not* render a claimed invention obvious does not sufficiently describe that invention for purposes of Section 112, ¶ 1." 119 F.3d at 1567 (citing *In re Deuel*, 51 F.3d 1552, 1558 (1995) and *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993)). Whatever their relevance to issues of written description, *Deuel* and *Bell* have been effectively overruled by *In re Kubin*, 561 F.3d 1351, 1358-59 (Fed. Cir. 2009). Under *Kubin*, particular DNA molecules encoding a protein may be obvious over a prior art disclosure of a protein, and a known method for isolating the cDNA encoding it. *Id.* at 1360. Therefore, even if the *Lilly* panel's reliance on obviousness decisions was proper, its analysis was not correct.

The *Lilly* panel also relied on *In re Smythe*, 480 F.2d 1376 (CCPA 1973), and its statement that "[i]n other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus…." *Id.* at 1383. In *Smythe*, however, the Court found sufficient support for generic claims that were broader than the embodiments disclosed in the specification. The issue in *Smythe*

was whether the disclosure contained a written description for the recitation "inert fluid." *Id.* at 1382. The specification disclosed examples of air or another gas, but did not disclose the generic fluid, which also encompassed liquids. *Id.* at 1383. Thus, the disclosure was narrower than the scope of the claims. Nevertheless, in *Smythe*, the Court concluded that the applicant complied with the written description requirement, explaining that "we find in the facts here a description of the use and function of the segmentizing medium which would convey to one skilled in the sample-analysis art the knowledge that applicants invented a sample analyzer with an inert *fluid* segmentizing medium." *Id.* at 1384.

The Court observed that "where there is unpredictability in performance of certain species or subcombinations *other than those specifically enumerated*, one skilled in the art may be found not to have been placed in possession of a genus or combination *claimed at a later date* in the prosecution of a patent application." *Id.* at 1383 (footnote omitted, emphases added). However, this statement is inapplicable, and a rejection under the written description requirement is improper, where language appearing in the written description is as broad as that used in the broadest generic claims. *In re Mattison*, 509 F.3d 563, 565 (CCPA 1975).

Finally, the *Lilly* panel relied on the statement in *In re Grimme*, 274 F.2d 949 (CCPA 1960) that "[i]t has been consistently held that the naming of one

member of such a group is not, in itself, a proper basis for a claim to the entire group." Once again, in *Grimme*, the issue was whether the disclosure of a genus in a prior application was an adequate written description of an undisclosed subgenus that was later claimed. 274 F.2d at 952.

None of the cases cited by the *Lilly* panel requires, or even suggests, a general written description requirement mandating a precise definition, provided by disclosure of specific sequence information, for claims to biomolecules such as cDNAs and proteins.

b) Disclosure Of A "Representative" Number Of Species To Support Generic Claim Scope Is Not Required For An Adequate Written Description

The *Lilly* panel recognized that it has long been the rule that "[m]ention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute." 119 F.3d at 1569 (quoting *Robins*, 429 F.2d at 456-57). However, the practical effect of *Lilly* in the biotechnology arts is in fact to require the disclosure of a "representative" number of species within the scope of a generic claim, even where the scope of the generic invention is described in *ipsis verbis* in the specification. The USPTO has interpreted *Lilly* to require disclosure of multiple species as a precondition for obtaining generic claim scope, imposing a heightened standard that applies only to

biotechnology inventions.[1] This "super-enablement" requirement applied to biotechnology inventions clearly departs from the traditional written description doctrine uniformly followed for the previous half century.[2]

Prior to *Lilly*, a written description rejection was improper where language appearing in the written description was as broad as that used in the broadest generic claims. *Only* when an applicant claimed a broader (or narrower) genus than explicitly disclosed in the specification did the Court look to a "representative" number of species to show possession of the later-claimed genus. As Judge Rich explained in *Robins*:

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[1] *See* the current version of USPTO, *Written Description Training Materials*, at pages 1-2 *(*March 25, 2008), available at www.uspto.gov/web/menu/written.pdf ("For each claim drawn to a genus, consider each of the above factors to determine whether there is disclosure of a representative number of species which would lead one skilled in the art to conclude that the applicant was in possession of the claimed invention. The number of species required to represent a genus will vary, depending on the level of skill and knowledge in the art and the variability among the claimed genus. For instance, fewer species will be required where the skill and knowledge in the art is high, and more species will be required where the claimed genus is highly variable."). The 2008 *Training Materials* cite USPTO, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1103 (2001).

[2] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1652-54 (2003) ("In biotechnology, however, the doctrine has been applied as a sort of 'super-enablement' requirement, forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences. (footnote omitted). The written description doctrine as currently applied is a macro policy lever. The Federal Circuit has applied the doctrine to biotechnology cases in a way that would be inconceivable in other industries, such as software.").

> Both the examiner and the board seem to have taken the position that in order to "justify" as the examiner said, or to "support" as the board said, broad generic language in a claim, the specification must be equally broad in its naming, and use in examples, of representative compounds encompassed by the claim language. This position, however, misapprehends the proper function of such disclosure. Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification (which is not the case here) mention of representative compounds may provide an implicit description upon which to base generic claim language.

429 F.2d at 456-57. *See also, In re DiLeone*, 436 F.2d 1404, 1405-06 (CCPA 1971) (originally filed claims reciting "a diamine" without limitation support broad claim scope under § 112, first paragraph, where the specification describes using only certain classes of diamines); *In re Smythe*, 480 F.2d 1376, 1383 (CCPA 1973) (the specification is examined to determine support when a genus or combination not specifically enumerated in the specification is claimed at a later date in the prosecution of a patent application).

c) Defining An Invention By Using Functional Language Complies With The Written Description Requirement

The *Lilly* panel further held that "[a] definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." 119 F.3d at 1568. Instead, the written description must define the genus to enable one skilled in the art to "visualize or recognize the

identity of the members of the genus", *e.g.*, by providing a description of "structural features commonly possessed by members of the genus that distinguish them from others." *Id.*

This standard ignores the reality that persons skilled in the art typically refer to biological materials by their function. Indeed, certain types of compounds in the biotech arts are appropriately – and recognized by those of skill in the art to be – classified by a generic class or functional term, rather than by a specific sequence. For example, the function of encoding a specific protein adequately and precisely defines the genus of cDNAs performing this function, as the Court has recognized, because the description of a complete protein structure provides a written description of the genus encompassing all cDNAs capable of encoding the disclosed protein. *See, e.g.*, *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004); *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) ("an amino acid sequence supports 'the entire genus of DNA sequences' that can encode the amino acid sequence because 'the state of the art has developed' such that it is a routine matter to convert one to the other") (quoting *Wallach*); *Carnegie Mellon University v. Hoffman-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) ("it is now a 'routine matter' to convert between an amino acid sequence and the DNA

sequences that can encode it such that an applicant need not specify each possible permutation of nucleic acid sequences for a particular protein") (citing *Wallach*).

It is noteworthy that in *Lilly*, the structure of the human insulin protein was fully disclosed. 119 F.3d at 1567. The correspondence of generic cDNA encoding a specific protein structure was equally well known, and was specifically described in the patent at issue in *Lilly*. Although a person skilled in the art may not have been *enabled* to derive a specific cDNA encoding human insulin by the patent at issue in *Lilly*, the patent provided the same *written description* of the generic invention that the Court now considers sufficient to satisfy ¶ 112, first paragraph.

With respect to the *Lilly* panel's statement that "[a] definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is" (*id.* at 1568), the Court should clarify that cDNAs, enzymes, and other biomolecules may properly be described solely by reference to their specific biological functions. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071-73 (Fed. Cir. 2005) (claims reciting any polypeptide isolated from a class of organisms and viruses, claimed solely by a combination of functions (DNA polymerase and RNH activity) supported by disclosure of one DNA sequence and one amino acid sequence); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) (functional descriptions of

genetic material do not necessarily fail as a matter of law); *Enzo Biochem, Inc v. Gen-Probe Inc.*, 323 F.3d 956, 961, 965-66 (Fed. Cir. 2002) (a nucleic acid defined only by its biological activity or function may be adequately described by a deposited biological material, without disclosure of the nucleic acid's structure).

Following the traditional written description doctrine, a patentee is entitled to claims of broad generic scope, if the genus is identified in the original application, without any requirement of further supporting disclosure. *See, e.g.*, *In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973); *In re Robins*, 429 F.2d 452, 456-57 (CCPA 1967); *In re Mattison*, 509 F.3d 563, 565 (CCPA 1975).

2. Courts Have Consistently Recognized That The Enablement Requirement Of § 112 Exists To Police Claims Of Undue Breadth

It is well-established that enablement of the claimed invention is a *quid pro quo* for the grant of a patent monopoly. The Supreme Court in *Universal Oil Products Co. v. Globe Oil & Refining Co.*, 322 U.S. 471 (1944) explained that "[a]s a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret. *But the quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired.*…" *Id.* at 484 (emphasis added) (citing

Bene v. Jeantet, 129 U.S. 683, 685-86 (1889); *General Electric Co. v. Wabash Corp.*, 304 U.S. 364, 368 (1938)). More recently in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), the Court reaffirmed the principle stating that "to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires." *Id.* at 142. It is the *disclosure* of the invention to the public sufficient to fully enable its use by the public upon patent expiration that justifies a patent grant, not a written *description* somehow divorced from the public's ability to practice the claimed invention.[1] Indeed, a "purpose[] of the federal patent system" is to "promote[] disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires…." *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979).

[1] *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945) ("By the patent laws Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time, on condition that he make full disclosure for the benefit of the public of the manner of making and using the invention, and that upon the expiration of the patent the public be left free to use the invention. *See Special Equipment Co. v. Coe*, 324 U.S. 370, 378. As has been many times pointed out, the means adopted by Congress of promoting the progress of science and the arts is the limited grant of the patent monopoly in return for the full disclosure of the patented invention and its dedication to the public on the expiration of the patent. *Grant v. Raymond*, 6 Pet. 218, 241-242; *Gill v. Wells*, 22 Wall. 1; *Bauer v. O'Donnell*, 229 U.S. 1; *Motion Picture Co. v. Universal Film Co.*, 243 U.S. 502, 510-511, and cases cited.").

As such, both this Court and its predecessor have recognized that it is the enablement requirement of Section 112 that exists to police the issuance of claims of undue breadth. Decades ago, in *In re Fisher*, 427 F.2d 833 (CCPA 1970) the CCPA held that an applicant who was the first to achieve a potency of greater than 1.0 for adrenocorticotrophic hormones ("ACTHs"), had not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of "at least 1" rendered the claims insufficiently supported under the first paragraph of § 112. *Id.* at 839 ("an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 USC 112."). More recently, this Court applied the *Fisher*-based reasoning in *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), and stated that "[t]o be enabling, the specification of the patent must teach those skilled in the art how to make and use the *full scope* of the claimed invention without 'undue experimentation.'" (quoting *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361,

1365 (Fed. Cir. 1997)). The Court explained that "[t]he first paragraph of 35 U.S.C. § 112 effectively requires that 'the *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.'" *Id*. at 1339-40 (emphases added) (quoting *Fisher*, 427 F.2d at 839).

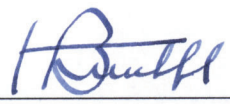
Because the ability of the public to practice a claimed invention after patent expiration is at the heart of the *quid pro quo*, the enablement requirement is the standard against which claim scope must be measured. For only the enablement requirement demands consideration of the skilled practitioner in reproducing the claimed invention based on, *e.g.*, the patent disclosure, the knowledge in the art, and the many factors articulated in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

In summary, applicants should be able to obtain generic claims to any originally-identified subject matter, without additional "written description," provided that the disclosure fully enables the scope of the claimed subject matter. Ignoring this Court's precedent, the *Lilly* panel departed from the traditional written description doctrine, which applies only in the context of later-claimed subject matter.

CONCLUSION

The Court should restore the written description requirement to its proper scope, which is to ensure that claims added to an application after its original filing or benefit date are supported by the original disclosure. The written description requirement, thus confined, should be distinguished from the enablement requirement of 35 U.S.C. § 112, first paragraph.

Respectfully submitted,



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October 13, 2009

Ariad Pharmaceutical v. Eli Lilly, 2008-1248

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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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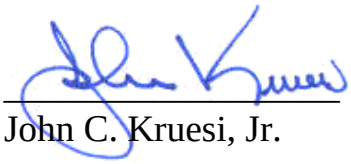

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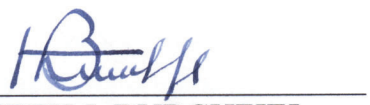

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