No. 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 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 MONSANTO COMPANY IN SUPPORT OF ELI LILLY & COMPANY AND AFFIRMANCE

Dennis R. Hoerner
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167
(314) 694-1000
Of Counsel

Nancy J. Linck
Minaksi Bhatt
Martha Cassidy
Rothwell, Figg, Ernst & Manbeck, P.C.
1425 K Street, N.W., Suite 800
Washington, DC 20005
(202) 783-6040

Attorneys for Amicus Curiae Monsanto Company

November 19, 2009

CERTIFICATE OF INTEREST

Counsel for amicus curiae, Monsanto Company, certifies the following:

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

Monsanto Company.

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

Monsanto Company.

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

None.

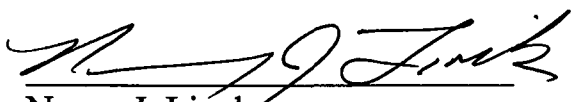
4. The names of all law firms and the partners or associates that appeared for the party of amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Monsanto Company: Dennis R. Hoerner

Rothwell, Figg, Ernst & Manbeck: Nancy J. Linck, Minaski Bhatt and Martha Cassidy

Dated: November 19, 2009

Rothwell, Figg, Ernst & Manbeck, P.C.



Nancy J. Linck

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

STATEMENT OF INTEREST OF AMICUS CURIAE

Monsanto Company ("Monsanto") is a leading global provider of agricultural products, including biotechnology seed traits and herbicides that improve agricultural productivity to feed, fuel and clothe a constantly growing world population. Monsanto spends over $2 million per day on research and development of seeds for transgenic plants to make such improvements. That research and development generally requires 5 to 8 years from concept through regulatory agency approval in multiple countries before commercial launch of a product. There are two significant factors relating to patent rights that directly impact Monsanto's willingness to make this investment.

First, Monsanto, like other biotechnology companies, must be able to accurately determine whether a future patent will impede either the research and development or the commercial use of its innovations. At the time of filing, a patent application should reasonably identify unclaimed inventions that would be entitled to the original filing date, if later claimed. The description of the patent specification must serve the notice function to inform the skilled artisan that the patent applicant or patentee earlier invented and therefore is entitled to claim any described subject matter. The traditional written description requirement in existence prior to *Regents of the University of California. v. Eli Lilly & Co.*, 119

F.3d 1559 (Fed. Cir. 1997)[1] ("*Lilly* 1997"), is adequate to address this issue, if applied correctly and coupled with vigorous enforcement of the separate enablement requirement.

Second, Monsanto must be able to obtain suitably broad patent claims to prevent competitors from simply designing around its inventions and must be able to assess accurately the scope of protection it will be able to obtain. Without broad patent protection, competitors can easily make insubstantial changes in the specific DNA of the commercial product and cheaply reap the benefit of any of the valuable biotechnology inventions that are enabled by Monsanto's specification.

The enhanced written description requirement that has developed under *Lilly* 1997 imposes a severe burden on biotechnology innovators because it frequently limits claim scope that can be obtained in the United States to a small number of specific protein and gene sequences and affords little protection against design-arounds by competitors. Investment in research and development in agricultural biotechnology that relies on patents with claims relating to DNA is discouraged by the enhanced written description requirement.

---

[1] Judge Lourie, the author of *Lilly* 1997, relied upon *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), an interference case he also authored, to support the enhanced written description requirement. While *Fiers* espoused the enhanced written description requirement in 1993, it went little noticed until *Lilly* 1997, likely due to the peculiarities expected in interference law. Many in the patent field consider *Lilly* 1997 to be the first non-interference case in which it was applied.

I. RESPONSE TO EN BANC QUESTIONS

Amicus Monsanto responds to this Court's two questions as follows:

1. Does 35 U.S.C. § 112 ¶ 1 contain a written description requirement separate from an enablement requirement?

Answer: Yes. The first paragraph of § 112 contains a written description requirement separate from the enablement requirement, *i.e.*, the traditional written description requirement, analogous to the prohibition against adding new matter to the rest of the specification under 35 U.S.C. § 132. The parties have taken extreme positions on this issue. Ariad claims there is no separate written description requirement (Ariad Br., at § I), and Lilly claims the enhanced written description requirement has existed at least since *O'Reilly v. Morse*, 56 U.S. 62 (1853). Lilly Br., at p. 2. In fact, neither of these positions is supported by the history of the written description 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 scope and purpose of the traditional written description requirement is limited, requiring only recitation of the claimed invention in an original claim or in the specification in such a manner to reasonably identify the later claimed invention, thereby giving third parties reasonable notice that the applicant invented the subject matter as of the filing date.

II. SUMMARY OF THE ARGUMENT

The written description and enablement requirements have been recognized as separate requirements for a very long time, at least since *Ruschig* and perhaps earlier. The written description requirement serves an important notice function that enablement does not—that of identifying with reasonable certainty what the inventor actually invented at the time the application was filed. By doing so, it permits others in the relevant art the opportunity to build upon what has been disclosed but not identified as belonging to another.

Unlike the enhanced written description requirement imposed by *Lilly* 1997, the traditional written description analysis is straightforward for originally-filed claims and later-added claims that are supported *in haec verba*. With respect to other later-added claims, pre-*Lilly* 1997 precedent provides clear guidance to those charged with examining claims for written description support.

The traditional written description requirement prevents hindsight aggregation of words and/or phrases in a specification in order to claim subject matter not contemplated at the time of filing. In this regard, at least some anticipation cases acknowledge that an anticipatory reference must identify all the elements of the claim "as arranged in the claim," or that the reference must "describe" the claimed invention. Thus, by analogy, these cases also can aid the written description analysis.

The traditional written description requirement, when coupled with the requirement that claims must be enabled for their full scope, fully addresses the concerns § 112, ¶ 1 was designed to address. In this case, enablement prevents over-reaching by claiming all ways to reduce NF-κB activity without resort to applying an often confusing enhanced written description requirement.

For these reasons, Monsanto urges this Court to

(1) abolish the enhanced written description requirement imposed by *Lilly* 1997;

(2) recognize there is a separate written description requirement, *i.e.*, the traditional written description requirement, and reaffirm its impact on aggregating elements such as was attempted in *In re Ruschig*, 379 F.2d 990, 993-95 (CCPA 1967);

(3) acknowledge that the enhanced written description requirement, applied in *Lilly* 1997, has confused and frustrated the law on written description and has denied inventors protection of otherwise meritorious inventions, particularly in the biotechnology arts; and

(4) recognize the important role the enablement requirement plays and its impact on claims defined by recitation of a single function, as was previously done in *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983).

III. ARGUMENT

A. The Written Description Requirement Furthers Progress In The Art By Providing Notice Of Inventions That Can Be Claimed As Of The Effective Filing Date

Important benefits of the patent system flow from the opportunity to further advance the art based on information published in new patent applications and newly issued patents and to design around published claims. When a skilled artisan working in the relevant field cannot ascertain with reasonable certainty from a patent specification what inventions can be claimed by amendment, in a continuing application or through reissue, these benefits are frustrated. See *Muncie Gear Works v. Outboard, Marine & Mfg.*, 315 U.S. 759, 870 (1942) ("To sustain the claims [to an invention not described until more than two years after the claimed device was used in public or sold] . . . would require a plain disregard of the public interest sought to be safe-guarded by the patent statutes . . . .").

Thus, the skilled artisan attempting to design a clear path forward, free of infringement liability, must have reasonable notice of what a patent applicant or patentee considers his or her invention to be. That notice can be provided through a written statement of the invention in the specification. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991) (quoting *Evans v. Eaton*, 20 U.S. 356, 434 (1822)) (one object of the specification before claims were required

was "to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented").

When properly applied, the traditional written description requirement prevents addition of new (undescribed) matter to patent claims and thus provides others in the relevant field sufficient notice of what an applicant or patentee is entitled to claim. However, imposing an enhanced written description requirement, as has been done following *Lilly* 1997, does not benefit this purpose, has introduced uncertainty in the law, and has frustrated the protection of potentially valuable biotechnological inventions. For instance, USPTO examiners routinely frustrate the granting of otherwise enabled, originally-filed claims by imposing improper written description rejections under the enhanced standards of *Lilly* 1997.

1. The written description requirement is satisfied where claimed subject matter is identified in the original claims

An original claim satisfies the traditional written description requirement, regardless of its scope, because the underlying concept of ensuring notice as to what the applicant invented as of the application filing date is satisfied.[2] *See, e.g.,*

[2] At least theoretically, the specification could be amended such that the claim scope is changed, for example, by changing the definition of a claim term and thereby effectively amending the claim. In such a case, however, the claim would no longer be considered an original claim and would not be protected from scrutiny for written description under § 112, ¶ 1.

In re Koller, 613 F.2d 819, 823-24 (CCPA 1980) ("[O]riginal claims constitute their own description"); *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971) (while recognizing there is a written description requirement apart from the enablement requirement, finding that the broad recitation of "a diamine" in an originally filed claim provided the needed written description for the claim term); *In re Wertheim*, 541 F.2d 257, 264 (CCPA 1976) ("claim 4, an originally filed claim, is its own written description").

The breadth of an original claim does not negate the general proposition that an original claim is its own written description. Regardless of its breadth, the language of an original claim puts skilled artisans on notice that the inventor is claiming such subject matter as the inventor's own invention. *See, e.g., In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973) (hereinafter "*Gardner I*") ("Claim 2, . . . 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."). Of course, satisfying § 112, ¶ 1 also requires the claim be enabled for its full scope--a requirement that grows in difficulty with claim breadth. *See In re Gardner*, 480 F.2d 879, 879 (CCPA 1973) (hereinafter "*Gardner II*") (explaining the court's affirmance of the

§ 112, ¶ 1 rejections of original claims in two earlier cases: "there was insufficient support for claims of such breadth, in the sense of enabling disclosure").

2. The written description requirement is satisfied where claimed subject matter is identified in the original disclosure

With respect to amended or later-added claims, the traditional written description requirement is sufficient to serve the notice function, if properly applied to these claims. Language found in the originally filed specification and placed into a claim *in haec verba* satisfies the requirement, just as an original claim does. *See, e.g., Gardner II*, 480 F. 2d at 880 (delineation of a subgenus "was equally a 'written description' whether located among the original claims or in the descriptive part of the specification"). However, the notification of the written description requirement may be satisfied without *in haec verba* support for the newly claimed subject matter. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). When such literal support is lacking, the analysis becomes somewhat more difficult but is guided by many years of precedent prior to *Lilly* 1997. *See id.* at 1323 ("one skilled in the art, reading the original disclosure, must 'immediately discern the limitation at issue' in the claims"); *In re Robins*, 429 F.2d 452, 456 (CCPA 1970) (specification satisfies § 112, first paragraph, if it "contains a statement of appellant's invention which is as broad as appellant's broadest claims"). This analysis also is guided by anticipation cases

discussing the need for a description of the claimed invention in the alleged anticipation reference. *See infra* at pp. 10-11.

3. The written description requirement should preclude aggregating elements to describe a later-recognized invention

When the language in an originally-filed application does not provide *in haec verba* support for amended or later-added claims, words and/or phrases in the originally-filed application cannot be cobbled together to form such claims without reasonably clear teachings to do so. The specification must reasonably convey to the skilled artisan that the inventor has identified in writing what he or she invented and later sought to be claimed. *See, e.g., Ruschig,* 379 F.2d at 995-96; *In re Arkley*, 455 F.2d 586, 576 (CCPA 1972).

Hindsight reconstruction to create a description of an invention not originally contemplated is not permitted. As a simple example, if one of ordinary skill in the art would not have envisioned the combination of individually identified elements A, B and C in view of the teachings in the specification, then a claim to a combination ABC is not described under the traditional written description requirement. This situation is analogous to the requirement that a reference cannot anticipate a claim unless each and every claim element is taught by the reference *and* the elements in the reference are "*arranged as in the claim.*" *Finisar Corp. v. DirectTV Group, Inc.*, 523 F.3d 1323, 1334-35 (Fed. Cir. 2008)

(emphasis added) (remanding to the district court to determine whether the elements in the reference were "arranged" as in some of the claims). *Accord, e.g., Arkley*, 455 F.2d at 576 (in reversing a § 102 reference because it did "not identically describe the claimed subject matter," the CCPA noted that such a reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference").

The Federal Circuit has recognized that there must be teachings in the originally-filed disclosure directing the skilled artisan to the later claimed invention, like "blaze marks" on trees marking a trail:

> The case of *In re Ruschig* . . . is instructive here. . . . The claim at issue in that case was directed to a single compound. The applicants argued that, although the compound itself was not disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The *Ruschig* court rejected that argument, stating:
>
> > It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared—or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. . . . We are looking for blaze marks which single out particular trees. We see none.

> . . . As Ruschig makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention." In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.

Purdue Pharma, 230 F.3d at 1327 (quoting *Ruschig,* 379 F.2d at 994-95). "Blaze marks" also have been treated as relevant to the anticipation inquiry. *See Arkley*, 455 F.2d at 589 (quoting Ruschig's "blaze marks" language).

In a very recent case, this Court rejected an attempt to aggregate elements by relying on a later-constructed table that listed the number of times words appeared in the specification and pages where the words appeared as support for written description. More specifically, in addressing claim limitations lacking written description, this Court noted that the Board had rejected Hyatt's tabulation of the individual words in the claims and their location as "unhelpful in identifying written description support." This Court then quoted language from the Board opinion:

> We agree with the examiner that merely pointing to isolated words scattered throughout the specification does not describe the invention claimed as a combination of elements, functions, and interconnections, anymore than a dictionary provides written description support for a book where words are used in combination to provide a certain meaning.

Hyatt v. Doll, 576 F.3d 1246, 1252 (Fed. Cir. 2009). In deciding *Hyatt v. Doll*, this Court also rejected Hyatt's attempt to aggregate elements saying: "To suggest

Table-1 is helpful in determining where in the specification support for these limitations may be found borders on insolent." *Id.* at 1275 n.32.

The following quotation illustrates the Court's reasoning in *Hyatt*:

> Hyatt argues . . . the record before the Board cited and contained adequate written description for all the claims rejected by the Board. . . . Hyatt's arguments rely almost entirely on Table-1. . . . Table-1 simply lists certain individual words used within various multi-word limitations, the number of times each such word appears in the specification, and "representative" pages in the specification where each word appears . . . . For example, certain claims were rejected for lacking written description support for a "processor responsive to an accessed block of video pixel image information." Table-1 indicates that "block" was used over 80 times on at least pages 25-83 and 128-164 of the specification; "information" was used over 100 times "throughout" the specification; "video" was used exactly eight times on at least pages 77, 166, and 168-71; etc. Table-1 does not, however, explain how any of these individual occurrences of these substituent words discloses a "processor responsive to an accessed block of video pixel image information."

Id. at 1278-79 (citations omitted).

Prohibiting such cobbling together of words and/or phrases to amend or add new claims prevents patent applicants from circumventing the notice function of the traditional written description requirement to effectively add new inventions to their application. *See, e.g., Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office"). The notice function permits those working in the relevant art to rely on their assessment of the scope of protection

available to the inventor at the time the application was filed. Consistent with pre-*Lilly* 1997 law, including *Ruschig* and *Hyatt v. Doll*, this Court should reaffirm that mere words within an originally-filed specification cannot be cobbled together to support later-added claims when one of ordinary skill in the art would not have been taught to do so by the originally-filed specification.

B. Ariad Claims All Ways for Reducing NF-κB Activity Through the Use of Functional Language and By Doing So Has Failed to Enable the Full Scope of Its Claims

There appears to be no allegation that the language of Ariad's claims was not recited in Ariad's specification as of the effective filing date of April 21, 1989 which is the filing date of the seventh in a series of nine prior applications filed between January 9, 1986 and April 6, 1995. *See Ariad Pharmaceuticals v. Eli Lilly & Co.*, 529 F. Supp. 2d 106, 139 (D. Mass. 2007). In any case, it is not necessary to decide the written description issue in this case, as the claims clearly are not enabled for their full scope.

All the Ariad claims at issue recite a single functional limitation: "reducing NF-κB activity" in a eukaryotic, mammalian or human cell. See claims 80, 95, 144 and 145 in U.S. Patent No. 6,410,516 (reproduced in *Ariad Pharmaceuticals v. Eli Lilly & Co.*, 560 F.3d 1366, 1370 (Fed. Cir. 2009)).

Such claims are analogous to the "'single means claim'. . . reciting only a single element" for performing a given function that this Court held did not satisfy

the enablement requirement in *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983). In *Hyatt*, this Court identified the "long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor." *Id.* (citing *Morse*, 56 U.S. at 112) (footnote omitted).

At one time, claiming solely by a means or step for performing a function rendered the claim invalid. *See Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 12 (1946) (rejecting functional claiming because of its breadth and ambiguity). However, as part of the Patent Act of 1952, Congress enacted legislation that partly superseded *Halliburton*. *See, e.g., In re Donaldson Co.*, 16 F.3d 1189, 1194 (Fed. Cir. 1994) (Congress enacted predecessor of § 112, ¶ 6 in response to *Halliburton*). "Section 112, ¶ 6, now expressly allows so-called 'means' claims, with the proviso that application of the broad literal language of such claims must be limited to only those means that are 'equivalen[t]' to the actual means shown in the patent specification." *Warner-Jenkinson Co. v. Hilton Davis Chemical*, 520 U.S. 17, 27 (1997) (citations omitted; modification Court's). More specifically, the statute addresses the Court's concern about claim breadth by requiring that broad functional language be "construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." § 112 ¶ 6.

The statute does not protect all functional claiming, however, but limits its protections to combination claims: "An element in a claim *for a combination* may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof . . . ." § 112, ¶ 6 (emphasis added). Therefore, only combination claims fall under this language. Single means claims do not and thus fail to meet the enablement requirement. *See In re Hyatt*, 708 F. 2d at 714-715. Likewise, single acts or steps, such as that claimed here, would not fall under the limiting impact of § 112, ¶ 6 to save a functional claim from invalidity under *Halliburton* and would fail to meet the enablement requirement, just as the means claim in *Hyatt* failed.

As noted by Judge Linn, this Court did not consider the applicability of *Hyatt* to this case. *Ariad*, 560 F.3d at 1381 (Linn, J., concurring in judgment) (characterizing this enablement issue as "an important issue that we have left unresolved"). Monsanto respectfully submits that the Court should reconsider this important unresolved issue and conclude that Ariad's functional claims are overly broad and therefore fail the enablement prong of § 112, ¶ 1.

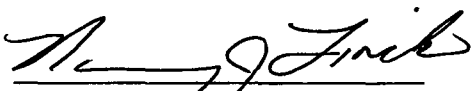
IV. CONCLUSION

For the foregoing reasons, Monsanto respectfully requests this Court to (1) overrule *Lilly* with respect to its imposition of an enhanced written description requirement and to restore the more limited traditional written description requirement;

(2) reaffirm that the written description requirement's notice function prohibits the aggregation of words and/or phrases to form new claims for which the skilled artisan had no notice in the originally filed specification; and

(3) reaffirm that claims must be enabled for their full scope and extend its reasoning in *In re Hyatt* to claims limited only to a single function such as those in this case.

Respectfully submitted,



Nancy J. Linck
Minaksi Bhatt
Martha Cassidy
ROTHWELL, FIGG, ERNST & MANBECK
1425 Street, N.W., Suite 800
Washington, DC 20005
(202) 783-6040

Attorneys for Amicus Curiae
Monsanto Company

Of Counsel:
Dennis R. Hoerner
Monsanto Company
800 N. Lindbergh Blvd
St. Louis, MO 63167

November 19, 2009

CERTIFICATE OF SERVICE

The undersigned hereby certify that two true and correct copies of the foregoing **BRIEF OF AMICUS CURIAE MONSANTO COMPANY IN SUPPORT OF ELI LILLY & COMPANY AND AFFIRMANCE** were served this 19th day of November, 2009 by Federal Express, overnight courier, postage pre-paid, on the following principal attorneys of record:

Leora Ben-Ami
Kaye Scholer LLP
425 Park Avenue
New York, NY 10022
Principal Attorney for Plaintiff-Appellees ARIAD Pharmaceuticals, Inc., The President and Fellows of Harvard College, Massachusetts Institute of Technology, and The Whitehead Institute for Biomedical Research

Charles E. Lipsey
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
Principal Attorney for Defendant-Appellant Eli Lilly and Company

Christopher M. Holman
University of Missouri-Kansas City School of Law
5100 Rock Hill Road
Kansas City, MO 64110-2499
Principal Attorney for Amicus Curiae Christopher M. Holman

Herbert C. Walmsley
Intellectual Property Owners Association
1501 M Street, N.W., Suite 1101
Washington, DC 20005
Principal Attorney for Amicus Curiae Intellectual Property Owners Association

Mark D. Janis
Indiana University
Maurer School of Law
211 South Indiana Avenue
Bloomington, IN 47405-7001
Principal Attorney for Amici Curiae Mark D. Janis and Timothy Holbrook

William P. Atkins
Pillsbury Winthrop Shaw Pittman, LLP
1650 Tysons Boulevard, 14th Floor
McLean, VA 22102-4856
Principal Attorney for Amicus Curiae Medtronic, Inc.

Lynn H. Pasahow
Fenwick & West, LLP
801 California Street
Silicon Valley Center
Mountain View, CA 94041-2008
Principal Attorney for Amici Curiae NDSU Research Foundation, Rensselaer Polytechnic Institute, Research Corporation Technologies, Inc., STC.UNM, The Regents of the University of California, The Research Foundation of State University of New York, The University of Texas System, University of Rochester, and Wisconsin Alumni Research Foundation

Charles A. Weiss
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004-1007
Principal Attorney for Amicus Curiae New York Intellectual Property Law Association

Kenneth J. Burchfiel
Sughrue Mion, PLLC
2100 Pennsylvania, Ave., N.W., Suite 800
Washington, DC 20037-3213
Principal Attorney for Amicus Curiae Novozymes A/S

Roberta J. Morris
Stanford Law School
Crown Quadrangle
559 Nathan Abbott Way
Stanford, CA 94305-8610
Principal Attorney for Amicus Curiae Roberta J. Morris, Esq., Ph.D.

Mark R. Freeman
U.S. Department of Justice
950 Pennsylvania Avenue, N.W., Room 7237
Washington, DC 20530
Principal Attorney for Amicus Curiae United States of America

Nancy J. Linck

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing BRIEF OF AMICUS CURIAE MONSANTO COMPANY IN SUPPORT OF ELI LILLY & COMPANY AND AFFIRMANCE contains 3,820 words as measured by the word processing software used to prepare this brief.

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

Dated: November 19, 2009

Nancy J. Linck