

2008-1248

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**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

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

Plaintiff-Appellees,

v.

ELI LILLY & COMPANY,

Defendant-Appellant,

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS IN  
CASE NO. 02-CV-11280, JUDGE RYA W. ZOBEL

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**BRIEF OF AMICUS CURIAE AMGEN INC.  
IN SUPPORT OF AFFIRMANCE OF JUDGMENT**

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November 19, 2009

## CERTIFICATE OF INTEREST

Counsel for Amicus Curiae, Amgen Inc., certifies the following:

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

AMGEN INC.

2. The name of the real party in interest represented by me is:

AMGEN INC.

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.

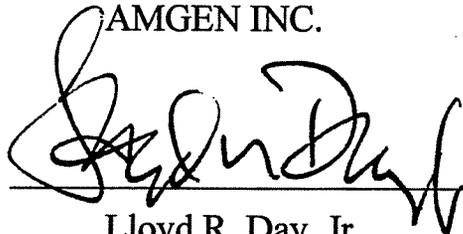
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

- |    |            |  |
|----|------------|--|
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Dated: November 19, 2009

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## **I. STATEMENT OF AMICUS CURIAE**

### **A. Identification of Amicus Curiae**

Amgen Inc. (“Amgen”) is a Delaware corporation with its principal place of business in Thousand Oaks, California. Founded in 1980, Amgen helped pioneer the biotechnology industry by discovering, developing and manufacturing novel, life-saving human therapeutics based on advances in genetic engineering and molecular biology. Today, Amgen employs over 18,000 scientists, researchers, clinicians, production engineers and others engaged in the discovery, development and commercialization of innovative human therapeutics for severe unmet medical needs. Its products have dramatically improved the lives of millions of cancer, kidney disease and rheumatoid arthritis patients over a broad range of treatment modalities, including recombinant proteins, antibodies and small molecules.

To establish the therapeutic benefits of such products and obtain regulatory approval for their manufacture and sale currently requires the investment, on average, of more than a billion dollars over 10-15 years of development. Even with this amount of investment, most product candidates fail in development as either unsafe or ineffective. Given this high risk and extensive investment, meaningful patent protection and clearly delineated patent rights are critical not just to Amgen, but to the entire biotech industry. Amgen and its biotech

colleagues rely on the ability to obtain and enforce patents in order to protect the investments they make in discovering and developing new products.

**B. Interest of Amicus Curiae**

*Interest in Questions Raised By Court's En Banc Order.* As consistently interpreted and applied by the Supreme Court and this Court, the written description requirement of § 112, paragraph 1, ensures that an applicant for patent discloses sufficient information to justify its later claimed invention. Rather than stifling innovation, Amgen submits that the written description requirement actually promotes innovation by encouraging inventors to carry their work to fruition in order to file a patent application that adequately describes the inventions they ultimately claim. The written description requirement further allows others working in competition with the applicant to assess—well before final patent claims may ever issue—whether and to what extent a patent applicant may be able to dominate or exclude their endeavors. For these reasons, Amgen supports the continued application of the written description requirement, as exemplified and consistently stated in this Court's precedent.

*Related Litigation.* Amgen was a plaintiff in a lawsuit involving each of the plaintiff-appellees (“Ariad”) and the same patent at issue here. That lawsuit, *Amgen Inc. v. Ariad Pharmaceuticals, Inc.*, was filed in the United States District Court for the District of Delaware, No. 06-CV-259 (Magistrate Judge Mary Pat

Thynge) and sought declaratory judgment that U.S. Patent No. 6,410,516 is invalid and not infringed by Amgen's Enbrel<sup>®</sup> product. The district court in that action determined that Amgen's Enbrel<sup>®</sup> product does not infringe the '516 patent and that determination was affirmed by this Court on June 1, 2009 (Appeal No. 09-1023, June 1, 2009 Opinion). In the litigation, Amgen also filed summary judgment motions demonstrating that Ariad's patent was invalid for lack of both written description and enablement. The district court declined to rule on these motions based on its non-infringement judgment. The matter is currently administratively stayed in the district court. Although Amgen agrees with the Panel's decision here that the claims of Ariad's patent are invalid for inadequate written description, Amgen does not argue the lack of written description of the Ariad patent in this brief.

## **II. AUTHORITY TO FILE**

Amgen submits this brief as an *amicus curiae* pursuant to Fed. R. App. P. 29(a) and Rule 29(a) of this Court to address the questions set forth by this Court in its August 21, 2009 Order setting the case granting rehearing *en banc* and allowing the filing of amicus briefs without leave of the Court. Both the plaintiffs and the defendant have consented to the filing of an amicus brief by Amgen.

### III. QUESTIONS PRESENTED

In response to the specific questions posed by this Court in its August 21, 2009 Order granting *en banc* review:

1. Amgen submits that 35 U.S.C. § 112, paragraph 1, requires a written description of the invention as well as a description of the manner and process for making and using the invention.

2. The written description requirement properly applies to all patentability and validity inquiries in furtherance of the statutory policies applied by the courts for nearly 200 years to ensure that patent applicants disclose what they consider to be their invention in sufficient detail “to put the public in possession of what the party claims as his own invention.”<sup>1</sup> As such, the written description requirement delimits what can later be claimed by the applicant to the subject matter that is reasonably described in the specification of the patent, as read and understood by a person skilled in the relevant art.

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<sup>1</sup> *Evans v. Eaton*, 20 U.S. 356, 433-34 (1822).

#### **IV. SUMMARY OF ARGUMENT**

As the Founders long ago decreed, the purpose of our patent system is to promote innovation. But innovation requires much more than just a novel idea or an unfulfilled conception. Real innovation requires solutions. In many fields, these solutions are the result of extensive experimentation and research, repeated trial and error, making adjustments and adaptations, and validating the results. This is especially true in highly advanced fields, such as human therapeutics, where innovation occurs at the very margins of scientific discovery and human understanding. In such fields, innovation is encouraged by a patent system that requires inventors to disclose their solutions in such a way that others understand what the applicant can legitimately claim as an invention.

Congress wisely recognized, as early as our first Patent Act, that indeterminate and unbounded claims of invention can stifle future innovation just as much as the failure to protect patentable inventions. Without a reliable, objective basis to discern what a patent applicant can and cannot ultimately claim as his or her invention, others striving to explore, develop or improve the same or related subject matter must proceed at their peril.

As nearly 200 years of Supreme Court jurisprudence establish, the “written description of the invention” requirement of §112, paragraph 1, is a separate requirement for patentability that is not subsumed by the enablement requirement,

nor was it replaced by the statutory requirement for the presentation of claims. Rather, as the case law makes clear, the written description requirement serves to *define* what an applicant conceives to be his or her invention, and in so doing, acts to *delimit* the subject matter that the applicant can later claim as his or her invention. In contrast to the enablement requirement of § 112, paragraph 1, which serves to ensure that the public has the ability to practice each claimed invention once a patent expires, the written description requirement ensures that the boundaries of exclusionary power during the term of patent protection are properly defined and not overstated. In contrast to the claims requirement of § 112, paragraph 2, which requires a precise delineation of the boundaries of exclusionary power granted to a patentee, the written description requirement ensures that the applicant possessed—at the date of application—what he later claims as his invention, and that whatever claims may ultimately issue on that application are consistent with the applicant’s description of his invention.

The fulfillment of these statutory purposes is particularly important in high risk and large investment areas of research, such as human therapeutics. Amgen and others who aspire to discover, make and sell innovative therapeutics for significant unmet medical needs must be able to reliably assess the legitimate metes and bounds of its own and conflicting patent positions, often long before an applicant’s final patent claims ever issue, in order to intelligently weigh the risks

and benefits of alternative pathways for continued innovation. Without a written description requirement, there would be no reliable basis to assess the future patent risk of continued research and development, and far less enthusiasm or incentive to proceed. In short, by requiring each applicant to describe in writing and thereby delimit their professed invention, the written description requirement promotes rather than quells innovation.

Viewed through this lens, this Court's holdings in *Lilly*, *Rochester* and the present case correctly effectuate the long-standing purpose of the written description requirement of §112, paragraph 1, to define the applicant's invention in his or her patent specification and thereby delimit what scope of patent protection may ultimately result from the application. As the facts in these holdings all demonstrate, the written description requirement prevents a patent applicant from "preempt[ing] the future before it has arrived."<sup>2</sup> And certainly, that is also the case here, where simply disclosing the discovery of NF-κB as an agent in an intracellular signal pathway and postulating a few hypothetical ways of interdicting that pathway merely describes an attractive, but as yet unrealized, possibility. The specification falls far short of supporting method claims to any and all ways of "reducing NF-κB activity in a cell." By ensuring that a hoped-for research objective is not later transformed into a claimed invention, the written description

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<sup>2</sup> *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

requirement sets an appropriate, objective standard that protects future innovation against unjustified preemption.

## V. ARGUMENT

### A. Ariad’s deconstruction of § 112, paragraph 1, misreads the statute’s plain meaning and ignores the legislative origins and judicial interpretation of the written description requirement

The “grammatical” deconstruction of §112, paragraph 1, argued by Ariad<sup>3</sup> and various amici,<sup>4</sup> misreads the statute’s plain meaning by eliminating the express requirement for a written description of the invention. In short, the proper deconstruction of §112, paragraph 1, is:

The specification shall contain a written description

[a] of the invention, and

[b] of the manner and process for making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, . . .

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<sup>3</sup> Ariad’s Principal Brief for Plaintiffs-Appellees on Rehearing *En Banc*, dated October 5, 2009, at pp. 2-7.

<sup>4</sup> Brief of Amicus Curiae Roberta J. Morris, Esq., Ph.D. in Support of Neither Party, Urging Attention to the Grammatical Structure and Words of 35 U.S.C. §112 ¶ 1, dated October 13, 2009, at pp. 3-12; Brief of Amici Curaie Mark D. Janis and Timothy R. Holbrook in Support of Neither Party, dated October 14, 2009, at pp. 2-4.

The separate written description and enablement policies underlying § 112, paragraph 1, are clearly revealed in the congressional enactments<sup>5</sup> and Supreme Court jurisprudence that interpret and explain the statutory language,<sup>6</sup> as Lilly correctly stated. For example, in construing section 3 of the 1793 Patent Act, the Supreme Court carefully explained the separate statutory policies underlying the written description and enablement requirements:

The specification, then, has two objects; one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . *The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim any thing that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the*

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<sup>5</sup> See 1790 Patent Act, § 2; 1793 Patent Act, § 3; 1836 Patent Act, § 6; 1870 Patent Act, § 26.

<sup>6</sup> *Evans v. Eaton*, 20 U.S. at 433-35 (construing § 3 of the 1793 Act); *O'Reilly v. Morse*, 56 U.S. 62, 118-121 (1853) (construing § 6 of the 1836 Patent Act); *Permutit Co. v. Graver Corporation*, 284 U.S. 52, 60 (1931) (construing § 26 of the 1870 Patent Act).

*patentee is required to distinguish his invention in his specification.*<sup>7</sup>

In short, the statutory requirement for a written description of the invention requires an inventor to describe his or her invention, not only as a notice to the public, but to delimit what he or she may ultimately claim as an invention. By adopting, nearly verbatim, the original statutory language of the written description requirement into § 112, paragraph 1, Congress necessarily adopted the policies underlying that requirement as previously interpreted and elaborated by the Supreme Court. Moreover, as the Supreme Court repeatedly recognized,<sup>8</sup> the

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<sup>7</sup> *Evans v. Eaton*, 20 U.S. at 433-34 (emphasis added). Ariad’s assertion that *Evans v. Eaton* supports the conclusion that the 1793 Act contained only an enablement requirement ignores the above passage from the Court’s decision.

<sup>8</sup> *O’Reilly v. Morse*, 56 U.S. at 120-121 (Morse “prevents others from attempting to improve upon the manner and process which he has described in his specification—and may deter the public from using,[sic] it, even if discovered. *He can lawfully claim only what he has invented and described, and if he claims more his patent is void.*” (emphasis added)); *Permutit Co. v. Graver Corporation*, 284 U.S. at 60 (the requirements of § 26 of the Patent Act serve two purposes: so that others “may construct and use [the invention] after the expiration of the patent” and “to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.” (emphasis added)); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 58-59 (1938) (“Even if those skilled in the art would have known that a piston with webs which would yield enough laterally to accommodate the constriction of the split skirt under the pressure developed by thermal expansion would work most effectively if the webs were laterally flexible rather than rigid, that was not the invention which Gulick described by his references to an extremely rigid web.”); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (“In addition, the patent

express statutory requirement for a description of *both* the invention *and* the means for making and using the invention did not change when the Patent Act was amended to add an express requirement for the presentation of claims.<sup>9</sup>

Consequently, the addition of a separate statutory requirement for the presentation of claims did not supplant the statutory policies served by the written description requirement. Because the wording, scope and meaning of proposed claims can and frequently does change prior to issuance, the specification provides an unchanging description of the invention against which to judge whether the claims as ultimately issued conform to the invention as originally conceived and described in the applicant's specification.

**B. By defining and delimiting an invention, the description requirement promotes innovation, especially in high-risk, capital-intensive industries.**

This Court has long held that the statutory requirement in § 112, paragraph 1, for a “written description of the invention” means ““the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.””<sup>10</sup> In making that determination, this Court has further held that ““[t]he test for sufficiency of support in a parent application is whether the

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application must describe, enable, and set forth the best mode of carrying out the invention.”).

<sup>9</sup> 1836 Patent Act, § 6; 1870 Patent Act, § 26.

<sup>10</sup> *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted).

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.’”<sup>11</sup> The written description requirement thus prevents an applicant from later claiming that which he did not invent and, in so doing, delimits the legitimate scope of any claims ultimately resulting from the application.<sup>12</sup>

The written description requirement is especially important in fields such as human therapeutics, where there is rarely a proven or obvious way forward, and successful innovation requires large investments of time and money to create, develop, and test potential solutions. In such fields, only a tiny fraction of initially promising product ideas actually matures into successful products with proven

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<sup>11</sup> *Id.* at 1561 (quoting *Evans v. Eaton* (citation omitted)); *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1382-83 (Fed. Cir. 2009); *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1376-77 (Fed. Cir. 2009).

<sup>12</sup> *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000) (holding claims to all methods for inhibiting PGHS-2 activity with a non-steroidal compound invalid for lack of written description where specification does not disclose any such compounds because “the purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification’”). *See also, Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004) (holding claims covering chimeric antibodies that bind a human breast cancer antigen were not adequately described because specification did not describe such antibodies).

utility to treat important unmet needs.<sup>13</sup> Indeed, Amgen’s researchers often spend years pursuing promising product leads without ever achieving the hoped-for therapeutic benefit. From 2005 through 2008 Amgen invested approximately \$11.5 billion to research and develop new therapeutic products.<sup>14</sup> During that same period, Amgen received FDA approval to market and sell 2 new therapeutic products,<sup>15</sup> both of which had been in development for over ten years.

Amgen’s rate of success (or failure) is consistent with the biotechnology industry as a whole. As reported by economists and academicians, the average research and development costs range from \$800 million to \$1.2 billion for each successful therapeutic product,<sup>16</sup> the average time between submission of an

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<sup>13</sup> See generally, Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, Science and Cents: The Economics of Biotechnology, Federal Reserve Bank of Dallas 87, 89 (John Duca ed., 2003) (“Typically, less than 1 percent of the compounds examined in the preclinical period make it into human testing. Only 20 percent of the compounds entering clinical trials survive the development process and gain FDA approval.”); *id.* at 99 (“Economic analyses of the R&D process in pharmaceuticals indicate that it is a very costly and risky process, even for large established firms. Most compounds in the R&D pipeline never reach the marketplace. The process takes a long time, and the distribution of profits among those that are marketed is highly skewed. A few blockbuster successes cover the losses on many other R&D investment projects.”); DiMasi, J. Risks, *New Drug Development: Approval Success Rates for Investigational Drugs*, *Clinical Pharmacological Therapy* 69:297 (2009).

<sup>14</sup> Amgen 2005-2008 Annual Reports, <http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-reportsannual>.

<sup>15</sup> FDA approved Vectibix® in 2006 and Nplate® in 2008. *Id.*

<sup>16</sup> Tufts Center for the Study of Drug Development, Average Cost to Develop a New Biotechnology Product is \$1.2 Billion (Nov. 9, 2006),

Investigational New Drug Application to FDA to begin human testing until final approval for marketing is 15 years,<sup>17</sup> only five out of 250 products ever make it to human testing, and for every product that does make it to market, approximately nine products fail in clinical trials.<sup>18</sup> Moreover, of those products that make it to

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<http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69>; Gardiner Harris, *Health & Technology: Cost of Developing Drugs Found to Rise*, Wall St. J., Dec. 3, 2001. See also, *Sanofi-Synthelabo v. Apotex Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (affirming injunction based in part on district court's finding that "the average cost of developing a blockbuster drug is \$800 million"); Joseph A. DiMasi and Henry G. Grabowski, *The Cost of Pharmaceutical R&D: Is Biotech Different?*, 28 Managerial and Decision Economics 469, 469-70 (2007); Pharmaceutical Research and Manufacturers of America, 2008 Annual Report, at 11 ("The \$1 billion plus average cost of creating a new medicine is enormous.").

<sup>17</sup> Susan Thaul of the Domestic Social Policy Division, CRS Report for Congress: FDA Fast Track and Priority Review Programs (2008), [http://assets.opencrs.com/rpts/RS22814\\_20080221.pdf](http://assets.opencrs.com/rpts/RS22814_20080221.pdf) (citing Pharmaceutical Research and Manufacturers of America (PhRMA), <http://www.phrma.org>).

<sup>18</sup> Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, Science and Cents: The Economics of Biotechnology, Federal Reserve Bank of Dallas 87, 89 (John Duca ed., 2003) ("Typically, less than 1 percent of the compounds examined in the preclinical period make it into human testing. Only 20 percent of the compounds entering clinical trials survive the development process and gain FDA approval."); DiMasi, J. Risks, *New Drug Development: Approval Success Rates for Investigational Drugs*, Clinical Pharmacological Therapy 69:297 (2001); C. Conaway, *The Pros and Cons of Pharmaceutical Patents*, Federal Reserve Bank of Boston, Regional Review, Vol. 13, No. 1 (Q1 2003); Pharmaceutical Research and Manufacturers of America, Research and Development (2009), [http://www.phrma.org/index.php?option=com\\_content&task=view&id=382&Itemid=118](http://www.phrma.org/index.php?option=com_content&task=view&id=382&Itemid=118) ("Of the 250 compounds that enter preclinical testing, only five make it [to clinical testing.]").

market, only about 20% ever recoup the average investment cost.<sup>19</sup>

In highly advanced fields, such as human therapeutics, real solutions require much more than a description of the problem. For example, as this Court held in *University of Rochester v. G.D. Searle & Co.*, the description of a potential therapeutic target, without more, does not adequately describe to those skilled in the art a compound that successfully acts against the target to inhibit a disease state.<sup>20</sup> Rather, it is merely an invitation for further research to find a real solution, such as an active product or useful method of treatment.<sup>21</sup>

Because the risk of ultimate failure can be so high, because the clinical development process can be so long, costly and fraught with uncertainty, and because the investment required to drive and sustain such risky innovation can cost billions of dollars, it is critically important that the patent system broadly protect

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<sup>19</sup> Vernon, J. *et al.*, *Drug Development Costs when Financial Risk is Measured Using the Fama-French Three Factor Model*, Unpublished Working Paper, January 2008.

<sup>20</sup> *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); see also *In re Alonso*, 545 F.3d 1015 (Fed. Cir. 2008) (affirming rejection of claim directed to method for treating neurofibrosarcoma using an antibody where specification does not disclose antigen to be bound except by reference to the antigen's molecular weight).

<sup>21</sup> *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (to demonstrate possession, the specification must describe “*the invention*, with all of its claimed limitations, not that which makes it obvious.” (emphasis in original)); *In re Wallach*, 378 F.3d 1330 (Fed. Cir. 2004) (affirming Board decision that claims, while enabled, were not decried).

and reward those who provide new therapeutically useful products. Without meaningful patent protection, such innovation would come to a grinding halt.

At the same time, it is also important to ensure that such innovation is not preempted by those who provide no solution but only describe a problem and attempt to claim in a patent any or all solutions to the problem. Equally important is the need to assess, as early as possible, the legitimate scope of third party patent rights, particularly given the very substantial resources and investments required for continued innovation in such risky fields. The ability to reliably assess whether and how third party patent rights may impact an innovator's ability to commercialize a potential product can be determinative in any decision to invest time and substantial resources in a particular research opportunity, or instead move on to the next research opportunity.

Often, this assessment must be made years before patents actually issue to that third party.<sup>22</sup> If innovators, such as Amgen, are required to wait until the PTO issues final claims to a third party patentee before it can reliably ascertain what the

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<sup>22</sup> For 2008, the average pendency based on the "most recent filing date" was 32.2 months. USPTO Annual Report, Performance and Accountability Report Fiscal Year 2008, Other Accompanying Information, Table 4: Patent Pendency Statistics (FY 2008); available at [http://www.uspto.gov/web/offices/com/annual/2008/oai\\_05\\_wlt\\_04.html](http://www.uspto.gov/web/offices/com/annual/2008/oai_05_wlt_04.html). If pendency is calculated from the filing date of the first filed application (i.e., pendency time is not based on filing date for continuing applications (file wrapper continuation, continuation, divisional, and C-I-P applications)), the average pendency time is greater.

applicant considers to be his or her patentable invention, the pace of innovation will slow dramatically. And without a reliable basis to assess which pathways of innovation may legitimately be dominated or blocked by a third party's future patent claims, the incentive to pursue such innovation will be greatly reduced if not eliminated.

Similarly, if an applicant for patent is unconstrained by the original description of his invention from recasting the claimed scope of his invention to dominate the innovations of others in the field, the incentive for continued innovation is further undermined. While failure is an orphan, success knows many fathers. Few patent-holders assert their claims against products that fail in the clinic. But when innovators are successful after years of painstaking, costly research and development, others with patent applications still pending often try to dominate that proven success by claiming the innovator's success as their own invention. The written description requirement prevents patent applicants from treating their disclosures as "a nose of wax."

This is why Congress, in "taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects,"<sup>23</sup> required the inventor's specification to set forth a written description of his or her invention.

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<sup>23</sup> *Evans v. Eaton*, 20 U.S. at 434.

As Congress recognized, it is important for patent applications to describe the professed invention, so that the scope of any exclusionary power ultimately resulting from the application can be confined to the inventions reasonably described in the application.

By requiring an applicant to describe his or her invention and thus the useful boundaries of his or her contribution, the written description requirement allows the Patent Office as well as other innovators to make an objective, reliable assessment whether the applicant's specification in fact demonstrates possession of that invention, as well as the legitimate scope of patent protection that may ultimately be granted based on that description. This not only facilitates the examination of claims, but it also accelerates the pace of innovation and helps to avoid unnecessary future litigation, by allowing others to direct their future energies and investment mindful of whatever patent risk their actions may entail.<sup>24</sup>

**C. The written description requirement is distinct from the enablement requirement.**

The written description and enablement requirements serve two distinct purposes to effectuate the constitutional mandate to “promote the Progress of

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<sup>24</sup> *In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009) (“A purpose of the written description requirement is to provide the public with knowledge of the patented technology, thereby to advance the useful arts.”).

Science and useful Arts”<sup>25</sup> Whereas the enablement requirement ensures that the public has been given the ability to practice a claimed invention *after* a patent expires, the written description requirement ensures that the boundaries of an invention are adequately described and properly delineated *before* the patent even issues, and that the scope of patent protection during the life of a patent does not exceed the inventions described in the patent specification.

The distinction between the written description and enablement requirements is well illustrated by the “situation ‘where the specification discusses only compound A and contains no broadening language of any kind. This might ... enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.’”<sup>26</sup>

Relying solely on enablement to define the appropriate scope of patent claims, some argue that patent applicants should be entitled to claim whatever their applications enable others to do regardless of the application’s description of the invention. They would argue that the applicant in the above scenario is entitled to claim A, B, and C.

This approach, however, would introduce much confusion into the patent system and inject even greater uncertainty and risk in the ability of research-based

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<sup>25</sup> U.S. Constitution, Art. 1, Sec. 8.

<sup>26</sup> *Vas-Cath*, 935 F.2d at 1561-62 (restating an example provided by the court in *In re DiLeone*, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971)).

innovators like Amgen to determine what areas of scientific research to pursue. If, irrespective of the inventions described in a third party's patent application, the third party applicant could nonetheless assert that it enabled Amgen's inventions and pursue claims to cover Amgen's work, there would be far less incentive to pursue continued innovation. By requiring an applicant for patent to describe his or her invention in terms sufficient to inform others skilled in the art what the applicant considers the invention to be,<sup>27</sup> the written description requirement prevents this "overclaiming."<sup>28</sup>

In assessing the validity of claim scope, the written description requirement provides a separate and, in many instances, a more discernible and specific test than the enablement requirement. Focusing on the description provided in the patent specification, the written description requirement asks: Is the claimed subject matter fairly described in the disclosure? In contrast, the enablement analysis examines what an applicant's disclosure has made possible—without

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<sup>27</sup> See *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996); *In re Ruschig*, 379 F.2d 990, 994-95 (CCPA 1967) ("It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding the trail . . . 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.").

<sup>28</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 313 F.3d 1313, 1330 (Fed. Cir. 2002) ("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(1991)).

undue experimentation—when added to the universe of knowledge available in the art at the time of the application.

Amgen submits that it is better policy to require patent applicants to adequately describe their inventions, thus making it more certain that they have defined a legitimate scope of a patentable invention, than to cause every person who analyzes the patents to consider what might be enabled by a disclosure without “undue experimentation.” In this way, the written description requirement ensures that an applicant for patent cannot claim what he or she did not conceive as the invention, even if that invention would have been obvious to others skilled in the art based on the applicant’s disclosure.<sup>29</sup>

Contrary to the arguments of some, the written description requirement is not a “super-enablement” requirement. Rather, it simply and appropriately confines the scope of exclusionary power that an applicant may ultimately claim to the inventions that are described in his or her specification at the time the application is filed. Nor does the written description requirement raise the enablement bar. As this Court has made plain, even in the context of highly advanced biotechnology-related inventions, the adequacy of description presents a question of fact that depends on the relevant state of the art at the time of the

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<sup>29</sup> *Lockwood v. American Airlines, Inc.*, 107 F.3d at 1572; *In re Wallach*, 378 F.3d 1330.

invention, and does not necessarily require an actual reduction to practice or extensive empirical testing.<sup>30</sup>

**D. The written description requirement does not stifle patentable inventions or prejudice universities or small institutions.**

Both Ariad and the University amici argue that the written description requirement stifles the research incentives of universities and small institutions. Specifically, the University amici argue that the requirement has “far-reaching implications for the patentability of research,” “impacts the ability of university researchers to obtain recognition and patent protection for their innovations,” and “jeopardizes the viability of technology transfer programs at universities,” because it “imposes an actual reduction to practice requirement on biotech inventions” to their great prejudice because they do not have the resources to reduce pioneering biotech innovations to a “precise definition.”

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<sup>30</sup> *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) (remanding for further consideration of claims directed to chimeric genes where actual chimeric gene sequence is not disclosed but the component parts comprising the sequence were known and/or described in the specification); *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (“We hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate description of an invention that involves a biological macromolecule must contain a recitation of known structure.”); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (patents to recombinant protein and related processes involving expression of DNAs in vertebrate and mammalian host cells found to comply with the written description requirement because cells were not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend).

Amgen shares the concern that overly stringent application of the written description requirement could be used to deny legitimate patent protection, and that this result would have an adverse impact on research intensive areas of scientific innovation. But the written description requirement has a long and well-developed body of precedent to guide its future application. For example, in its amicus brief, the Intellectual Property Owners Association (IPO) lists several “well-established tenets” that serve to limit the reach of the written description requirement. Amgen agrees that requiring excessive detail or analysis in a patent disclosure or narrowing the scope of claims to the precise details of the disclosure would be injurious to the patent system and stifle innovation. But, in our view, the written description pendulum has not swung that far. Indeed, under the existing case law, research-based universities and small institutions have prospered and companies like Amgen continue to invest in and reward such research.

While Amgen is a relatively successful company today, its experience with the patent system as a small research-based institution proves instructive on this issue. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, this Court considered whether Dr. Lin’s “pioneering” inventions to recombinant erythropoietin, and the manufacturing processes and cells used to make it<sup>31</sup> satisfied the written

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<sup>31</sup> *Id.* at 1321 (“Amgen is recognized as the pioneer.”).

description requirement articulated in *Lilly and Enzo Biochem*.<sup>32</sup> Based on the district court's factual findings, this Court held that Dr. Lin's specification adequately described methods for manufacturing erythropoietin in all vertebrate and mammalian cell types.<sup>33</sup> At the time of Dr. Lin's invention, Amgen was a small biotechnology start-up company that had yet to commercialize any therapeutic product, and indeed, had licensed some of its product rights to larger companies in order to finance the clinical development of Dr. Lin's breakthrough products. As a small company, Amgen was able to conduct sufficient experiments and to describe the work in its patent applications in sufficient detail to support the scope of its patent claims.

Thus, contrary to Ariad's position, application of the written description requirement does not prejudice universities or small companies, or mean that pioneering biotech-related discoveries are unpatentable. Nor does the written description requirement, in the context of biomedical and biotechnology inventions, necessarily require an actual reduction to practice or corresponding example for every embodiment of a claimed invention.<sup>34</sup> Rather, as the Patent Office, the Board of Patent Appeals and Interferences, and the courts have recognized, where an applicant (including an academician at a university or a

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<sup>32</sup> *Id.* at 1331-32.

<sup>33</sup> *Id.* at 1332-33.

<sup>34</sup> *Falkner v. Inglis*, 448 F.3d at 1366.

scientist at a small start-up company) provides a sufficient written description of an invention to demonstrate his or her possession of that invention to others skilled in the art, commercially significant patent protection can be obtained.<sup>35</sup>

But, as the Supreme Court recognized in *Brenner v. Manson*, “a patent is not a hunting license[;] [i]t is not a reward for the search, but compensation for its successful conclusion.”<sup>36</sup> In other words, patent protection extends to new and useful discoveries, not “research,” not laws of nature, abstract concepts, or natural phenomena.<sup>37</sup> Thus, insofar as the University amici argue that academic

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<sup>35</sup> See *Capon v. Eshhar*, 418 F.3d 1349 (vacating BPAI decision of invalidity under § 112 for lack of written description where Capon was then part of a small biotechnology start-up and Eshhar was part of the University of California); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005) (affirming district court’s grant of summary judgment of no invalidity under § 112 for lack of written description where Invitrogen was then a one-year old start-up company); *Regents of the Univ. of California v. Monsanto Co.*, No. C 04-0634 PJH, 2005 U.S. Dist. LEXIS 40379 (N.D. Cal. Dec 16, 2005) (rejecting Monsanto’s argument that the University of California’s invention was invalid for inadequate written description); accord *Regents of Univ. of California v. Dako North America, Inc.*, No. C 05-03955 MHP, 2009 U.S. Dist LEXIS 33637 (N.D. Cal. Apr. 22, 2009). See also, e.g., *Ex parte Usman*, BPAI Appeal No. 2002-1251, Application No. 08/459,340 (assignee: Massachusetts Institute of Technology); *Ex parte Tully*, BPAI Appeal No. 2003-0835, Application No. 09/419,371 (assignee: Cold Spring Harbor Laboratory).

<sup>36</sup> 383 U.S. 519, 536 (1966).

<sup>37</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (stating that patent protection is not available for “laws of nature, natural phenomena, and abstract ideas.”); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (stating that “Einstein could not have patented his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity.”). See also, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) (“The justification for the principle

“research” is motivated by and should be rewarded with patent protection, the argument rests on the false premise that “research,” in and of itself, is patentable. It is not. Only inventions are subject to patent protection.<sup>38</sup>

The description requirement, as currently applied, walks the fine line between rewarding a patentee for his/her actual invention and encouraging innovation by a competitor by requiring that a specification reasonably convey to an ordinarily skilled artisan “possession” of the claimed invention. It is only if this balance is tipped, as *Ariad* and some of the amici suggest, to do away with the description requirement all together, or alternatively, to require an actual reduction to practice in all instances, that innovation will be quelled.

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does not lie in any claim that ‘laws of nature’ are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ the constitutional objective of patent and copyright protection. U.S. Const., Art. I, § 8, cl. 8.” (emphasis in original)).

<sup>38</sup> *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d at 929 (invalidating claim seeking to cover all methods related to the use non-steroidal compounds to inhibit COX-2 for lack of written description where university only identified COX-2 and specification provides no description or examples of non-steroidal compounds that may be used in the claimed therapies); *Noelle v. Lederman*, 355 F.3d 1343, 1348-50 (Fed. Cir. 2004) (affirming Board’s decision that claims to all monoclonal antibodies to a specific T-cell antigen are inadequately described where the specification does not characterize any antibody or the antigen to which the antibody must bind).

**E. The written description requirement is appropriately applied in biotechnology.**

Some of the amici argue that the written description requirement has been inconsistently and inappropriately applied in biotechnology. But the written description requirement presents a question of fact: does the specification adequately describe the invention as ultimately claimed? The answer to that question depends on the content of the specification and the evidentiary record before the court as to the state of the relevant art at the time of the application as applied to each claimed invention.<sup>39</sup>

Consequently, a mere comparison of the holdings in *In re Wallach*<sup>40</sup> and *In re Kubin*,<sup>41</sup> or *Capon v. Eschar*<sup>42</sup> and *Carnegie Mellon University v. Hoffmann La-Roche, Inc.*,<sup>43</sup> without a thorough comparison of the underlying specifications and the evidentiary record on the state of the art at the time of the claimed inventions does not establish any “inconsistency” in the requirements application.<sup>44</sup> Rather, it only represents exactly what this Court has already acknowledged—“the precedential value of cases in this area is extremely limited” and each case “must

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<sup>39</sup> *Id.* at 1349.

<sup>40</sup> 378 F.3d 1330 (Fed. Cir. 2004).

<sup>41</sup> 561 F.3d 1351 (Fed. Cir. 2009).

<sup>42</sup> 418 F.3d 1349 (Fed. Cir. 2005).

<sup>43</sup> 541 F.3d 1115 (Fed. Cir. 2008).

<sup>44</sup> See Brief of *Amicus Curiae* Law Professor Christopher M. Holman In Support Of Neither Party, at pp. 6-24.

be decided on its own facts.”<sup>45</sup>

Thus, appropriately, the description requirement does not and should not draw a bright line that is industry dependent. Rather, as currently stated, it is a standard with sufficient flexibility to apply to all industries as the technology in each evolves and progresses over time.

## **VI. CONCLUSION**

Accordingly, the Court should affirm the judgment of the court below, and confirm that 35 U.S.C. § 112 includes a written description requirement consistent with the precedent of this Court.

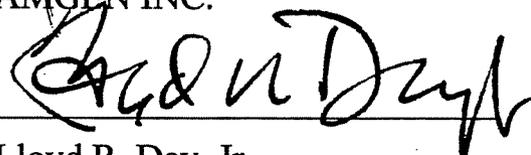
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<sup>45</sup> *Noelle v. Lederman*, 355 F.3d at 1349 (quoting *Vas-Cath*, 935 F.2d at 1562).

November 19, 2009

Respectfully submitted,

For the Amicus Curiae,  
AMGEN INC.

A handwritten signature in black ink, appearing to read "Lloyd R. Day, Jr.", written over a horizontal line.

Lloyd R. Day, Jr.

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## PROOF OF SERVICE

I hereby certify that on November 19, 2009, two (2) copies of **BRIEF OF AMICUS CURIAE AMGEN INC IN SUPPORT OF AFFIRMANCE OF JUDGMENT** were duly served upon counsel for Plaintiffs-Appellees, counsel for Defendant-Appellant, and counsel for Amicus Curiae at the following addresses by electronic mail and federal express:

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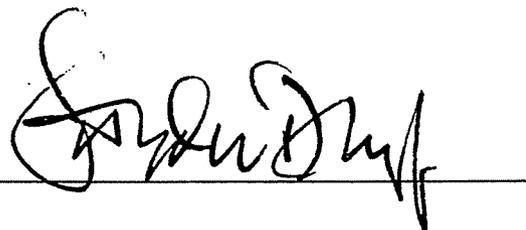
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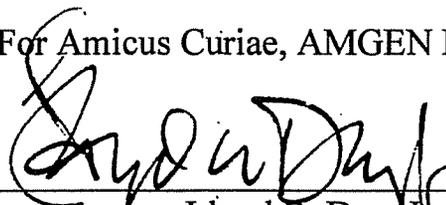
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## CERTIFICATE OF COMPLIANCE

I, Lloyd R. Day, Jr., hereby certify under Federal Rules of Appellate Procedure 32(a)(7)(B) and 28.1(e)(2)(B) that the word count of the **BRIEF OF AMICUS CURIAE AMGEN INC. IN SUPPORT OF AFFIRMANCE OF JUDGMENT** is 6,456, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b) (table of contents, table of authorities, statement of *amicus curiae*, certificate of service, certificate of compliance, certificate of interest, and statement of related cases). Microsoft Word 2002 was used to calculate the word count for all relevant parts of the brief.

Amgen Inc.'s brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2002 in 14-point, Times New Roman font.

For Amicus Curiae, AMGEN INC.



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Lloyd R. Day, Jr.