

July 2012

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Recommended Citation

Barkume, Sharon and Bielski, Michael R. (2012) "Strict Interpretation of 35 U.S.C. § 112: Requires Universities to Examine Their Patenting Methods," *Touro Law Review*: Vol. 28: No. 1, Article 8.

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STRICT INTERPRETATION OF 35 U.S.C. § 112: REQUIRES UNIVERSITIES TO EXAMINE THEIR PATENTING METHODS

Sharon Barkume and Michael R. Bielski***

I. INTRODUCTION

The commercialization of technologies developed at universities is a catalyst for entrepreneurship and contributes significantly to economic development in the United States.¹ Since the enactment of the Bayh-Dole Act,² universities have licensed numerous technologies to both new and established companies; however, there is still an opportunity to more efficiently translate the billions of federal research dollars invested in basic and applied research at academic institutions into commercially viable

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¹ Roland Helm & Oliver Mauroner, *Success of Research-based Spin-offs. State-of-the-art and Guidelines for Further Research*, REV. MANAGERIAL SCI. 237, 238 (2007).

Two of the main forces of economic life are entrepreneurship and technological development. Today, in a competitive and globalised world, the ability to create new innovative products and companies is crucial for promoting rapid structural change and national or regional development (NIW/Fhg-ISI 2000). Universities and other public research organisations are some of the main sources of innovations. The generation and specifically the application of new ideas, technologies and scientific knowledge are conducive to economic development, job creation and the formation of a competitive industrial structure. To spin off a venture from a research organisation is an excellent way to commercialise research results and a method by which publicly financed research will contribute to economic and social welfare and regional development.

Id. (citations omitted).

² 35 U.S.C. §§ 202-212 (2006 & Supps. IV 2010, V).

technologies.³

Most university technologies require significant funding to further develop the prototypes and proof-of-concepts into products and services that can be sold in the marketplace.⁴ This funding often comes from investments made by angel investors, venture capitalists, and/or corporate partners. These investments are generally made for the sole purpose of generating profits, and therefore, are only made for commercializing university technologies when the technologies can survive a rigorous due diligence process. Commercially viable university technologies that do not survive this due diligence process fail to attract the investments necessary to advance them from prototypes and proof-of-concepts into products and services, a chasm known as the “Valley of Death,”⁵ which contributes significantly to the inefficient translation of federal research dollars into economic impact in the United States.

A significant component of the due diligence process is a thorough evaluation of the patents protecting the university technology. Investors and corporate partners are aware that there are risks associated with university technology because often there is a “disconnect” between the current fundamental university technology and the future commercial embodiments of that technology. The due diligence process evaluates whether the claims of the patent are broad enough to protect the current and future products and services derived

³ Jerry Thursby & Sukanya Kemp, *Growth and Productive Efficiency of University Intellectual Property Licensing*, 31 RES. POL’Y 109, 109 (2002) (“It has been suggested in a number of venues that university resources are not fully exploited as a source of economic growth and competitiveness and recent public policy has been aimed at increasing the commercial impact of universities.”).

⁴ Richard Jenson & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240, 240-41 (2001).

Perhaps the most striking result of the survey is that when they are licensed, most university inventions are little more than a “proof of concept.” No one knows their commercial potential because they are in such an early stage of development. Indeed, they are so embryonic that additional effort in development by the inventor is required for a reasonable chance of commercial success.

Id.

⁵ Steve H. Barr, Ted Baker, Stephen K. Markham, & Angus I. Kingon, *Bridging the Valley of Death: Lessons Learned from 14 Years of Commercialization of Technology Education*, 8 ACAD. MGMT. LEARNING & EDUC. 370, 371 (2009) (“The missing link in these efforts is the transition from an existing or emerging technology to the creation of a compelling new market-driven business. This institutional, financial, and skill gap is referred to as the ‘valley of death’ in [commercialization of technology].” (citations omitted)).

from the university technology. However, the due diligence process also includes an assessment of whether these claims will survive reexamination and litigation without being invalidated or significantly narrowed.

The purpose of this paper is to explore recent interpretations of patent law doctrines by the courts and how these interpretations affect the scope and validity of patents covering fundamental university technologies. Many of these interpretations have the goal of increasing the quantity and quality of information disclosed in a patent, a significant issue for early stage technology. A better understanding of the effects of these holdings on fundamental university patents by the stakeholders in university technology commercialization will enable more efficient technology transfer mechanisms in the United States.

Section II of this paper presents background information associated with commercialization and patenting of fundamental university technology. Section III discusses the claim construction doctrine used for determining the scope of claim coverage and analyzes a recent case where this ideological difference is brought to the foreground. The claim construction doctrine does not invalidate claims, but instead interprets what subject matter the patent may exclude based on the terms used in the claims.⁶ Section IV discusses the claim indefiniteness doctrine, which invalidates a claim because the meaning of a claim term is not clearly defined in the specification⁷ and a recent Federal Circuit case that applied the indefiniteness doctrine. Section V presents the evolution of the written description doctrine. The written description doctrine invalidates claims where the inventor did not possess (invent) the entire scope of the claim.⁸ Section VI explains the enablement doctrine, which has long been used to police the adequacy of the disclosure in the specification.⁹ The enablement doctrine invalidates claims that cover subject matter that is not sufficiently described so that one skilled in the art could practice the claimed invention

⁶ See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (establishing *Markman* hearings to determine the scope of patent claims prior to patent infringement trials).

⁷ See 35 U.S.C. § 112 (2006) (requiring the invention to be distinctly claimed).

⁸ See Gene Quinn, *Patent Drafting: Defining Computer Implemented Processes*, IPWATCHDOG.COM (March 14, 2011), <http://ipwatchdog.com/2011/03/14/patent-drafting-defining-computer-implemented-processes/id=15758> [hereinafter Quinn, *Patent Drafting*].

⁹ See *id.*

without undue experimentation.¹⁰ Recently, the courts have become even stricter in their application of the enablement requirement.¹¹ Finally, Section VII discusses how the different doctrines of patent law work together and how the stricter interpretations of Section 112 achieve better quality patents. However, this stricter interpretation requires that universities make sure that their patents include commercial applications and contain an adequate disclosure that describes and enables the entire scope of their inventive technology.

II. BACKGROUND

Commercializing university technologies is an important component of the economic development policy in the United States.¹² President Barack Obama has recently stated that helping small businesses commercialize innovative technologies discovered from federally funded research and development will create jobs and help the country recover from its economic crisis.¹³ Congress has long recognized the usefulness of transferring federally funded university technology¹⁴ to private businesses for commercialization.¹⁵

¹⁰ 35 U.S.C. § 112 (“The specification shall enable any person skilled in the art to which it pertains . . . to make and use the same.”); *see also* Quinn, *Patent Drafting*, *supra* note 8.

¹¹ *See* Quinn, *Patent Drafting*, *supra* note 8.

¹² Helm & Mauroner, *supra* note 1.

¹³ *Startup America*, THE WHITE HOUSE, www.whitehouse.gov/issues/startup-america (last visited Sept. 3, 2011) (quoting a speech by President Obama on Jan. 31, 2011 regarding the Startup America initiative); *see also* Wendy H. Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, CONG. RES. SERV. REP. Paper 23, 14 (2006) (“It is now widely accepted that ‘from one-third to one-half of all U.S. growth has come from technical progress, and that it is the principal driving force for long-term economic growth’ ”); *see also* MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY – INDUSTRIAL COMPLEX 2-3 (1986) (“[I]n stagnation periods entrepreneurs with new ideas come forward to lead capitalism into technologies that form the basis of new industries.”).

¹⁴ KENNEY, *supra* note 13, at 30 (“[Three] great task[s] of the university [are] to perform research that has no immediate application to production[,] . . . to perform basic science[,] and [to] provide ‘scientists [who are] able to offer fresh insights.’ ”) (citation omitted); *see also* Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (allowing federal laboratories to apply for patents and transfer their technology, similar to university technology transfer). The term “university” may include government research facilities, where federally funded research and development is similar to research performed at universities. *Id.* at § 2(6)(d)(1-2).

¹⁵ *See* Gene Quinn, *Happy Anniversary: USPTO Celebrates 30 Years of Bayh-Dole*, IPWATCHDOG.COM (Dec. 12, 2010), <http://ipwatchdog.com/2010/12/12/happy-anniversary-uspto-celebrates-30-years-of-bayh-dole/id=13759> [hereinafter Quinn, *Happy Anniversary*]; *see also* DRAFTING LICENSE AGREEMENTS § 26.01, 26-28 (Michael A. Epstein & Frank L.

Under the Bayh-Dole Act universities are able to patent their technology and license or transfer their patents to private companies so that the technology can be brought to market.¹⁶ Consequently, the Bayh-Dole Act has been lauded for the creation of thousands of new businesses.¹⁷

UNIVERSITY ISSUES WITH PATENTING

Nonetheless, many university scientists are not interested in patenting their technology (so that the university can profit from licensing that patent), but rather, they are interested in “engag[ing] the scientific community” through scientific presentations and publications.¹⁸ However, patenting the result of research and development plays an important role in commercializing university technologies. Universities use patent licenses, both to new (start-ups) and established companies, as the primary mechanism of technology transfer.¹⁹ In return for royalties and fees back to the university, companies can move forward with commercializing a patent-protected technology.²⁰ Commercialization of university technologies also serves society by creating new companies, new jobs, and most importantly, by bringing the inventive technology to market.²¹

Even though patents are critical to technology

Politano eds., Aspen Pub. 4th ed. 2010).

¹⁶ See 35 U.S.C. §§ 202-212; see also Schacht, *supra* note 13, at 4.

¹⁷ Quinn, *Happy Anniversary*, *supra* note 15.

¹⁸ Jennifer Carter-Johnson, *Unveiling the Distinction Between the University and Its Academic Researchers: Lessons for Patent Infringement and University Technology Transfer*, 12 VAND. J. ENT. & TECH. L. 473, 475, 483 (2010).

[I]n spite of a government requirement to disclose government-funded inventions to the university for licensing and the university’s considerable interest in licensing such inventions, academic researchers routinely publish their inventions in scientific journals without university disclosure rather than spending the extra time required to also disclose the inventions to the university.

Id.

¹⁹ See DRAFTING LICENSE AGREEMENTS, *supra* note 15, at 26-10.

²⁰ See *id.*

²¹ Schacht, *supra* note 13, at 5 (“Special consideration concerning patent title is given to small businesses in part because of the role these companies were seen as playing in the generation of new jobs and in technological advancement.”); see also DRAFTING LICENSE AGREEMENTS, *supra* note 15, at 26-6 (“[T]echnological breakthroughs can benefit both humankind when the breakthroughs are patented and developed into products . . . and further science when they are published in respected journals and presented at scientific meetings.”).

commercialization, many university scientists prefer to publish their results to increase their chances of receiving further grant money.²² However, if a patent is not applied for prior to publication or presentation of the scientific research, it may cause a loss of patent rights.²³ In order to avoid the loss of patent rights, the university may need to quickly file a patent application that possibly does not have an adequate disclosure of the inventive technology.²⁴ Similarly, attempting to patent the technology before the research is completed or before a commercial application has been determined may also produce an inadequate disclosure.²⁵ As explained in this paper, an inadequate disclosure will result in patent claims being invalidated or being narrowed significantly.²⁶ A company that licenses a weak patent will likely have difficulties acquiring funding, ultimately resulting in not being able to commercialize the inventive technology.²⁷ Universities and scientists need to increase the strength of their patents, so that commercialization of their innovative technologies can be increased.

The importance of patents was explained by the Supreme Court in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,²⁸ where the Court stated that science is promoted when inventors receive patent protection for their discoveries because a patent discloses those discoveries to the public, particularly to those skilled in the art, stimulating further work and discovery.²⁹ Furthermore, patent

²² Carter-Johnson, *supra* note 18.

²³ 35 U.S.C. § 102(b) (2006) (“A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . .”); *see also* CONSTANCE E. BAGLEY & CRAIG E. DAUCHY, *THE ENTREPRENEUR’S GUIDE TO BUSINESS LAW*, 521, 531 (James W. Calhoun & Robert Dewey eds., Westgroup 3d ed. 2008) (“[M]any countries will not grant a patent if the invention is disclosed before the patent application is filed in that country.”).

²⁴ *See, e.g.*, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

²⁵ *E.g., id.* at 1358 (Newman, J., additional views) (stating that a patent application for basic scientific research was filed before a practical application was demonstrated).

²⁶ *See supra* text pp. 187-88 and accompanying notes 6-11.

²⁷ *See* Schacht, *supra* note 13, at 2; *see also* Mario W. Cardullo, *Intellectual Property – The Basis for Venture Capital Investments*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, http://www.wipo.int/sme/en/documents/venture_capital_investments.htm (last visited October 12, 2011) (“Without the strength of the intellectual property and its protection, little if any investments would be made into new or growing enterprises.”).

²⁸ 489 U.S. 141 (1989).

²⁹ *Id.* at 150-51 (explaining that the purpose of the patent system is to encourage the creation and disclosure to the public of new, useful, and non-obvious advances in technology

protection encourages companies to invest in the costly work of innovation because competitors will not be able to copy their technology.³⁰ Nevertheless, some people believe that patent protection, with its monopoly of seventeen plus years, increases the cost of goods and services and holds back innovation rather than promoting it.³¹ The speed at which new technologies are advancing highlights this issue.³² By the time a patent is published, typically eighteen months after the patent is filed, technological advances have already made the invention obsolete in some areas, such as computer electronics.³³ In these areas, the technology progressed without a patent disclosure, and yet, a subsequently obtained patent may be used as a weapon to stop all others in the field from pursuing

and design in return for the exclusive right to exclude others from making, using, or selling the invention for a period of years and upon expiration of that period, the knowledge of the invention is available for people to make and use the invention without restriction. Absent the patent system, inventors would keep the details of their invention secret and innovation would not progress as effectively as the patent system allows.); *see also* U.S. CONST. art. I, § 8, cl. 8 (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure which . . . will stimulate ideas and the eventual development of further significant advances in the art.

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974).

³⁰ *Bilski v. Kappos*, 130 S. Ct. 3218, 3253 (2010) (“Although there is certainly disagreement about the need for patents, scholars generally agree that when innovation is expensive, risky, and easily copied, inventors are less likely to undertake the guaranteed costs of innovation in order to obtain the mere possibility of an invention that others can copy.”); *see also* Schacht, *supra* note 13, at 3-4.

³¹ Schacht, *supra* note 13, at 3; *see also* Paul Basken, *Patents, Not Just Politics, Create Obstacles to University Stem-Cell Research*, CHRON. HIGHER EDUC. (Jan. 24, 2011), <http://chronicle.com/article/Patents-Not-Just-Politics/126045/>.

³² Robert Unikel & Douglas Eveleigh, *Protecting Inventors, Not Fortune Tellers: The Available Patent Protection for After-Developed Technologies*, 34 AIPLA Q.J. 81, 85 (2006).

Given the rapid pace of technological advance in many industries today (biotechnology, computers, and telecommunications, to name just a few), and given the potentially serious consequences of misapprehending and/or misapplying the law in these areas, it is extremely important for patentees and potential infringers/improvers to be aware of, and for courts to come to grips with, the confusing morass of judicial decisions regarding patent protection for after-developed technologies.

Id.

³³ Dennis D. Crouch, *Is Novelty Obsolete? Chronicling the Irrelevance of the Invention Date in U.S. Patent Law*, 16 MICH. TELECOMM. & TECH. L. REV. 53, 81 (2009).

advancements in the technology area.³⁴ This problem is further exacerbated when one considers the many questionable patents that have been issued by the United States Patent and Trademark Office (“PTO”).³⁵

In *Bilski v. Kappos*,³⁶ the Supreme Court explained that patent laws need to balance “the tension . . . between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design.”³⁷ The Court stated that finding this balance requires an invention to be: (1) of the type the patent laws are designed to protect (Section 101 requirement);³⁸ (2) novel (Section 102 requirement);³⁹ (3) non-obvious (Section 103 requirement);⁴⁰ and (4) “fully and particularly described” (Section 112 requirement).⁴¹ Recently, the courts and the PTO have emphasized the importance of fully and particularly describing an invention to increase the quality of patents.⁴² Patents of poor quality

³⁴ Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U.J. SCI. & TECH. L. 1, 12-15 (2005); see also *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1258 (Fed. Cir. 2011) (Lourie, J., concurring in part and dissenting in part).

³⁵ See *Bilski*, 130 S. Ct. at 3229 (“[S]ome business method patents raise special problems in terms of vagueness and suspect validity.”).

³⁶ 130 S. Ct. 3218.

³⁷ *Id.* at 3229.

³⁸ *Id.* at 3225.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Bilski*, 130 S. Ct. at 3225.

⁴² Press Release, United States Patent and Trademark Office, USPTO Issues Examination Guidelines to Better Define the Scope of Patent Protection Thereby Improve Patent Quality, Release 11-11 (Feb. 9, 2011), available at http://www.uspto.gov/news/pr/2011/11_11a.jsp (“Patent quality is essential to the proper functioning of the patent system and the intellectual property community has long wanted the USPTO to provide additional guidance to examiners and applicants to ensure better compliance with Section 112.” (quoting Director of the USPTO, David Kappos)); see also 35 U.S.C. § 112 (“The specification shall contain a written description of the invention, and of the manner and process of 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 . . . to make and use the same . . . [and] shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”). Section 112 also has a best mode requirement. *Id.* This requirement will not be discussed in this paper because Congress is expected to vote to eliminate this requirement. See Dennis Crouch, *Patent Reform Act of 2011: An Overview*, PATENTLY-O BLOG (Feb. 10, 2011), <http://www.patentlyo.com/patent/2011/02/patent-reform-act-of-2011-an-overview.html>. This paper will discuss claim construction, indefiniteness, written description, and enablement doctrines because these doctrines affect the requirement to fully and particularly describe an invention. There are other doctrines that affect the scope of the claims such as a disclaimer, doctrine of equivalents, and reverse doctrine of equivalents, but these are beyond the scope of this paper. This paper will not

do not give the public notice of the protected scope of the patent—thereby creating an unknown risk that discourages research and development, rather than promoting it.⁴³

A patent is comprised of a specification, which gives a broad comprehensive description of a design, and also comprised of the claims, which define the legal “metes and bounds” of the invention using terms known in the art (technology field) or terms defined in the specification.⁴⁴ Typically, the attorney describes embodiments known to the inventor (i.e. commercial applications) in the specification and then generates broad claims that cover not just the known embodiments, but also embodiments that one of ordinary skill in the art would be able to practice based on the description of the invention in the specification.⁴⁵ The claims can cover a physical design (apparatus or device claims), an activity (process or method claims), or a combination of both; and based on prior patents or publications found by the PTO examiner, the claims may be deleted or changed—and new claims can be added during the patent examination process.⁴⁶ In some cases, a functional claim (a method or a method of using a device) is written to cover a multitude of ways to perform an activity, but the specification fails to disclose

discuss the disclaimer doctrine because this doctrine pertains to the statements made by an attorney during patent prosecution. This paper will also not discuss the doctrine of equivalents because this doctrine is used by the courts to determine if “two devices do the same work in substantially the same way, and accomplish substantially the same result.” *Graver Tank & Mfg., Co. v. Linde Air Prods.*, 339 U.S. 605, 608 (1950).

⁴³ Aljalian, *supra* note 34, at 12-14.

⁴⁴ Ronald B. Hildreth, *Definition of a Patent*, PRAC. L. INST. PAT. L.: PRAC. GUIDE § 1:2 (2011) (“A patent is a contract between an inventor and the U.S. government under which the government grants the inventor a limited monopoly” for approximately 20 years from the filing of the application and “the inventor discloses the complete invention to the public . . .”). *See generally id.* at § 2:2 (stating every patent contains “a specification and at least one claim. The specification describes the complete invention. Each claim defines the legal rights of the patent owner.” (footnote omitted)); *see generally id.* at 3:3 (stating that an examiner at the PTO examines a patent application to determine if the “claimed subject matter is new, useful, and unobvious over the prior art” in light of the specification). The examiner may reject the claim as being non-statutory subject matter under 35 U.S.C. § 101; anticipated subject matter under 35 U.S.C. § 102; obvious subject matter under 35 U.S.C. § 103; or claimed too broadly and/or not fully described by the specification under 35 U.S.C. § 112. *See* DONALD S. CHISUM, *CHISUM ON PATENTS* §§ 1.01, 3.01, 5.02[4], 7.01, 7.03 (2010). An applicant may appeal a decision from an examiner at the Board of Patent Appeals and Interferences (“BPAI”), and thereafter, the United States Court of Appeals for the Federal Circuit, and finally the United States Supreme Court. *See* Hildreth, *supra* at § 2:4.

⁴⁵ *See, e.g., Ariad*, 598 F.3d at 1350.

⁴⁶ *See Arlington*, 632 F.3d at 1257-58 (Lourie, J., concurring in part and dissenting in part).

(describe) embodiment covered by the claim because either (1) a patent draftsman failed to provide the information in the patent; (2) the inventor did not know the embodiments; or (3) the inventive technology was “pioneering” technology—so new and basic that it starts a whole new technology area—and therefore, the inventor could not have known about later developments (also called “after-arising technology”) in this new technology area.⁴⁷

Should the courts allow these functional claims to exclude an undisclosed design or activity? Should the claims be read narrowly to cover only the disclosed design or activity? Or, on a more extreme basis, should the claims that do not disclose in the specification the claimed design or activity be found invalid? This depends on whether one believes that (1) the scope of the invention is determined *by the claims* and the specification should be used only to interpret the claim terminology and to enable one skilled in the art to make and use the claimed invention; or (2) the scope of the invention is determined *by both the claims and the description of the invention in the specification* (the specification must also define claim terminology and enable one skilled in the art to make and use the claimed invention).⁴⁸ These different views represent an ideological disagreement that recently has been debated in a number of cases tried before the U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”).⁴⁹

⁴⁷ See *id.*

⁴⁸ See Jason Rantanen, *Arlington Industries v. Bridgeport Fittings: “The specification is the heart of the patent,”* PATENTLY-O BLOG (Jan. 25, 2011), <http://www.patentlyo.com/patent/2011/01/arlington-industries-v-bridgeport-fittings-the-specification-is-the-heart-of-the-patent.html>. Compare *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575 (Fed. Cir. 1997) (finding a claim to be invalid because it failed to satisfy the requirements of an adequate written description), with *Phillips v. AWH Corp.*, 415 F.3d 1303, 1326-28 (Fed. Cir. 2005) (reversing a lower court’s holding which construed a claim term to be limited to less than the full scope of its ordinary meaning). See also *Ariad*, 598 F.3d at 1350 (holding description of a generic invention, failed to meet the written description requirement); see also *Arlington*, 632 F.3d at 1257-58 (Lourie, J., concurring in part and dissenting in part) (stating that claims should not be construed beyond the descriptions embodied by the inventor).

⁴⁹ See Rantanen, *supra* note 48; see, e.g., *Eli Lilly*, 119 F.3d 1559 (affirming invalidity of claims because of insufficient description in the claim). Compare *Phillips*, 415 F.3d at 1328 (reversing district court’s application of claims construction, because claim in court’s view was not ambiguous), with *id.* at 1329 (Lourie, J., dissenting) (disagreeing with majority largely because “the specification contains no disclosure of baffles at right angles”); compare *Ariad*, 598 F.3d at 1350 (holding the asserted claims of the patent invalid for failure to meet the written requirement by describing only a generic invention), with *id.* at 1361 (Rader, J., dissenting in part) (describing the majority as “rejecting that statutory balance in

This ideological disagreement greatly impacts university patents where there is an inadequate description, the commercial applications of the research were not known by the inventor, or where the subject matter of the patent was pioneering technology and the claims for that technology cover advances that are later invented.⁵⁰ If the courts hold that the scope of an invention is determined *by both the claims and the description of the invention in the specification*, which is the direction in which some of the judges on the Federal Circuit seem to be headed, then many university patents may be invalidated, or at a minimum, greatly narrowed in scope.⁵¹

III. CLAIM CONSTRUCTION

It has been held by the courts for many years that “the name of the game is the claim,” meaning that the scope of the invention is determined solely *by the claims*.⁵² In *Phillips v. AWH Corp.*,⁵³ the Federal Circuit en banc addressed to what extent a patent’s

favor of an undefined ‘written description’ doctrine, this court ignores the problems of standardless decision making and serious conflicts with other areas of patent law.”); *compare Arlington*, 632 F.3d at 1257 (Lourie, J., concurring in part and dissenting in part) (dissenting because the written description provided by the inventor defines the limits to a patent, because “[a] patent is a teaching document. In almost all cases, the inventors, and their patent solicitors, knew what was invented and generally disclosed their invention in competent language.”), *with id.* at 1255-56 (majority opinion) (finding error in the lower court limiting “spring metal adapter” to mean only a “split” absent any extrinsic evidence supporting such a construction). The Federal Circuit has exclusive jurisdiction over patent application appeals, patent interferences, and decisions of district courts throughout the country related to patent law. See 28 U.S.C. § 1295(a) (2006 & Supp. V 2011). Hence, decisions from the Federal Circuit regarding patent law are similarly precedential to decisions by the Supreme Court. See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 274-76 (2002). Federal Circuit cases are heard by a panel of three judges and depending on the ideological make-up of the panel, case outcomes sometimes differ and when this happens, the Federal Circuit will take the case en banc before a panel of nine judges. See, e.g., *Ariad*, 598 F.3d at 1340.

⁵⁰ See *Ariad*, 598 F.3d at 1353; see also Unikel & Eveleigh, *supra* note 32, at 86; see also *Invention, Creation, & Public Policy Symposium: Patent Reform & Innovation Incentive: Enabling After-Arising Technology*, 34 IOWA F. CORP. L. 1083, 1085-86 (Summer 2009).

⁵¹ See *Ariad*, 598 F.3d at 1353 (stating that many university patents usually include groundbreaking research which limits the patent protection since they are unable to describe the patent with detailed specification).

⁵² Harold C. Wegner, *Arlington Indus. v. Bridgeport Fittings: The 20 Year Claim Construction Debate*, IPFRONTLINE (Jan. 26, 2011), <http://www.IPFrontline.com> (quoting Giles S. Rich, *The Extent of the Protection and Interpretation of Claims-American Perspectives*, 21 INT’L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990)); *Arlington Indus.*, 632 F.3d at 1256 (quoting Rich, *supra*).

⁵³ 415 F.3d 1303.

specification is relied on to determine the scope of its claims.⁵⁴ The court stated that “[i]t is a ‘bedrock principle’ of patent law” that the claims define the scope of the invention, for which the patentee can exclude all others from making or using.⁵⁵ Yet, the claims are “read in view of the specification.”⁵⁶ This means that a person trying to understand the meaning of the claims looks to “ ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence.’ ”⁵⁷ The court also stated that one should “avoid the danger of reading limitations from the specification into the claim.”⁵⁸ In fact, the court expressly stated that the claims are not limited merely to the disclosed embodiment.⁵⁹ In deciding *Phillips*, the Federal Circuit found that even though the specification did not disclose “baffles at right angles,” the claims, reciting “inward extending structures,” did not limit the angle of the baffles (structures); therefore, “baffles at right angles” were covered by the claims.⁶⁰ Since *Phillips* was decided, it has been the most cited case in patent law.⁶¹ Its precedent has been carefully followed with respect to device claims, but has occasionally been brought into question with respect to functional claims.⁶²

Functional claims are method claims that recite steps to achieve a particular result.⁶³ The issue with these claims is that all devices that perform the steps to achieve the result are covered by these claims, including devices the patent owner never thought of or described in the patent.⁶⁴ These are the types of patents that many people worry hold back innovation rather than promote it.

⁵⁴ *Id.* at 1312 (holding that the specification and the prosecution history should have greater emphasis than extrinsic sources in determining the definition of claim terms).

⁵⁵ *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also *Markman*, 52 F.3d at 980 (“The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.”).

⁵⁶ *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978-79).

⁵⁷ *Id.* at 1314 (quoting *Innova/Pure Water, Inc.*, 381 F.3d at 1116).

⁵⁸ *Id.* at 1323.

⁵⁹ *Id.*

⁶⁰ *Id.* at 1329 (Lourie, J., concurring in part and dissenting in part).

⁶¹ See Dennis Crouch, *Top Ten Most Cited Patent Cases 2007-2010*, PATENTLY-O BLOG (May 30, 2010), <http://www.patentlyo.com/patent/2010/05/top-ten-most-cited-patent-cases-2007-2010.html>.

⁶² See *Ariad*, 598 F.3d at 1350.

⁶³ *Id.* at 1349-50.

⁶⁴ *Id.*

In *Arlington Industries v. Bridgeport Fittings, Inc.*,⁶⁵ Chief Judge Rader cited *Phillips* as the basis for holding that the district court improperly imported a claim limitation from the specification.⁶⁶ The question in *Arlington Industries* was whether the term “spring metal adaptor” in the asserted claim means “an adaptor made of a spring metal” or a metal adaptor that expands and contracts (springs) because of a “split.”⁶⁷ The defendant, Bridgeport Fittings, Inc., argued that although the claim did not recite a split as other claims did, the split was nevertheless required by the specification because all the drawings showed a split in the adaptor, and there was no description of an embodiment without a split.⁶⁸ However, the court found that the language in the specification did not indicate that the inventor intended “to limit the claims to ‘split’ embodiments.”⁶⁹

In an interesting separate opinion, Judge Lourie questioned whether the precedent set in *Phillips* should be followed.⁷⁰ Judge Lourie argued that the scope of the invention is determined *by both the claims and the description of the invention in the specification.*⁷¹ “[T]he basic mandate is for claims to be interpreted in light of the specification of which they are a part because the specification describes what the inventors invented.”⁷² In Judge Lourie’s view, a patent specification is a teaching document not only for the definition of a claim term, but also for the definition of what the invention is.⁷³ Judge Lourie stated that if the inventor invented an adaptor with a split, the inventor should not be able to claim an adaptor without a split.⁷⁴ Perhaps, an adaptor without a split might be held to infringe the claims under the doctrine of equivalents, but it should not literally

⁶⁵ 632 F.3d 1246.

⁶⁶ *See id.* at 1253.

⁶⁷ *Id.* at 1248.

⁶⁸ *Id.* at 1253. In this litigation there were two patents at issue. *Id.* at 1248. The first had no mention of an embodiment without a split, while the second incorporated by reference another patent where there was an embodiment without a split. *Arlington*, 632 F.3d at 1248.

⁶⁹ *Id.* at 1254.

⁷⁰ *Id.* at 1258 (Lourie, J., concurring in part and dissenting in part).

⁷¹ *See id.* at 1257. Judge Lourie concurred with the decision regarding the patent that incorporated by reference the other patent, which had an embodiment without a split, but dissented with the decision regarding the first patent where there was no embodiment with a split design. *Id.*; *see also* Rantanen, *supra* note 48.

⁷² *Arlington*, 632 F.3d at 1257.

⁷³ *Id.*

⁷⁴ *See id.* at 1258; *see also* Rantanen, *supra* note 48.

infringe the claims.⁷⁵ Judge Lourie explained that most inventors teach what they have invented.⁷⁶ However, a problem arises when inventors use their patents “as a business weapon” by asserting them “against someone engaged in activity not contemplated by the inventors as part of their invention.”⁷⁷ In this situation, the claims are modified during prosecution to incorporate the non-contemplated activity.⁷⁸ In Judge Lourie’s view, “patents should be narrow” and limited to what one has invented, and the specification should “always play a role in determining what the inventor has invented and thus help shape the scope of protection” that the claims cover.⁷⁹ Judge Lourie advised, “[T]he claims should not mean more than what the specification indicates . . . the inventors invented.”⁸⁰

The position advocated by Judge Lourie would require the inventor to think of and disclose numerous possible embodiments—an onerous task for anyone, particularly the university scientist who is patenting basic technology with few known commercial applications.⁸¹ Judge Lourie “seems willing to pay this cost because of the greater certainty” of disclosure.⁸²

In the quest for better quality patents, might the Federal Circuit, the Supreme Court, or Congress accept Judge Lourie’s view?⁸³ As *Arlington Industries* continues to be litigated, the district court stated that the “Federal Circuit’s [broad claim construction] is controversial and has some likelihood of being re-heard en banc.”⁸⁴ It is likely that the Federal Circuit will adjust the claim construction doctrine to be more in line with the indefiniteness doctrine, the written description doctrine, and the enablement doctrine, each

⁷⁵ See Rantanen, *supra* note 48.

⁷⁶ *Arlington*, 632 F.3d at 1257.

⁷⁷ *Id.* at 1257-58.

⁷⁸ *Id.* at 1258.

⁷⁹ Wegner, *supra* note 52.

⁸⁰ *Arlington*, 632 F.3d at 1258.

⁸¹ See Rantanen, *supra* note 48.

⁸² *Id.*

⁸³ See *Bilski*, 130 S. Ct. at 3253 (quoting *O’Reilly v. Morse*, 56 U.S. 62, 121 (1853) (stating that an inventor “can lawfully claim only what he has invented and described, and if he claims more his patent is void”)).

⁸⁴ Dennis Crouch, *Patently-O Bits & Bytes by Lawrence Higgins*, PATENTLY-O BLOG (Mar. 11, 2011), <http://www.patentlyo.com/patent/2011/03/patently-o-bits-bytes-by-lawrence-higgins-1.html> (regarding the *Arlington* district court opinion citing Jason Rantanen’s Patently-O blog post). Furthermore, “[t]he district court favorably noted the ‘over 100’ comments that had been added to the post.” *Id.*

described below. If this is the case, it is imperative that university patents contain an adequate disclosure of their inventive technology with as many commercial applications as possible.

IV. CLAIM INDEFINITENESS

Judge Lourie's position finds some support in the claim indefiniteness doctrine. Under this doctrine, a claim that does not clearly delineate the boundaries of an invention will be found invalid.⁸⁵ This typically occurs when a claim term is not clearly defined in the specification.⁸⁶ When a university quickly files a patent application to avoid the loss of patent rights, it is likely that one or more of the claim terms are not clearly defined in the specification. This can also happen when the scientist has minimal industrial contact and does not know the multiple meanings of one or more terms within that industry.

In *Halliburton Energy Services, Inc., v. M-I LLC*,⁸⁷ the Federal Circuit stated:

Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent. Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims.⁸⁸

In *Halliburton*, the court held that the asserted patent was invalid because the degree of fragility for the claim term "fragile gel" was not identified in the specification causing the claim to be indefinite.⁸⁹ The court reasoned that this allowed the claims to cover not only Halliburton's invention, but also the prior art and all future improvements to the gel's fragility.⁹⁰

⁸⁵ See 35 U.S.C. § 112 (requiring the invention to be distinctly claimed).

⁸⁶ See *Halliburton Energy Servs., Inc., v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) (stating that a claim is indefinite when the bounds of a claim are so ambiguous that a skilled artisan cannot determine the boundaries of the claim based on the specification).

⁸⁷ 514 F.3d 1244.

⁸⁸ *Id.* at 1249.

⁸⁹ *Id.* at 1254.

⁹⁰ *Id.*

The Federal Circuit has also used the indefiniteness doctrine to invalidate means-plus-function claims that do not have a corresponding structure in the specification,⁹¹ claims that include numeric limitations “without disclosing [in the specification] which of multiple methods of measuring that number should be used,”⁹² and claims that contain a term that is “completely dependent on a person’s subjective opinion.”⁹³

V. WRITTEN DESCRIPTION

The Federal Circuit explained in *Ariad Pharms. Inc. v. Eli Lilly & Co.*⁹⁴ that in many instances the specification of a university patent does not contain specific examples, and the functional claims are directed to a process that solves a problem and covers every device that can perform the process or every compound developed by the process.⁹⁵ This happens because “universities may not have the resources or inclination to work out the practical implications of [their] research” (the patent was applied for too early or the commercial application was not determined).⁹⁶ This is different, however, from after-arising technologies, which cannot be described in the specification of a pioneering patent because the inventor could not have known about further developments in the new technology area.⁹⁷ In his dissenting opinion in *Ariad*, Chief Judge Rader explained that it has been long-established law that pioneering patents which block the practice of after-arising technology must be licensed.⁹⁸ Furthermore, “[t]his blocking condition can exist even where the original patentee ‘failed to contemplate’ an additional element found in the improvement patent.”⁹⁹ However, Judge Lourie and other judges on the Federal Circuit have held that the written

⁹¹ *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007) (“If there is no structure in the specification corresponding to the means-plus-function limitation in the claims, the claim will be found invalid as indefinite.”).

⁹² *Halliburton Energy Servs., Inc.*, 514 F.3d at 1250 (citing *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003)).

⁹³ *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005).

⁹⁴ 598 F.3d 1336.

⁹⁵ *Id.* at 1352.

⁹⁶ *Id.* at 1353.

⁹⁷ Unikel, *supra* note 32, at 86; *see also* *Invention, Creation, & Public Policy Symposium*, *supra* note 50, at 1086.

⁹⁸ *Ariad*, 598 F.3d at 1365 (Rader, J., dissenting).

⁹⁹ *Id.* (quoting *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983)).

description requirement mandates that an inventor “possess” an invention in order for his patent to exclude others from making it.¹⁰⁰

The requirement for a written description has been a conflicting area of law for more than a decade.¹⁰¹ Although there has always been a written description requirement with regard to a later filed application claiming priority (an earlier filing date) to an earlier filed application, the requirement was not applied to patents not claiming priority.¹⁰² However in *The Regents of the University of California v. Eli Lilly*,¹⁰³ decided in 1997, the Federal Circuit applied the written description requirement “apart from enablement and beyond the priority context.”¹⁰⁴ In *Eli Lilly*, the Federal Circuit, with Judge Lourie writing the opinion for the court, held that the written description requirement is separate from the enablement requirement and is necessary in all specifications for patent validity.¹⁰⁵ The court found that the specification provided an adequate description for rat insulin cDNA, but it did not provide an adequate description for mammalian insulin cDNA even though the method claims covered both.¹⁰⁶ The court stated that the written description requirement of Section 112 required that the invention be described in the specification “in sufficient detail that one skilled in the art can clearly conclude that ‘the inventor invented the claimed invention.’”¹⁰⁷ The requirement mandates that a “ ‘precise definition, such as by structure, formula, chemical name, or physical properties’ ” be in the specification.¹⁰⁸ A mere statement of the DNA and a “potential method for isolating it” is not enough.¹⁰⁹ In addition, “a description

¹⁰⁰ *Id.* at 1351.

¹⁰¹ *Id.* at 1360 (Gajarsa, J., concurring); *see also id.* at 1340 (majority opinion) (agreeing to hear the case en banc to settle written description requirement); *see also* Lizardtech, Inc. v. Earth Res. Mapping, Inc. (*Lizardtech II*), 433 F.3d 1373, 1381 (Fed. Cir. 2006) (Rader, J., dissenting from the court’s decision not to hear the case en banc); *see also* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 989 (Fed. Cir. 2002) (Rader, J., dissenting from the court’s decision not to hear the case en banc).

¹⁰² *Ariad*, 598 F.3d at 1367 (Linn, J., dissenting in part and concurring in part).

¹⁰³ 119 F.3d 1559 (Fed. Cir. 1997).

¹⁰⁴ *Ariad*, 598 F.3d at 1367 (Linn, J., dissenting in part and concurring in part); *see also id.* at 1365 (Rader, J., dissenting in part and concurring in part) (stating that the doctrine of claim construction and the enablement doctrine provide the required limitations for the scope of an invention). The enablement doctrine is described in the next section.

¹⁰⁵ *Eli Lilly*, 119 F.3d at 1562.

¹⁰⁶ *Id.* at 1566.

¹⁰⁷ *Id.* (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

¹⁰⁸ *Id.* (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

¹⁰⁹ *Id.* at 1566-67 (quoting *Fiers*, 984 F.2d at 1170).

which renders obvious a claimed invention” is also not enough.¹¹⁰ The University of California argued that it disclosed a general method of isolating cDNA and a specific example of a species covered by the generic claimed, which together enabled one skilled in the art to make and use the entire genus.¹¹¹ The court held that a description of one species of a genus is not a description of the whole genus and that the specification must contain a description of the entire invention in addition to enabling the entire invention.¹¹² The court explained that a description by function only describes what a genus does, and not what the genus is.¹¹³

After *Eli Lilly*, a number of Federal Circuit cases specifically addressed the written description requirement.¹¹⁴ Many of the technologies were developed and patented by universities,¹¹⁵ and most of these cases involved patents for biotechnology or pharmaceuticals that had broad generic functional claims with a description of only one species.¹¹⁶ In *Carnegie Mellon University v. Hoffman-LA Roche Inc.*,¹¹⁷ the Federal Circuit refined its standard stating that “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.”¹¹⁸ The

¹¹⁰ *Eli Lilly*, 119 F.3d at 1567 (citing *Lockwood*, 107 F.3d at 1572).

¹¹¹ *Id.*

¹¹² *Id.* at 1568.

¹¹³ *Id.*

¹¹⁴ *E.g.*, *Ariad*, 598 F.3d at 1340; *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1117 (Fed. Cir. 2008); *Lizardtech II*, 433 F.3d at 1374; *Invitrogen Corp. v. Clontech Labs.*, 429 F.3d 1052, 1057 (Fed. Cir. 2005); *Capon v. Eshhar*, 418 F.3d 1349, 1350 (Fed. Cir. 2005); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 917 (Fed. Cir. 2004); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1320 (Fed. Cir. 2003); *Enzo*, 323 F.3d at 960.

¹¹⁵ *E.g.*, *Ariad*, 598 F.3d at 1340 (involving “methods for regulating cellular responses to external stimuli by reducing NF-kB activity in a cell” developed by MIT and Harvard College); *Carnegie Mellon*, 541 F.3d at 1118 (involving isolated DNA developed by Carnegie Mellon); *Univ. of Rochester*, 358 F.3d at 918 (involving a pharmaceutical product developed by the University of Rochester).

¹¹⁶ *E.g.*, *Ariad*, 598 F.3d at 1340 (involving “methods for regulating cellular responses to external stimuli by reducing NF-kB activity in a cell”); *Carnegie Mellon*, 541 F.3d at 1118 (involving isolated DNA); *Univ. of Rochester*, 358 F.3d at 918 (involving a pharmaceutical product).

¹¹⁷ 541 F.3d 1115 (Fed. Cir. 2008).

¹¹⁸ *Carnegie Mellon*, 541 F.3d at 1124 (italics omitted) (quoting The Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. 10-99, 1106 (Jan. 5, 2001)).

written description will only be adequate if a representative number of species are disclosed that show “one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.”¹¹⁹ The court further explained:

[W]hat is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.¹²⁰

One case, where the asserted claims were not for a technology in the unpredictable arts of chemistry and biology, was *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*¹²¹ The method claims asserted by Lizardtech and the Regents of the University of California were directed to software.¹²² The court held that the claims for software that perform an image compression technique called seamless discrete wavelet transformation (DWT) were invalid because the specification only described “maintaining updated sums of [the] DWT coefficients” rather than performing a seamless DWT.¹²³ The court further explained that the written description requirement usually rises and falls with the enablement requirement because “a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa.”¹²⁴ The court reasoned that in this case “a person of skill in the art would not understand how to make a seamless DWT generically and would not understand Lizardtech to have invented a method for making seamless DWT,” only a method of maintaining updated sums of the DWT.¹²⁵ In a dissenting opinion for the court’s denial to rehear the

¹¹⁹ *Id.* (citing The Guidelines for Examination of Patent Applications, *supra* note 118).

¹²⁰ *Id.* at 1126 (quoting *Capon*, 418 F.3d at 1359).

¹²¹ (*Lizardtech I*), 424 F.3d 1336, 1337 (Fed. Cir. 2005).

¹²² *Id.* (involving a software image compression technique developed by the Regents of the University of California).

¹²³ *Id.* at 1344.

¹²⁴ *Id.* at 1345.

¹²⁵ *Id.*

case en banc, Judge Rader discussed the lack of clarity for the proper written description test.¹²⁶ Judge Rader further explained that the evolving written description doctrine is inconsistent with the court's decision in *Phillips*, because *Phillips* states that limitations from the specification should not be read into the claims, yet the written description doctrine requires the claims to be limited to what is described in the specification.¹²⁷

Notably, in *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*,¹²⁸ the Federal Circuit held that the claims, which were *device* claims directed to subject matter in the predictable arts, were invalid.¹²⁹ The court stated that the device claims overreached the scope of the inventor's contribution to the field of art because the claims were broad enough to cover both valves that had a spike and valves that did not have a spike, but the specification only disclosed valves with a spike; therefore, the written description requirement was not fulfilled and the claims were invalid.¹³⁰ Although the court questioned importing limitations from the specification, citing *Phillips*, the court explained, “ ‘[T]he line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.’ ”¹³¹ The court determined that one skilled in the art would understand the claims to cover only valves with a spike because the specification did not describe piercing by the spike as being optional, there was no suggestion the piercing could be accomplished by anything other than a pointed spike, and the figures only showed a pointed spike.¹³² These cases show that even in the stable arts, patent scope is narrowed when all embodiments are not envisioned to allow a sufficient description in the specification—likewise a concern for university patents.

¹²⁶ *Lizardtech II*, 433 F.3d at 1380 (denying rehearing en banc).

¹²⁷ *Id.* at 1381.

¹²⁸ 558 F.3d 1368 (Fed. Cir. 2009).

¹²⁹ *Id.* at 1379; *but see* *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (stating that original claims can show possession of the invention however “claims to a functionally defined genus, will not satisfy the written description requirement without a disclosure showing that the applicant had invented species sufficient to support the claim”).

¹³⁰ *ICU Medical*, 558 F.3d at 1378.

¹³¹ *Id.* at 1375 (quoting *Phillips*, 415 F.3d at 1323).

¹³² *Id.*

In order to bring certainty to the written description doctrine, the Federal Circuit agreed to hear *Ariad* en banc.¹³³ *Ariad* asserted patent claims for a method of reducing the activity of “a previously unknown protein, called NF- κ B . . . found to mediate certain intracellular signaling . . . [thereby] reduc[ing] the symptoms of certain diseases.”¹³⁴ The technology was developed and patented by the Massachusetts Institute of Technology, Harvard College, and the Whitehead Institute for Biomedical Research.¹³⁵ Similar to *Eli Lilly*, the inventor claimed a method encompassing a genus while the specification disclosed only a single species.¹³⁶

The Federal Circuit upheld the requirement for a written description that teaches the entire scope of the claimed invention in the specification.¹³⁷ Judge Lourie, writing for the majority, asserted that “it is the specification itself that must demonstrate possession” of the claimed invention.¹³⁸ He explained that an invention must be fully and particularly described so 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.’ ”¹³⁹ The court’s decision clarified the test for a sufficient written description as, “whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.”¹⁴⁰ Showing possession of the invention varies depending on the scope of the claims, the existing knowledge in the technology field, the prior art, the maturity of the technology, and the predictability of the art.¹⁴¹ The court did not identify a specific form of disclosure required to meet the written description requirement; however, it did state that a description that merely makes the invention obvious is not enough.¹⁴² Judge Rader and Judge Linn did not agree with the majority’s position.¹⁴³ They believed that the

¹³³ *Ariad*, 598 F.3d at 1340.

¹³⁴ *Id.* at 1358-59 (Newman, J., additional views).

¹³⁵ *Id.* at 1340 (majority opinion).

¹³⁶ *Id.* at 1350.

¹³⁷ *Id.* at 1344.

¹³⁸ *Ariad*, 598 F.3d at 1352.

¹³⁹ *Id.* at 1353-54 (quoting *Univ. of Rochester*, 358 F.3d at 920).

¹⁴⁰ *Id.* at 1351 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

¹⁴¹ *Id.*

¹⁴² *Id.* at 1352.

¹⁴³ *Ariad*, 598 F.3d at 1361 (Rader, J., dissenting in part and concurring in part); *see also*

enablement doctrine is sufficient to meet the requirements of Section 112, and a written description requirement is only necessary in the priority context.¹⁴⁴ Judge Rader explained in his dissent that a patentee cannot foresee future improvements to incorporate them into the specification and yet “[t]he Supreme Court has long acknowledged the ‘well established’ rule that ‘an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such.’”¹⁴⁵ He further explained that a blocking condition typically occurs when “a pioneering patent claims a genus and an improvement patent later claims a species of that genus.”¹⁴⁶ Judge Rader’s concern with the new written description doctrine was that “mere improvements will likely invalidate genus patents.”¹⁴⁷ Because many university patents are for pioneering technologies with unknown improvements, the written description requirement will greatly impact the validity of their claims.

Ariad, sharing the same concern, complained that the written description doctrine disadvantages universities because “basic research cannot be patented.”¹⁴⁸ The court responded to this criticism by explaining that “[p]atents are not awarded for academic theories ‘but compensation for its successful conclusion.’”¹⁴⁹ Judge Newman joined the court’s opinion, but in an additional views section stated that the real issue Ariad faced was that its research “was taken to the patent system before its practical application was demonstrated.”¹⁵⁰ In requiring a written description that is separate from enablement and the priority context, the Federal Circuit is requiring universities to apply their basic research to at least one practical application and preferably many more when trying to

Univ. of Rochester v. G.D. Searle & Co., Inc. (*Univ. of Rochester II*), 375 F.3d 1303, 1307 (Rader, J., dissenting from denial of rehearing en banc); see also *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc); see also *Enzo*, 323 F.3d at 976 (Rader, J., dissenting from denial of rehearing en banc); see also *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc).

¹⁴⁴ *Ariad*, 598 F.3d at 1361-64 (Rader, J., dissenting in part and concurring in part); *id.* at 1367 (Linn, J., dissenting in part and concurring in part).

¹⁴⁵ *Id.* at 1365 (Rader, J., dissenting in part and concurring in part) (quoting *Temca Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928)).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 1366.

¹⁴⁸ *Ariad*, 598 F.3d at 1353 (majority opinion).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 1358 (Newman, J., additional views).

achieve broader patent scope.

VI. ENABLEMENT

When universities quickly file a patent application, it is likely that they have not enabled their invention because they have not put enough thought and time into providing an adequate disclosure.¹⁵¹ In *Ariad*, Judges Rader and Linn questioned whether Section 112 requires a separate written description of the invention; however, there was no question that Section 112 requires the invention to be “enabled.”¹⁵² The enablement doctrine requires “the specification of a patent [to] teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’”¹⁵³ “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.”¹⁵⁴ The factual considerations the courts will look at are the *Wands* factors, which are:

- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.¹⁵⁵

In *Penda Corp. v. United States*,¹⁵⁶ the Federal Circuit stated that the scope of the enablement in the specification “must bear a reasonable relationship” with the scope of the claims.¹⁵⁷ “In arts involving predictable factors, such as patents in the mechanical or electrical arts, a single embodiment provides broad enablement [I]n arts involving unpredictable factors, such as chemistry and

¹⁵¹ *E.g., id.* (stating that a patent application for basic scientific research was filed before a practical application was demonstrated).

¹⁵² *Id.* at 1361 (Rader, J., dissenting in part and concurring in part); *Ariad*, 598 F.3d at 1367 (Linn, J., dissenting in part and concurring in part).

¹⁵³ *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (citing 35 U.S.C. § 112).

¹⁵⁴ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

¹⁵⁵ *Id.*

¹⁵⁶ 29 Fed. Cl. 533 (1993).

¹⁵⁷ *Id.* at 556.

physiology, the requisite scope of enablement varies inversely with the degree of unpredictability of the factors involved.”¹⁵⁸ To improve the quality of patents, the Federal Circuit has shifted this philosophy and, even in the predictable arts, has limited the ability of a single embodiment to provide support for broad claims that cover different embodiments.

In *Liebel-Flarsheim v. Medrad*,¹⁵⁹ the Federal Circuit heard two appeals: first on the district court’s claim construction¹⁶⁰ and then, after remand, on whether the claims were invalid due to the lack of a written description and enablement.¹⁶¹ The claims, as originally filed, recited a pressure jacket, but during prosecution the pressure jacket limitation was removed, likely because Liebel found out Medrad’s device did not have a pressure jacket.¹⁶² The district court construed the claims as requiring a pressure jacket.¹⁶³ The Federal Circuit in *Liebel I* held that the scope of the claim was broader than the district court’s interpretation because “although all the described embodiments include a pressure jacket, the disclosure did not clearly disavow embodiments lacking a pressure jacket.”¹⁶⁴ On remand, the district court held that “the claims were invalid for lack of written description because the specification d[id] not describe a jacketless injector.”¹⁶⁵ Furthermore, the district court, after considering the *Wands* factors, held that the claims were also invalid for lack of enablement because “no prototypes of a jacketless injector had been made or described at the time of filing, and that the state of the art was such that a jacketless system with a disposable syringe would have been a ‘true innovation.’”¹⁶⁶ On appeal, the Federal Circuit did not consider invalidity based on written description because it first held that the claims were invalid based on lack of enablement.¹⁶⁷

Liebel argued that the claims were enabled because the

¹⁵⁸ *Id.*

¹⁵⁹ *Liebel I*, 358 F.3d 898 (Fed. Cir. 2004); *Liebel II*, 481 F.3d 1371 (Fed. Cir. 2007).

¹⁶⁰ *Liebel I*, 358 F.3d at 900.

¹⁶¹ *Liebel II*, 481 F.3d at 1373.

¹⁶² *Id.* at 1374. “[A] pressure jacket [is] necessary to ‘maintain the integrity of the syringe housing against pressures the syringe encounters during operation of the injector.’” *Id.* at 1375.

¹⁶³ *Id.* at 1374.

¹⁶⁴ *Id.* at 1374-75.

¹⁶⁵ *Liebel II*, 481 F.3d at 1375.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 1380.

asserted claims required neither a pressure jacket nor the absence of a pressure jacket and the specification enabled its preferred embodiment of a syringe with a pressure jacket.¹⁶⁸ Liebel also argued that after reading the specification, one skilled in the art would only be required to do additional work and not undue experimentation to produce a jacketless injector because its invention pertained to the mechanical arts in which “a single embodiment can enable a broad claim.”¹⁶⁹ Medrad argued that “although every embodiment of a claim does not need to be disclosed in the specification, the disclosure must teach the full range of embodiments in order for the claims to be enabled, and here the disclosure does not teach an injector without a pressure jacket.”¹⁷⁰ The Federal Circuit agreed with Medrad and stated “[t]hat [the] full scope must be enabled.”¹⁷¹ The court reasoned that the patent taught away from jacketless injectors, that pressure jackets were in every figure and every discussion of every figure, and that testimonial evidence showed that a jacketless injector was not known at the time of filing.¹⁷² The court ended with this final statement:

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, “beware of what one asks for,” might be applicable here.¹⁷³

Similarly, in *Automotive Technologies International, Inc. v. BMW*,¹⁷⁴ the Federal Circuit held that broad claims that covered both mechanical and electrical sensors for side impact airbags were not enabled because the specification described mechanical sensors but had only a vague description of an electronic switch.¹⁷⁵ The court explained that the specification and the figures only had a concept

¹⁶⁸ *Id.* at 1378.

¹⁶⁹ *Id.* at 1378-79.

¹⁷⁰ *Liebel II*, 481 F.3d at 1378.

¹⁷¹ *Id.* at 1379.

¹⁷² *Id.*

¹⁷³ *Id.* at 1380.

¹⁷⁴ 501 F.3d 1274 (Fed. Cir. 2007).

¹⁷⁵ *Id.* at 1282; *see also* *Sitrick v. Dreamworks, LLC*, 516 F.3d 993 (Fed. Cir. 2008) (holding that broad claims that covered video games and movies were not enabled because the specification only taught the use of video games).

and not a specific design, and that the “mere boxed figure of the electronic sensor and the few lines of description” would not teach one skilled in the art to make and use an electronic sensor.¹⁷⁶ Even though Automotive Technologies International argued that one skilled in the art would know the missing information, the court stated:

[T]he rule that a specification need not disclose what is well known in the art is “merely a rule of supplementation, not a substitute for a basic enabling disclosure.” . . . “[O]mission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.”¹⁷⁷

The court noted that the mechanical sensor required two columns of description and the electronic sensor needed a similar disclosure.¹⁷⁸ Even though enablement of broad claims is more easily achieved in the mechanical and electrical arts because a description of how to make and use one or a few embodiments allows a person skilled in the art to make and use a broad range of embodiments, these cases show that this is not always the case.

VII. CONCLUSION

In his quest for better quality patents, the Director of the PTO, David Kappos, explained recently that the *Ariad* decision is important because after enablement, the written description requirement ensures that applicants’ claims do not cover more than they are entitled to cover, i.e. more than they have invented and disclosed.¹⁷⁹ The written description requirement protects the integrity of the patent system, by invalidating over-broad patents, especially method claims that claim the problem to be solved or the results to be achieved

¹⁷⁶ *Auto. Techs.*, 501 F.3d at 1283.

¹⁷⁷ *Id.* at 1283-84 (quoting *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

¹⁷⁸ *Id.* at 1284.

¹⁷⁹ Symposium, *Thoughts from the George Washington University Law School Symposium on Intellectual Property: Building Bridges and Making Connections Across the IP System*, 20 FED. CIR. B.J. 273 (2010) (Remarks by David J. Kappos).

rather than claiming how those results are actually achieved.¹⁸⁰

Kappos describes the use of three patent law filters working together to set the boundaries of claim coverage in each patent.¹⁸¹ He explains that some claims may be so over-broad that they fail to meet the requirements of patentable subject matter (Section 101) because their broadness makes them an abstract idea with no physical limitations.¹⁸² In this scenario, Section 101 acts as a coarse (first) filter invalidating claims that encompass mental processes performed by a person, laws of nature, or other such abstractions.¹⁸³ Next, Section 112 acts as a fine (second) filter because it ensures that the full scope of the claims is fully described and fully enabled, i.e. that the applicant described how to make and use an invention that the applicant actually possessed.¹⁸⁴ Finally, Sections 102 and 103 act as an even finer (third) filter so that the boundaries of the invention are defined to be novel and non-obvious over the prior art.¹⁸⁵ Since the Supreme Court decided *Bilski* in 2010, in which the Court declined to provide a test for determining what an abstract idea is, the PTO has begun to reject many broad claims using Section 112.¹⁸⁶

As the Federal Circuit and the PTO strive to increase the quality of patents, it appears that broad claim language and especially “functional claim language that sweepingly encompasses after-arising technology” will likely be found invalid under either the indefiniteness doctrine, the written description doctrine, or the enablement doctrine.¹⁸⁷ Furthermore, it is likely that the Federal Circuit will adjust the claim construction doctrine to be in line with these doctrines, thereby greatly narrowing the scope of broad claims.¹⁸⁸ Hence, broad functional claims, even for technology areas in the stable arts, which do not disclose specific embodiments (applications) in the specification, will be limited in scope to those

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*; *Bilski*, 130 S. Ct. at 3229.

¹⁸³ *See Bilski*, 130 S. Ct. at 3229.

¹⁸⁴ *Invention, Creation, & Public Policy Symposium*, *supra* note 50 at 1113, n.168.

¹⁸⁵ *Id.* at 1083.

¹⁸⁶ *Bilski*, 130 S. Ct. at 3258-59 (Breyer, J., concurring).

¹⁸⁷ Kevin Emerson Collins, *An Initial Comment on Ariad: Written Description and the Baseline of Patent Protection for After-Arising Technology*, *PATENTLY O-PATENT* L.J. 60, 70 (2010).

¹⁸⁸ *See supra* notes 84-85.

embodiments disclosed.¹⁸⁹ If the claims are *not* limited, they may be invalidated under the written description doctrine or the enablement doctrine.¹⁹⁰ Although one may think that a patent with broad claims is better for attracting business commercialization, if the courts invalidate similarly broad claims in other patents, then the claims will have a cloud over them (be in doubt) and investors will likely be discouraged from investing in technology that may lack patent protection.¹⁹¹

Patents that promote commercialization of a technology, are patents that (1) have claims that will be held valid by the courts, (2) protect the technology that will be brought to market, and (3) do not have claim limitations that can be easily designed around.¹⁹² Accordingly, universities should make sure that in addition to broad functional claims, they also have narrow claims that cover specific embodiments that are adequately described in the specification. This increased emphasis on the requirements of Section 112 necessitates that university patent applications are filed when research is further developed and at a minimum, one and preferably many commercial applications are known, so that it can be enabled, broader patent scope can be obtained, the terms can be properly defined, and it meets the requirement of the written description doctrine. Claims that are limited to specific embodiments, which are fully and distinctly described in the specification, will withstand scrutiny but may fail to prevent others from entering the technology field. Therefore, it is also important for universities to submit new patent applications for any future developments of the technology.

¹⁸⁹ See *supra* notes 84-85.

¹⁹⁰ *Liebel II*, 481 F.3d at 1378-80.

¹⁹¹ See Gene Quinn, *Show Me the IP! Venture Capital Success Based on Patents*, IPWATCHDOG.COM (Mar. 12, 2010), <http://ipwatchdog.com/2010/03/12/venture-capital-success-based-on-patents/id=9657/>.

¹⁹² *Id.*