In the Wake of *Enzo*: The Impact of the Federal Circuit's Decision on the U.S. Life Science Industry*

TABLE OF CONTENTS

* J.D. Candidate 2004, University of San Diego School of Law; B.S. Biology (Cellular) 1996, California State University, San Marcos. The author is employed by David Preston & Assocs., A.P.C., in San Diego.

The author would like to thank his lovely wife, Sheila, for making all of this possible. The author also thanks Professor Jane Henning, Henry Yorgey (J.D. Candidate 2004, University of San Diego School of Law), and Adam Welland, Esq., of Cooley Godward, L.L.P. Last but not least, to his former comrades, *Semper Fidelis* and his thoughts are with you.

Until the late nineteenth century, the profession of scientist in Western societies was comprised almost exclusively of men from the propertied classes or bourgeoisie who were educated at the elite European universities. It was a calling of sorts, not unlike the ministry, for those with means and pedigree who could afford the luxury of investigating the workings of the universe by expanding and challenging their intellect. There was no vast wealth to be made—maybe a comfortable living at the peak of one's career.[1]

I. INTRODUCTION

The United States spends more on health care than any other country in the world.[2] The U.S. Patent and Trademark Office (PTO) helps drive health care costs higher by awarding monopolies to scientific researchers whose inventions meet the requirements dictated by Title 35 of the U.S. Code.[3] Once the PTO awards such a monopoly, the inventor is the only party legally entitled to make, use, or sell the invention in the United States.[4] Though monopolies are thought to impair competition,[5] under

1. Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 15 (1999).

2. Health spending per capita in the United States was $4600 in 2000 (approximately $1.3 trillion total—13% of the Gross Domestic Product (GDP)). The United States spends more percentage wise on health care than Germany (10.6% of GDP), Canada (9.1%), Japan (7.8%), and the United Kingdom (7.3%). Alliance for Health Reform, *Covering Health Issues: A Sourcebook for Journalists (2003)*, *at* http://www.allhealth.org/sourcebook2002/ch8_tc.html (last updated Jan. 2003). The U.S. Department of Health and Human Services estimates that by 2011 the percentage of GDP spent on the nation's health will rise to 17%. Stephen Heffler et al., *Health Spending Projections for 2001–2011: The Latest Outlook*, HEALTH AFF., Mar./Apr. 2002, at 207, 210. Congress has attempted to address these skyrocketing costs, and in 2002, the Senate passed a bill granting consumers better access to generic versions of patented drugs once the patents expired. However, opposition to the measure in the House of Representatives (including input from the Bush administration as well as major drug companies) resulted in the defeat of the legislation. Alliance for Health Reform, *supra*. By comparison, the federal government spent almost $301 billion on national defense in 2000. The White House: Office of Management and Budget, *The Budget for Fiscal Year 2002*, *at* http://www.whitehouse.gov/omb/budget/fy2002/bud02.html (last visited Apr. 5, 2003).

3. 35 U.S.C. §§ 1–376 (2000).

4. *See id.* § 271. Strictly speaking, the patent allows the holder to *prevent others* from making, using, or selling the invention, but does not itself provide a legal right to use it herself (there may be legal prohibitions on the use of the patented device or the class to which it belongs). Regardless, the PTO has allowed a radar detector (whose only use is to evade speeding tickets) to be patented, and a court has upheld the patent.

the U.S. system these exclusionary rights are the rewards an inventor earns in exchange for enriching the pool of publicly available technology.[6] Perhaps in part because of the United States' historic resistance to monopolies, the PTO has always required the patent applicant to provide a significant amount of disclosure before a patent is granted. Recently though, the Federal Circuit[7] made it easier for researchers to patent deoxyribonucleic acid (DNA)[8] sequences[9] by

---

See Whistler Corp. v. Autotronics, Inc., No. CA3-85-2573-D, 1988 WL 212501, at *1, *2, *4, *5 (N.D. Tex. July 28, 1988).

> 5. Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2.

6. This quid pro quo lies at the heart of the U.S. patent system and has played a role in the Federal Circuit's consideration of the written description requirements. *See, e.g.*, Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1019 (Fed. Cir. 2002), *vacated by* 323 F.3d 956 (Fed. Cir. 2002). This exchange trades the monopolistic rights granted the patent holder for the public disclosure of the technology, thereby increasing the total technology available for public use. ARTHUR R. MILLER & MICHAEL H. DAVIS, INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL § 1.3, at 15 (2d ed. 1990). This exchange is often justified by either of the two theories behind the U.S. patent system: the "bargain" theory or the "natural rights" theory. *Id.* at 14–15. Under the bargain theory, the monopoly is the incentive provided to induce the pursuit of new inventions. *Id.* Under the natural rights theory, the inventor is the rightful owner of her invention, and the monopoly is the compensation awarded to encourage disclosure. *Id.*

7. The Federal Circuit holds exclusive appellate jurisdiction in cases brought under the Patent Act. MILLER & DAVIS, *supra* note 6, § 7.10, at 119.

8. DNA consists of phosphoric acid, a five-carbon sugar, D(-)2-deoxyribose, and a nitrogen base. NORMAN V. ROTHWELL, UNDERSTANDING GENETICS 217 (1993). The base is either a purine (adenine or guanine) or a pyrimidine (thymine or cytosine). *Id.* Individual DNA molecules are commonly referred to by the identity of the base: "A" for molecules containing adenine, "G" for those containing guanine, "T" for thymine, and "C" for cytosine. *Id.* The information-carrying capacity of DNA is a function of the selective binding of the component bases—while any of the bases A,T,C, or G can bind to each other in the same strand, DNA in its native form has a two-strand, double-helix structure. This double-helix structure is a combination of a "coding" or "sense" (specifying which amino acids are to be joined) and a "complementary" (noncoding) strand. Hydrogen bonding binds the strands together, and the bonding between one base and its corresponding base from the opposite strand is strictly controlled; As always bind to Ts and Gs always bind to Cs. *Id.* at 220. For example:

If a given strand is composed of these bases: A T G C G C G C A T
The complementary strand would look like this: T A C G C G C G T A

Discrete segments of these strands in turn code for the amino acids that make up

relaxing the disclosure requirements[10] for those types of patents.

These decreased disclosure requirements for DNA sequence patents threaten anyone who either pays for or receives health care in the United States. Recipients of U.S. health care face impeded development of new drugs and treatments because fear of patent infringement stifles innovation. Those paying for U.S. health care face increased out-of-pocket expenses, because the PTO will likely issue more DNA sequence patents as DNA sequence patentability standards are lessened. This increase in the issuance of DNA sequence patents will trigger spiraling transaction costs[11] because, as the "unfenced" stretches of our genome[12] are enclosed, the expense of research and commercial development increases. This chill on scientific progress is at odds with the original purpose of the U.S. patent system.

In accordance with the goal of promoting the "useful Arts" set forth in the Constitution,[13] 35 U.S.C. § 112 states the disclosure standards an applicant must meet to gain a patent.[14] Included are the requirements of enablement (to enable a practitioner of ordinary skill in the art to practice the invention),[15] best mode (describing the inventor's favored

---

proteins. These proteins form the tissues that compose the human body. *Id*. at 502. As a complete DNA blueprint for a human being is present in almost all human cells, each cell contains an extremely long strand of DNA (approximately two meters). When multiplied by the average number of cells in the human body, the total length of DNA present in each adult human is approximately $2*10^{14}$ meters, a length of over a thousand times greater than the distance between the Earth and the Sun ($1.5*10^{11}$ meters). ALBERT L. LEHNINGER ET AL., PRINCIPLES OF BIOCHEMISTRY WITH AN EXTENDED DISCUSSION OF OXYGEN-BINDING PROTEINS 794 (1993).

9. *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (holding that the public deposit of a DNA sequence may help satisfy the written-description requirements of 35 U.S.C. § 112).

10. These disclosure requirements ensure the inventor adequately informs the public of the invention. *See infra* note 14.

11. The expenses of information development, negotiation, and enforcement are transactions costs typically associated with the making of and compliance with business contracts. Paul M. Johnson, *Glossary of Political Economy Terms*, *at* http://www.auburn.edu/~johnspm/gloss/transaction_costs.html (last visited Apr. 5, 2003).

12. "Genome" refers to the genetic content comprising all the DNA in a single set of chromosomes. ROTHWELL, *supra* note 8, at 18.

13. U.S. CONST. art. I, § 8, cl. 8.

14. 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, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (2000).

15. *Id.* The theory behind the enablement requirement is preventing the applicant from claiming subject matter she has not "taught" to the public. *See In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970). The enablement requirement has remained fairly static in its judicial interpretation. In 1853, the Supreme Court applied the requirement to

embodiment of her invention),[16] and written description (demonstrating the inventor "possesses" what she is claiming).[17] Since the first Patent Act, federal courts have been the final determiners of what these patentability standards actually require, providing a judicial lens through which Title 35 must be viewed.

In April 2002, the Court of Appeals for the Federal Circuit affirmed the decision of the District Court for the Southern District of New York in *Enzo Biochem v. Gen-Probe Inc*.[18] The Federal Circuit found that, as a matter of law, the deposit of a DNA sample in a public depository did not satisfy the written description requirement in 35 U.S.C. § 112, first paragraph.[19] Despite petition from Gen-Probe, the court declined to rehear the case en banc, inspiring dissents from Judges Rader, Linn, and Gajarsa.[20] Unfortunately, the court reversed itself three months later,[21] stating that its prior decision finding a public deposit inadequate was incorrect.[22]

This Comment warns of the possible effects of the Federal Circuit's decision on DNA sequence patents and the life science industry.[23] While the court's action may further some of the policy goals that drive

---

Samuel Morse's patent claims and found Morse's claim to the use of *any* type of electromagnetism to communicate invalid for failure to adequately teach the claimed use. *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853). Because Morse had not enabled the use of *any* type of electromagnetism, that particular claim failed. *Id.*

16. 35 U.S.C. § 112. The best mode requirement compels the inventor to disclose the best mode of which he is aware. Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050 (Fed. Cir. 1995). Thus, while enablement entails an objective analysis as to the knowledge of one ordinarily skilled in the art, best mode suggests a subjective analysis as to what the *inventor* knew. *Id.*

17. 35 U.S.C. § 112; *see also In re* Ruschig, 379 F.2d 990 (C.C.P.A. 1967). The written description has been variously employed throughout its history. Historically, the written description informed the public of what exactly the inventor claimed to have invented. Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434 (1822). In 1870, the written description function was supplanted by statute with the practice of including "claims" in the patent application. Markman v. Westview Instruments, Inc., 517 U.S. 370, 379 (1996).

18. Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1023–24 (Fed. Cir. 2002), *vacated by* 323 F.3d 956 (Fed. Cir. 2002).

19. *Id.* at 1015–16.

20. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).

21. *Id*. at 960.

22. *Id.*

23. By "life science industry" I am referring to pharmaceutical companies, such as Glaxo Wellcome, biotechnology companies, such as Amgen or Genentech, and genomics companies, such as Celera. *See* Alexander K. Haas, *The Wellcome Trust's Disclosures of Gene Sequence Data into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERKELEY TECH. L.J. 145, 148–50 (2001).

our system of intellectual property protection,[24] such a radical departure from the traditional quid pro quo[25] long demanded by the U.S. patent system could fatally disturb the equilibrium so carefully developed over the last 200 years. While the U.S. system is based on certainty and disclosure, *Enzo* could very well usher in a new era of smoke and mirrors; though wonderfully enabling,[26] the public deposit of a DNA sequence does not adequately describe the researcher's invention. In short, public deposits give the public the proverbial fish instead of teaching us how to catch our own.[27]

The lower standards for DNA sequence patentability indicated by *Enzo* will impact several areas over the short-term. By patenting unsequenced[28] DNA samples, applicants merely shift the burden of identifying those sequences to others. This shift will create an informational vacuum and force the other players in the field, including researchers, venture capitalists, the court system, and the PTO, to shoulder the burden of determining DNA sequence patent boundaries themselves.

Over a somewhat longer timeline, *Enzo* will encourage scientists to prematurely patent basic research, thus driving up health care expenditures by inflating transaction costs because every DNA sequence patent is a licensing agreement[29] eagerly waiting to blossom. Further, as in any case where multiple parties claim discrete portions of a common resource, there is the very real danger of a "tragedy of the anticommons"[30] arising in such situations. The sheer volume of coordination, negotiation, and license agreements required to utilize the resource drives the cost prohibitively high, thereby discouraging research and stalling progress. With regard to our genomic heritage,[31] the stakes are simply too high to

---

24. These policy goals include facilitating the spread of new technologies. Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998). By making it easier to meet the requirements for patentability, it is at least arguable that the Federal Circuit's *Enzo* decision encouraged patenting new inventions, thus bringing more technology into the public domain.

25. *See supra* note 6.

26. The public deposit enables any competent researcher to practice the invention and study the sequence by contacting the depository and obtaining a sample of the patented sequence.

27. The Quotations Page, *Chinese Proverb*, *at* http://www.quotationspage.com/quotes/Chinese_Proverb (last visited Apr. 5, 2003).

28. "Sequencing" DNA means determining the exact chemical structure of the sequence, such as GGTCACCA etc. *See* ROTHWELL, *supra* note 8, at 487–90.

29. Licensing agreements are contracts granting nonpatent holders rights to the patent. MILLER & DAVIS, *supra* note 6, § 1.2, at 13.

30. *See* Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1243–44 (1968); *see also infra* note 194 and accompanying text.

31. The effects of DNA-based treatments and diagnostics will forever change the human race by providing doctors previously unimaginable capabilities. This power will impact our genomic future as the world community decides to either pursue or forego

allow shortsighted commercial considerations to subsume the promise that free discourse in this resource can fulfill.

Part II of the Comment addresses the history of the U.S. patent system as well as the origins and current state of the written description requirement; while the requirement dates to the first patent act, judicial interpretation of it has changed considerably over the last 200 years. Part III focuses on the Federal Circuit's *Enzo* decision, which relegated the written description requirement to the supporting cast at a time when it should assume the lead role in limiting and clarifying DNA sequence patents. Part IV describes how the Federal Circuit's decision may affect U.S. patent law as well as the U.S. life science industry. Part V offers suggestions as to what can be done to improve the current disclosure regime, including returning to the written description requirement as applied pre-*Enzo*. Finally, the Comment recommends several means to alleviate the problems *Enzo* raised, through the judicial process or alternatively by proactive life science industry action, such as mandatory cross licensing[32] and the creation of patent pools.[33]

II. U.S. PATENT LAW AND THE WRITTEN DESCRIPTION REQUIREMENT

A. English Origins of the U.S. System

Just as the modern United States, medieval England sculpted public policy in hopes of promoting economic development.[34] Long before the Pilgrims sighted Plymouth Rock, the English Crown granted privileges to merchant and craft guilds to encourage their pursuit of new technologies and trade and to make available to the public the fruits of those pursuits.[35] However, these early grants benefited the public only in the sense that they could purchase the resulting products; the public did not gain access to new technologies from these grants until the mid-fourteenth century[36] when the Crown began requiring the holder to

certain avenues of genomics-based research or treatment.

32. Cross-licensing is the granting of patent licenses between competitors to facilitate technological development. Joel I. Klein, Address Before the American Intellectual Property Law Association (May 2, 1997), *available at* http://www.usdoj.gov/atr/public/speeches/1123.htm.

33. Patent pools are aggregations of patent rights subject to cross-licensing. *Id.*

34. FLOYD L. VAUGHAN, THE UNITED STATES PATENT SYSTEM 13 (1956).

35. OUTLINE OF THE HISTORY OF THE UNITED STATES PATENT OFFICE 20 (Patent Office Society 1936).

36. The timing coincided with the rise of England's textile industry. VAUGHAN,

instruct others in his improved methods.[37] This system continued until the late fifteenth century, when the Tudor dynasty replaced this focus on national progress with a new aim—filling the Royal coffers.[38]

The Statute of Monopolies reconciled the Royal practice of granting patents for its own gain with Parliament's desire to preserve competition.[39] The Statute proscribed monopolies as contrary to English law, with an important exception[40]—patents could be granted to inventors bringing forth new technologies for the public benefit.[41]

B. The U.S. Patent System

"The Congress shall have Power . . . 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 . . . ."[42] So provided the Constitution, and Congress quickly exercised this power, passing the first Patent Act in 1790.[43]

---

supra note 34, at 13. England was quick to recognize the power that commercial development could create and encouraged the spread of technologies that increased economic efficiency. *Id*.

37. *Id.* at 13. These early grants were usually for new methods of working cloth. Indeed, by 1337, this policy was codified, granting textile workers from outside Britain the right to special privileges, provided they immigrated to England in order to practice and teach their crafts. *Id*.

38. *Id*. at 14. This sea change in national policy replaced the traditional system (a limited monopoly granted in exchange for benefiting the public) with a new consideration for the sovereign—cash or services. OUTLINE OF THE HISTORY OF THE UNITED STATES PATENT OFFICE, *supra* note 35, at 20. As the Crown granted these monopolies, competition disappeared and prices crept steadily upward. VAUGHAN, *supra* note 34, at 14. Eventually these monopolies impacted the market to the extent that the cost of staple products, such as salt and paper, increased geometrically. *Id.* Not until 1601 was English attention refocused on the original aim of these grants, the promotion of national industry. OUTLINE OF THE HISTORY OF THE UNITED STATES PATENT OFFICE, *supra* note 35, at 29. Even at that point, the refocusing was only as a side effect of the political scrum between Parliament and the Crown. *Id.* Under legislative pressure, Elizabeth I cancelled many patents and monopolies and submitted those remaining to judicial review (by courts of law, not equity). VAUGHAN, *supra* note 34, at 14. Despite Elizabeth's actions, the situation continued to deteriorate, and Royal abuse of patent grants continued under James I (ascended in 1603) until 1623, when Parliament passed the Statute of Monopolies. *Id.* at 15.

39. MILLER & DAVIS, *supra* note 6, § 1.1, at 5.

40. This exception provides the basis for English patent doctrine, and thus U.S. doctrine as well, as English patent doctrine was a well-entrenched aspect of the common law that the English colonists carried with them into the New World. VAUGHAN, *supra* note 34, at 13.

41. OUTLINE OF THE HISTORY OF THE UNITED STATES PATENT OFFICE, *supra* note 35, at 31–32.

42. U.S. CONST. art. I, § 8, cl. 8.

43. ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 127–28 (2d ed. 2000).

1. The Written Description Requirement

Though the current version of the disclosure requirement was codified in 1952,[44] U.S. patent applicants have always been obliged to precisely describe their inventions.[45] As early as 1822, the Supreme Court was asked to interpret this disclosure requirement. In *Evans v. Eaton*,[46] the Court found that the requirement demanded two things from inventors. First, the inventor must "make known the manner of constructing the machine (if the invention is of a machine), so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery, after the expiration of the patent."[47] Next, the inventor must

> put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything 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 [sic] 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 patentee is required to distinguish his invention in his specification.[48]

---

44. *Id.* at 129.

45. Patent Act of 1793, ch. 11, § 3, 2 Stat. 348, 349 (1793) (repealed 1836). The Act required inventors to

> deliver a written description of his invention, and of the manner of using, or process of compounding, the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person, skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound, and use, the same. And in the case of any machine, he shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions . . . .

Id.

46. 20 U.S. (7 Wheat.) 356 (1822) (finding a patent for an improved machine used by the flour industry void for lack of written description).

47. *Id.* at 433–34.

48. *Id.* at 434. Ten years later, the Court revisited the subject. Grant v. Raymond, 31 U.S. (6 Pet.) 218 (1832). The case concerned a patent for an improved method of manufacturing hat bodies, with the defendants alleging the patent was invalid for a written specification defect. *Id.* at 239. The Court indicated that the purpose of the written description was communicating the invention to the public, and failure to accurately do so would endanger both the inventor and the public—the public by granting the inventor a monopoly over something he did not invent and the inventor by providing the public with something he had not patented. *Id.* at 242. At the time both *Raymond* and *Eaton* were decided, patent applications did not require claims. *See infra* note 56 and accompanying text.

Thus, in 1822, inventors were obliged to submit a disclosure that fulfilled three requirements: enablement ("enable artizans [sic] to make and use"), best mode ("give the public the full benefit of the discovery"), and written description ("put the public in possession of what the party claims as his own invention"). Even at this early stage, however, the Supreme Court viewed the function of the written description requirement as one mainly of limitation—"taking from the inventor the means of practising [sic] upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is." Though the written description requirement, as currently applied, bears only facial resemblance to that of the nineteenth century, it is certainly relevant that judicial interpretation of the requirement's purpose 200 years ago (as protecting the public by requiring clarity in one's disclosure) was mirrored by today's Federal Circuit. At least it was until July 2002.

In 1952 patent law was recodified in Title 35.[49] Section 112, first paragraph, describes the written description requirement:[50]

> 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, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[51]

Thus, § 112 specifies the three disclosure hurdles all patent applicants must cross—written description, enablement, and best mode.[52]

As a result of the judicial application of the written description requirement to constrain patent boundaries, courts have required precision in its terms. For example, in *Georgia-Pacific Corp. v. United States Plywood Corp.*,[53] the Second Circuit found that while the district court's application of the precision requirement was too stringent, the written description itself must be precise enough to avoid discouraging

---

49. 35 U.S.C. §§ 1–376 (2000).
50. *Id.* § 112.
51. *Id.*
52. *See id.*
53. 258 F.2d 124 (1958). This case may set the standard for the most civilized opening salvo ever launched in patent litigation:

> "Dear Owen:
>
> "While imitation is supposed to be the sincerest form of flattery, I must confess to a different reaction when I learned that you are imitating Weldtex.
>
> "As you know, Weldtex is covered by U.S. Patents which have been recognized by the industry for more than thirteen years. Under the circumstances, we will of course take vigorous action to protect our patent rights and are turning the matter over to our counsel for appropriate action.
>
> "Sincerely,
>
> "Tony"

Id. at 127.

enterprise and experimentation "by the creation of an area of uncertainty as to the scope of the invention."[54]

However, despite occasional judicial recognition, the teeth of the written description requirement dulled during the nineteenth and twentieth centuries, as the "public notice" aim of the requirement was supplanted by the practice of "claiming" the patentable aspects of one's invention.[55] Over time, applicants began to use the claims of the patent application to provide public notice as to the boundaries of the patent.[56] During this period, the written description requirement itself came to be viewed as part of the enablement requirement, such that the two were often seen functionally as a single entity. If the written description adequately enabled one skilled in the art to practice the invention, it would usually be found to fulfill the actual written description requirement.[57] This interpretation changed dramatically in *In re Ruschig*.[58]

2. The Modern Written Description Requirement

Ruschig concerned the appeal from a PTO rejection of a single amended claim in a patent application.[59] The PTO had rejected the claim[60] based on the lack of support contained within the written description of the application. Although the description named a class of compounds, among which could be found the subject of the claim, it did not identify the actual structure of the claimed compound.[61] The appellants argued that one skilled in the art could readily discern the claimed compound from the written description, and the court agreed.[62] The court, however, went on to state that the written description requirement entailed more than just enablement. The description must prove to one ordinarily skilled in the art that the inventor possessed that which he claimed at the

54. *Id.* at 136.
55. Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996).
56. *See id.* at 373, 379 (noting that claiming was first required by the Patent Act of 1870).
57. "The purpose of the [written] description requirement of this paragraph is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined." Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987).
58. 379 F.2d 990 (C.C.P.A. 1967).
59. *Id.* at 991.
60. Claim 13 recited, in relevant part, "N-(p-chlorobenzenesulfonyl)-N'-propylurea." *Id.* The claim also contained a structural depiction of the compound. *Id.*
61. *Id.* at 993.
62. *Id*. at 995.

point in time he claimed it.[63] Finding the specification at issue to lack the specificity necessitated by § 112, the court held the claim invalid.[64]

Ruschig made the written description requirement viable after over a century of near-dormancy. After *Ruschig*, amended claims[65] would be examined in light of the applicant's written description to determine whether the applicant possessed the claimed invention at the time of filing.[66] The judicial goal was preventing applicants from unfairly broadening their patent rights by adding new material to an already pending application. This decision also delineated a clear demarcation between the requirements of enablement and written description, a division the court would continue to support.[67]

Over the next thirty years the Court of Customs and Patent Appeals (CCPA) and the Federal Circuit (which replaced the CCPA in 1982)[68] would, for the most part, adhere to the written description guidelines specified in *Ruschig*, using the initial written description as a net to "filter" amended claims. If the initial written description failed to encompass the amended claims, the court would usually find the amended claims invalid.[69] The written description requirement became a valuable judicial tool used to limit claim amendments to that which the inventor actually possessed as of the application filing date. Subject matter claimed in subsequent amendments would not gain the advantage of the earlier filing date if the new material was not covered by the applicant's initial disclosure.[70] This practice of requiring amended claims to fit within the initial disclosure is perhaps in tension with the traditional patent law doctrine of "constructive" reduction to practice,[71]

---

63. *Id.* at 995–96.

64. *Id.*

65. Often during patent prosecution the claims with the patent application will be modified as a result of the dialog between the PTO examiner and the patentee (or the patentee's attorney). STEPHEN ELIAS, PATENT, COPYRIGHT & TRADEMARK 207 (3d ed. 1999).

66. *Ruschig*, 379 F.2d at 996.

67. "[I]t is possible for a specification to enable the practice of an invention . . . and still not describe that invention." *In re* DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971). "Although a specification that meets the written description requirement *always* satisfies the enablement requirement, the converse is *not* always true." *In re* Hunter, 59 F.3d 181 (Fed. Cir. 1995).

68. MILLER & DAVIS, *supra* note 6, § 7.10, at 121.

69. *See, e.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633 (1998).

70. *Id.* at 635.

71. Reduction to practice refers to the point at which the inventor physically produces the invention. MILLER & DAVIS, *supra* note 6, § 3.9, at 61. Constructive reduction to practice is a legal presumption of actual reduction to practice on the filing date. Robert A. Hodges, Comment, *Black Box Biotech Inventions: When a "Mere Wish or Plan" Should Be Considered an Adequate Description of the Invention*, 17 GA. ST. U.

whereby an inventor is assumed to have constructively reduced the invention to practice by the date of filing the application. However, in the arts termed "unpredictable" by the Federal Circuit (or the CCPA),[72] such as chemistry and biotechnology, the court has used a more literal reading of "reduction to practice," often requiring an actual physical reduction.[73] In light of this, it is not surprising that the Federal Circuit has also required in these unpredictable fields more conclusive documentary proof of possession—a written description that actually proves the inventor possessed what was claimed.

The judicial standards for fulfilling the written description requirement in the unpredictable arts were further refined in *Fiers*,[74] which concerned the DNA sequence coding[75] for human fibroblast beta-interferon.[76] There, the Federal Circuit held that describing a claimed cDNA sequence as a product of an isolation method[77] did not satisfy the written description requirement;[78] what the court wanted was a description of the DNA itself.[79] Finally, in *Regents of the University of California v. Eli Lilly & Co.*,[80] the Federal Circuit found a claim for the DNA encoding human insulin invalid because the application's written

L. REV. 831, 843 (2001). The presumption arises when an applicant fulfills the requirements of 35 U.S.C. § 112 regardless of whether the applicant actually reduced the invention to practice. *Id.*

72. "Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a 'predictable' factor such as a mechanical or electrical element." *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).

73. This physical reduction to practice is in contrast to the constructive reduction to practice allowed in more predictable arts. *See supra* notes 71, 72.

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

75. Genes consist of long stretches of both protein-coding regions (or exons) and nonprotein-coding regions (or introns). ROTHWELL, *supra* note 8, at 293. Cellular mechanisms excise the introns of the coding (or sense) strand before the DNA is transcribed into RNA. *Id.* The resulting RNA can be converted *in vitro* into "cDNA," which represents the protein-coding regions of the gene in a single unbroken sequence. *Id*. at 499.

76. *Fiers*, 984 F.2d at 1166.

77. *Id.* at 1170. Fiers had described the sequence in terms of a method for its isolation using reverse transcription, converting RNA to DNA. *Id.* This practice requires the use of enzymes, called reverse-transcriptases, present in certain viruses and retroviruses and other nonhuman organisms. ROTHWELL, *supra* note 8, at 399.

78. *Fiers*, 984 F.2d at 1170, 1172. *Fiers* is another example of the difference between enablement and written description. While the description adequately taught one of ordinary skill in the art how to practice the invention, it did not adequately describe the claimed DNA sequence.

79. *Id.* at 1170.

80. 119 F.3d 1559 (Fed. Cir. 1997).

description contained only a description of the protein the cDNA coded for, as well as a method for isolating the human cDNA.[81] Quoting *Fiers*, the court stated that adequate written descriptions of DNA sequences require "a precise definition, such as by structure, formula, chemical name, or physical properties."[82] The court's decision was striking in light of the fact that the University of California had already cloned the rat insulin gene, and, to a person of ordinary skill in the art, this fact alone would probably indicate possession of the human gene also.[83] In addition, *Lilly* is of importance for the court's employment of the written description filter through which the original claims must pass. This was not a case of an inventor attempting to add claims under an earlier application, thereby gaining the benefit of the earlier filing date, but rather an apparent Federal Circuit intent to up the ante as far as the written description doctrine was concerned. Further, as the Federal Circuit was obviously aware of the importance of this issue, it seems unlikely that the court reached its decision without careful consideration.

Taken as a whole, these cases trace a clear arc in Federal Circuit jurisprudence, tightening the written description requirement such that, to claim a DNA sequence, one must describe the sequence precisely. Not only must inventors demonstrate possession, they must also demonstrate that they *knew what they possessed* by accurately and precisely describing the sequence with, in the words of the *Lilly* court, "a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA."[84] Clearly, in the eyes of the Federal Circuit, functional descriptions[85] (what something does rather than what something is) were not sufficient to surmount this obstacle. Just as clearly, this application of the written description requirement is an appropriate one for several reasons: First and foremost, this is our genetic heritage, not a canine watch[86] or a landing

81. *Id.* at 1567.

82. *Id.* at 1566 (quoting *Fiers*, 984 F.2d at 1171).

83. *Id.* at 1567. The rat and human insulin genes are highly homologous (very similar in sequence), so one of ordinary skill in the art might reasonably feel that possession of one indicated possession of the other. *See, e.g.*, European Patent Office, *Trilateral Project 24.1*, *at* http://www.european-patent-office.org/tws/sr-3-b33.htm (last visited Apr. 5, 2003).

84. *Eli Lilly & Co.*, 119 F.3d at 1569.

85. [A] functional description of DNA does not indicate which DNA has been invented. And simply acknowledging the presence of a DNA that serves a particular function, whose existence has been postulated since, perhaps, Mendel, plus a general process for finding it, is not a description of the DNA. It is a research plan at best, and does not show "possession" of any invention.

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 974 (Fed. Cir. 2002).

86. U.S. Patent No. 5,023,850 (issued June 11, 1991).

light on a toilet.[87] In such an important field, courts should be wary of validating overly broad or unclear patents,[88] as the repercussions of such acts will be as far-reaching as they are unpredictable. Furthermore, this danger is heightened in the emerging genomics, pharmaceutical, and biotechnology industries, where technology is advancing at staggering rates, and huge amounts of "upstream" research are required to produce beneficial products downstream. As such, the modern reemphasis on the written description requirement in this setting is both appropriate considering the subject matter and necessary with regard to the relative immaturity of current DNA technology.[89] Taken together, *Ruschig*, *Fiers*, and *Lilly* indicate a two-part test for gauging satisfaction of the written description requirement. First, does the written description adequately convey to one ordinarily skilled in the art that the inventor possessed the claimed invention? Second, does the written description adequately convey to one ordinarily skilled in the art that the inventor knew exactly[90] what she had invented? For several years, Federal Circuit jurisprudence required the written description for DNA sequences to pass this bright-line test, but the *Enzo* decision signified a sea change in the court's doctrinal approach.

III. *ENZO BIOCHEM, INC. V. GEN-PROBE INC.*[91]

Enzo Biochem[92] held a patent for nucleic acid probes[93] used in

87. U.S. Patent No. 5,263,209 (issued Nov. 23, 1993).

88. Overly broad and unclear patents often coincide. When the written description is inadequate, it is difficult for a court to accurately discern the appropriate patent boundaries.

89. Wilkins, Watson, and Crick are credited with discovering DNA's double-helix structure in the early 1950s, ROTHWELL, *supra* note 8, at 218–19, but recombinant DNA techniques were not developed until the 1970s. *See generally* Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. U.S. 3240 (1973).

90. *See supra* note 78 and accompanying text.

91. 285 F.3d 1013 (Fed. Cir. 2002), *vacated by* 323 F.3d 956 (Fed. Cir. 2002).

92. Enzo Biochem, founded in 1976, focuses on "harnessing genetic processes to develop research tools, diagnostics and therapeutics and provides reference laboratory services to the medical community." Enzo Biochem, Inc., *About Enzo Biochem, Inc.*, *at* http://www.enzobio.com/corp_about.htm (last visited Apr. 5, 2003). The company is publicly owned with a market capitalization of $377.2 million as of March 18, 2003 and has 205 employees. Yahoo! Finance, *Enzo Biochem*, *at* http://finance.yahoo.com/q?s=ENZ&d=t (last visited Apr. 5, 2003).

93. Enzo was the assignee of U.S. Patent No. 4,900,659. *Enzo Biochem, Inc.*, 285 F.3d at 1015. Nucleic acid probes are short, labeled (with radioactive or luminescent markers) sequences of DNA or RNA that can bind with complementary stretches of nucleic acid. They are used to detect the presence of a specific gene within a DNA

determining the presence of the bacteria that causes gonorrhea.[94] The beauty of Enzo's probes was their preferential binding to the DNA of the bacteria that cause gonorrhea over the DNA of the bacteria that cause meningitis.[95] The inventors had filed their application and deposited these probes as plasmids[96] within E. coli[97] host bacteria with the American Type Culture Collection (ATCC).[98]

A. The District Court Decision

Enzo sued Gen-Probe for infringement of their '659 patent, and the defendants responded with a motion for summary judgment, alleging the written description for '659 was inadequate, as Enzo did not describe the probes in terms of their specific DNA sequence,[99] but rather by reference to the probes' ability to preferentially bind *N. gonorrhoeae* DNA over that of *N. meningitidis* (a functional description).[100] The written description also referenced the ATCC deposit.[101] The District Court agreed with Gen-Probe,[102] stating that a functional description of the material was not sufficient to satisfy 35 U.S.C. § 112.

In light of Federal Circuit precedent, the district court's decision would seem correct. The inventors had described the claimed DNA

---

sample and are valuable as both research and diagnostic tools. ROTHWELL, *supra* note 8, at 502–03.

94. *Enzo Biochem, Inc.*, 285 F.3d at 1015.

95. *Id.* at 1015–16. Preferential binding (or hybridization) typically means that a probe will bind to a given DNA sequence more tightly than to an other DNA sequence, or under conditions more stringent (less conducive to binding) than those under which the probe will bind to another sequence. *See, e.g.*, J. SAMBROOK ET AL., 2 MOLECULAR CLONING: A LABORATORY MANUAL 11.45–11.49 (Nina Irwin et al. eds, 2d ed. 1989). For example, changing the ionic strength of the reaction conditions can make probes less likely to bind to a DNA sequence. *Id.* Therefore, if a probe does in fact bind to a sequence under such conditions, it is assumed that the probe is more specific for that sequence than a probe that will only bind to the particular sequence under less stringent conditions. *Id.* The end result is that Enzo's probe bound the *Neisseria gonorrhoeae* DNA more effectively than it bound the DNA of *Neisseria meningitidis*. *Enzo Biochem, Inc.*, 285 F.3d at 1015–16. This allowed Enzo to test for gonorrhea without the presence of *N. meningitidis* causing a "false positive" result, which had frustrated previous attempts. *Id.*

96. A plasmid is a replicating sequence of DNA that exists apart from the host's (usually a bacterium) genome. DNA sequences inserted into plasmids are replicated by the host. ROTHWELL, *supra* note 8, at 359–60.

97. E. coli is a commonly used bacterium for "hosting" plasmids. *Id.* at 362.

98. The ATCC is a nonprofit bioresource center that serves, among other things, as a repository for biological samples. *See* American Type Culture Collection, *About ATCC*, *at* http://www.atcc.org/About/AboutATCC.cfm (last visited Apr. 5, 2003). The ATCC is not affiliated with the U.S. Government. *Id.*

99. *See* U.S. Patent No. 4,900,659 (issued Feb. 13, 1990).

100. *Enzo Biochem, Inc.*, 285 F.3d at 1020.

101. *Id.*

102. *Id*. at 1015.

functionally[103] in their initial written description without including actual sequence data; clearly, under *Ruschig*, *Fiers*, and *Lilly*, such practice was not sufficient to satisfy § 112 in the context of DNA sequence patents. Indeed, the decision was deemed appropriate by the Federal Circuit when the case reached the court on appeal.[104]

B. The First Federal Circuit Decision

On appeal, Enzo presented several arguments. First, a genuine issue of fact existed as to the adequacy of the patent's specification.[105] Second, Enzo asserted the district court erred by granting summary judgment based entirely on the written description.[106] Next, Enzo argued that its description of the binding characteristics of the probes satisfied[107] the PTO guidelines.[108] Further, Enzo argued that *Lilly* did not apply because Enzo had in fact reduced the invention to practice and publicly deposited the probes, thereby demonstrating possession.[109] The court was unimpressed, stating, "We reject Enzo's characterization of the hybridization as a distinctive 'chemical property' of the claimed sequences."[110] The court went on to state that the PTO guidelines were not binding upon it, and, at any rate, the hybridization data set out in the written description was the only characteristic "purportedly describing the claimed nucleotide sequences."[111] The court then described the written description requirement as reflecting the "*quid pro quo* of our patent system, in which an inventor is only

103. U.S. Patent No. 4,900,659. The inventors' description stated the hybridization characteristics of the probes, but lacked sequence data. *Enzo Biochem, Inc.*, 285 F.3d at 1020.

104. *Id.* at 1015.

105. *Id.* at 1017.

106. *Id.*

107. *Id.*

108. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) (codified at 37 C.F.R. § 1.56 (2002)).

109. *Enzo Biochem, Inc.*, 285 F.3d at 1017.

110. *Id.* at 1018. In fairness to the appellants, the PTO examination guidelines do contain the following: "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.*, complete or partial structure, . . . functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. at 1106.

111. *Enzo Biochem, Inc.*, 285 F.3d at 1019. "Stated another way, Enzo claimed anything that works, without defining what works." *Id.* at 1020.

entitled to claim subject matter that is adequately described to the public,"[112] an apparent return to the public notice aspect of the written description requirement that had waned when claims came to serve that purpose. The court then turned its attention to the public deposit.

Enzo had argued that public deposit demonstrated its possession of the invention.[113] The Federal Circuit did not disagree, but rather stated that possession itself, while necessary, was not sufficient.[114] The inventor must also adequately describe the invention. Indeed, the court termed adequate identification of what one has invented the "most basic requirement of the patent law."[115] Continuing, the court indicated that public deposit alone does not ipso facto satisfy the requirements of § 112, first paragraph.[116]

This first Federal Circuit *Enzo* decision was not unanimous. In a spirited dissent, Judge Dyk pointed out that at the time the patent was filed (1986), sequencing the DNA would have taken, according to Enzo, 3000 scientists an entire month to complete.[117] Judge Dyk felt that patent law required no such "Herculean effort" when one ordinarily skilled in the art would understand the invention based on the written description filed by the applicants.[118] Judge Dyk may be right—perhaps no such Herculean effort is supportable by either patent law or public policy, but, on the other hand, Title 35 makes no special dispensations for cases where the effort required to meet the statutory requirements for patentability is great. In addition, it is probably appropriate that DNA sequence patents are subject to more stringent requirements, for the two reasons previously stated—low written description standards[119] for DNA sequence patents cause harm by creating uncertainty as to the extent of a patent holder's rights as well as by increasing transaction costs.[120]

---

112. *Id.* at 1019.

113. *Id.* at 1020 (citing Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991)). Enzo argued that the written description requirement was a mere possession requirement. *Id.* at 1017. The court did not agree. *Id.*

114. *Id.* at 1020–21.

115. *Id.* at 1021.

116. *Id.* at 1022.

117. *Id.* at 1026 n.2 (Dyk, J., dissenting).

118. *Id.*

119. This is so regardless of which aspect (novelty, obviousness, utility, etc.) of patentability the standards concern.

120. Of course, patents themselves, regardless of the standards used to award them, raise transaction costs, because patents limit the ability of others to use the patented technology. The patent holder may charge whatever the market will bear for the right to use the patented invention, and if the cost is too high, further development of the technology may be chilled. Even if the holder charges nothing to use the technology, it would be unwise to proceed without contracts and license agreements, all of which take time, and more often than not, money also. However, this is one of the trade-offs inherent in our system, a system that has, for the most part, worked well for the last 200

Response to the decision was underwhelming. Many felt that the Federal Circuit's general characterization of hybridization as a functional property to be shortsighted,[121] as it effectively threatened the validity of the claims of many previously issued patents.[122] Also, to some, it appeared that the Federal Circuit was disregarding PTO practices in an area where at least some degree of deference was in order.[123]

C. The Second Federal Circuit Decision

Unhappy with their first Federal Circuit result, Enzo petitioned for and was granted a rehearing.[124] Once again, Judges Lourie, Dyk, and Prost considered the case, which was, by this time, generating an impressive amount of interest from the intellectual property community, triggering amicus curiae briefs from Fish & Richardson P.C. as well as the Department of Justice.[125] Upon further consideration the court found Enzo's arguments more persuasive[126] and vacated its prior decision. The Federal Circuit reversed the lower court's grant of summary judgment and remanded the case as to certain genus claims.[127] As to the written description issue, the court held that "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with

---

plus years. The problem lies in the structure of the industry. As more companies work in basic research fields and seek to create value by patenting their discoveries, basic research itself will become property more and more.

121. Kevin Takeuchi, *The Federal Circuit Raises the Bar for Written Description of Genetic Materials*, CASRIP NEWSL., Spring–Summer 2002, at 1–2, *at* http://www.law.washington.edu/casrip.

122. A similar "reliance" issue previously presented itself to the Federal Circuit. *See* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998). In *State Street*, the court distinguished earlier cases that found business methods unpatentable due merely to the subject matter of the application. *Id.* at 1377. However, the PTO had already allowed business method patents before *State Street* was decided, perhaps suggesting that the PTO feels no more bound by the Federal Circuit than the Federal Circuit does by the PTO.

123. Takeuchi, *supra* note 121, at 2.

124. Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002), *reh'g denied en banc*, 323 F.3d 956.

125. *Id.* at 1319–20 & n.1.

126. *Id.* at 1330. The court's description of Enzo's position suggests that Enzo's argument did not change between the first and second Federal Circuit proceedings. *Compare Enzo Biochem, Inc.*, 296 F.3d at 1323, *with* Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1017 (Fed. Cir. 2002), *vacated by* 323 F.3d 956 (Fed. Cir. 2002).

127. *Enzo Biochem, Inc.*, 296 F.3d at 1330.

the written description requirement of § 112, ¶ 1."[128] In this second decision the Federal Circuit seemed to give more weight to the PTO guidelines,[129] stating, "[U]nder the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed."[130] Further, the court indicated it would adopt PTO guidelines for determining written description sufficiency.[131] Thus, the Federal Circuit found Enzo's DNA deposits combined with its functional descriptions of the probes to meet the requirements of § 112, first paragraph.[132]

Read narrowly, the decision could indicate merely that the Federal Circuit will allow written descriptions that combine public deposit with a functional description if a known or disclosed correlation between structure and function exists. Even so, this standard is clearly a step back from *Lilly*, which, while never explicitly requiring an inventor to provide the exact sequence of any claimed DNA, indicated that in the case of DNA patents a "particular" description was required.[133] Further, the *Enzo* decision seems to indicate that a public deposit can make up for a less precise written description in cases where it is difficult to provide the exact structure of the claimed material. It is in precisely those cases, however, where courts should refrain from relaxing patentability standards. Whether a reflection upon the particular industry, or upon the particular inventor, inability to accurately describe one's invention should not be excused or rewarded—if an invention cannot be described with precision, then perhaps it is premature to grant a monopoly on that invention.

---

128. *Id.* at 1325.

129. Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001).

130. *Enzo Biochem, Inc.*, 296 F.3d at 1324–25.

131. *Id*. at 1325. The court wrote, "We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement." *Id*.

132. *Id*.

133. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). "An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Id.* (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

IV. THE EFFECTS OF *ENZO*

The Federal Circuit's final *Enzo* decision[134] will have both immediate and long range impact. In the short term, the court's relaxation of the written description standards for DNA patentability will result in lower quality patents with undefined limits that will deter inventors as well as investors. These reduced standards will also increase the role of the court system in determining the boundaries of DNA sequence patents as litigation over patent infringement increases.[135] In addition, these lower patentability standards will increase the burden on an already strained PTO by creating an ever growing mass of unsearchable, poorly described prior art,[136] as well as by triggering a likely increase in DNA patent applications.[137] Over the long-term, these patents on basic research may create a tragedy of the anticommons,[138] with patents on DNA sequences "locking up" information and techniques and driving transaction costs and thus consumer expenses higher. Even more threatening, DNA sequences patents may prevent the drug development that depends on this basic research. The downstream result of the development may be rendered obvious, and thus unpatentable, by the sequence patent. Few pharmaceutical companies will be willing to invest the $800 million[139] on the research and development (R&D)

134. *Enzo Biochem, Inc.*, 296 F.3d 1316.

135. It seems likely that patent litigation will increase as the level of uncertainty surrounding any given patent rises. At the very least, the threat of strategic litigation by large, well-funded life science industry corporations should increase because these corporations are better equipped to finance protracted infringement suits. More uncertainty equates to more risk for the litigants, and larger companies are typically better suited to assume such risk.

136. PTO examiners already face a daunting task in determining the relevant prior art for any given patent application. Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 767 (2002). "From these insights, it is clear that information regarding the relevant prior art for any patent application is most likely to be known only to the patentee and his competitors." *Id.*

137. Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 WASH. U. J.L. & POL'Y 309, 309–10 (2002). Meurer uses the term "patent flood" to describe the resulting increase in business method patent applications following the Federal Circuit's decision in *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (1998) (upholding the patentability of business methods). In the case of DNA sequence patents, it is likely that the lowering of the written description requirements will trigger a similar increase.

138. *See* Hardin, *supra* note 30, at 1243–44.

139. This figure represents dollars in 2000, according to a study of information obtained from research-based drug companies. Tufts Center for the Study of Drug Development, News & Events (Nov. 30, 2001), *at* http://csdd.tufts.edu/NewsEvents/

necessary to put a new drug on the market if patent protection is unavailable, as generic drug development is considerably less expensive than new drug development. While the generic manufacturer can price the drug based on its manufacturing and marketing expenses, the original developer must attempt to recoup its entire R&D costs.[140]

A. The Short Term Impact of Enzo: *Patent Uncertainty*

Allowing public deposit of DNA sequences to satisfy the written description requirement will make it easier to patent DNA sequences. Unfortunately, this boon to patentees comes at the expense of the public who must attempt to discern the limits of the patented invention. For DNA sequence patents this boundary mapping often means sequencing the sample oneself.[141] While not as onerous a chore today as it was ten years ago,[142] the responsibility for sequencing the sample should rest with the holder of the patent, rather than with the public.[143] As a result of the judicial shifting of the description responsibility to noninventors, patent applicants can circumvent the traditional disclosure demands of the patent system while still gaining the advantage that patents have always provided: a monopoly in the manufacture, use, and sale of the

---

RecentNews.asp?newsid=6. The same R&D costs were $231 million in 1987, but inflation alone cannot account for the increase as this figure is only the equivalent of $318 million in 2000 when inflation is taken into account. *Id.* The rising cost has been attributed to several factors including spiraling R&D costs as well as the rapidly increasing expense of clinical trials. *Id*.

140. However, the developer cannot use its patents to impede the development of a competitor's generic. Recently, the Federal Trade Commission launched an investigation to determine whether Elan Corporation (an Irish pharmaceutical company) had used its patents to "block" generic competitors by using "multiple patents to extend their monopolies over medicines, thereby preventing less expensive generics from reaching the market." Jed Seltzer, *U.S. Regulators Look Closely at Elan's Practices*, SAN DIEGO UNION TRIB., Mar. 15, 2003, at C1.

141. DNA sequencing requires time, money, trained personnel, and access to laboratory equipment. Even if the sequencing itself is contracted out, the DNA sample must be generated and purified.

142. Ten years ago sequencing a DNA sample usually involved radioactivity, in the form of Sulphur-35, high voltage to run the sequencing gel, working in the dark so as not to expose the photographic film, and patience over the week to ten days the film would be exposed to the gel. Marcus Grompe et al., *Recombinant DNA and Genetic Techniques*, *in* PRINCIPLES OF MOLECULAR MEDICINE 9 (J.L. Jameson ed. 1998), *available at* http://www.humanapress.com/pdfs/9.pdf. Today, for a reasonable fee any of a number of labs will sequence your DNA sample in a matter of days. *See* Randall Parker, *On the Declining Costs of DNA Sequencing*, (explaining that DNA sequencing costs have drastically declined), *at* http://www.futurepundit.com/archives/001802.html (Nov. 19, 2003); *see also* Cleveland Genomics, *DNA Sequencing Services*, (stating that the turnaround time for DNA sequencing is generally two to three days), *at* http://www.clevelandgenomics.com (last visited April 20, 2004).

143. *See* Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434 (1822) (finding a patent for an improved machine used by the flour industry void for a written description defect).

patented item. Further, once the patent is issued, the inventor benefits from the presumption of validity[144] that all patents carry. Overall, it would seem that these unclear, low quality patents benefit the inventor much more so than the public, and in fact, these patents may directly harm several groups in the short-term.

1. The Impact on Inventors

Low quality DNA sequence patents resulting from this relaxed written description standard will immediately affect life science industry inventors. In the wake of *Enzo* they will face the daunting task of having to determine on their own the limits of the patents they might brush up against in their research. For example, any company wishing to market a product similar to Enzo's probes faces a Hobbesian choice of either determining the DNA sequence of Enzo's probes or risking a crippling infringement suit.

Suppose a company named STD-Away wants to develop a treatment for gonorrhea, the disease that Enzo's probes could identify, using antisense technology.[145] STD-Away is aware that Enzo has a patent on certain probes that preferentially bind to the genome of the bacteria that causes gonorrhea. They know they will have to be careful of infringing, but therein lies the problem. STD-Away has no way of knowing the exact sequence of Enzo's probes,[146] so they have no way of designing around them. It is unlikely that STD-Away will continue with its project in the informational vacuum created by Enzo's patent. Biotech companies, especially young ones, are subject to brutal selective pressure, and to run

144. *See* 35 U.S.C. § 282 (2000).

145. Antisense technology is a method of using the complementary binding capability of DNA (and RNA) to inhibit protein production and thus treat disease. Isis Pharmaceuticals, *Basic Science*, *at* http://www.isispharm.com/basic_sci.html (last visited Nov. 2, 2003). Antisense technology works by interrupting the translation of DNA into protein. *Id.* Normally, DNA is composed of two strands, the coding (or sense) strand and noncoding (or antisense) strand. *Id.* To make proteins, the sense strand is transcribed into messenger RNA (mRNA) by cellular enzymes that build mRNA molecules in the same manner other enzymes build DNA molecules. *Id.* As are matched with Us (for uracil, replacing thymine), and Gs are matched with Cs, with the antisense strand serving as the template. *Id.* Thus, the mRNA is a copy of the sense DNA strand with the Ts replaced with Us. *Id.* Antisense drugs are short sequences of DNA that code for mRNAs capable of binding to the sense mRNA and prevent it from forming a template for protein production. *Id.*

146. STD-Away could sequence the probes themselves, but up until *Enzo*, § 112's disclosure requirements imposed that duty upon the patentee.

such a risk would be foolhardy. Thus, if STD-Away wants to proceed, they will have to sequence Enzo's probes themselves, completing a task the patentee should have been obliged to accomplish in exchange for exclusionary patent rights. Alternatively, they may abandon their project out of reluctance to expend time and capital in a market another company might have already cornered.

In addition to the advantage of relaxed disclosure standards that now apply when a patent applicant makes an ATCC deposit, once the patent is granted, the holder may arrange to be notified by the ATCC whenever the deposited sample is accessed.[147] Thus, a patentee who publicly deposits a DNA sequence is provided a convenient early warning device that can identify potential threats before they impact the patentee's market share.

2. The Impact on Investors

Investors may face a similar obstacle in not being able to determine what is truly new because they cannot determine what is truly old. For example, in the typical industry scenario, venture capitalists[148] extensively research companies they are considering for investment. As the worth and potential of young biotechnology companies is often measured by assessing their patent portfolios,[149] venture capitalists engage patent attorneys to draft opinion letters regarding the target[150] company's patents or conversely the patents belonging to the target company's competitors. These opinion letters can easily run into the tens of thousands of dollars,[151] but are an invaluable aid in determining the advisability of funding a company.[152] A major aspect of these letters

147. Interview with Dan Altman, Partner, Knobbe, Martens, Olson & Bear, in San Diego, Cal. (Feb. 6, 2003).

148. Venture capital firms are usually private partnerships or closely held corporations that provide funding for, among other things, smaller companies at their early stage of development. National Venture Capital Association, *The Venture Capital Industry: An Overview*, *at* http://www.nvca.org/def.html (last visited Apr. 5, 2003). Venture capital firms often focus on "high-tech" companies at the stage before an initial private offering (IPO). *Id.* Almost 3000 venture capital-funded companies have conducted IPOs in the last twenty-five years. *Id.*

149. Seminar Speaker Summary, *Eileen McMahon: Patents and Biotech: An Overview of the Leading Issues*, *available at* http://www.erin.utoronto.ca/mbiotech/page/astrazen/em.html (last visited Apr. 5, 2003). "A company's IP is one of the major criteria evaluated by investors." *Id.*

150. "Target company" refers to the company of interest (the investment candidate).

151. Interview with Sheila R. Gibson, Associate Attorney, Knobbe, Martens, Olson & Bear, in San Diego, Cal. (Feb. 8, 2003).

152. Opinion letters can also serve as a shield from some damage awards in the event of an infringement suit. *Id.* Following a course of action that was previously examined by an attorney eases the threat of multiplied (treble in the case of willful patent infringement) damages. *Id.*

is mapping the limits of patent coverage in order to avoid infringement. It strains credulity to imagine that *Enzo* will aid in this task, as the decision has lessened the disclosure requirements patent applicants face. It will of course still be possible for the limits of these patents to be determined, but post-*Enzo*, this responsibility is placed on parties who have no exclusionary rights to the patented device. This starkly contrasts with the historical practice of demanding informative disclosure in return for the monopoly rights that accompany all patents.[153] This added burden on patent attorneys will translate into higher costs for their customers. When the costs of due diligence on the part of venture capitalists begin to increase as a result of *Enzo*'s relaxed disclosure standards, it is quite possible that investment capital will be diverted from those fledgling companies whose courses track too closely to patents with written descriptions referring to public deposits in lieu of detailed descriptions. Over time, venture capitalists may come to view patents like that of Enzo's in the same way ancient mapmakers viewed the far edges of the known world—"here there be monsters."

Even if venture capitalists are not dissuaded from investing as a result of unclear DNA sequence patents, they will probably require more in return from young life science companies to offset their increased risk. Whether in the form of higher interest rates or larger equity positions, the increased demands of venture capitalists could in turn increase the selective pressure[154] upon these young companies.[155] Though selective pressure is the driving force behind competition, and competition generally benefits consumers, excess selective pressure may eliminate young companies prematurely. As the number of companies competing in a market declines, market share, and thus power, becomes

153. The historical quid pro quo. *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1019 (Fed. Cir. 2002), vacated by 323 F.3d 956 (Fed. Cir. 2002).

154. "Selective pressure" describes the "pressure placed by a selective agent upon certain individuals within the population that results in the change of allele frequencies in the next generation." Selective Pressure, *at* http://www.webref.org/anthropology/s/selective_pressure.htm (last visited Apr. 5, 2003). The term is most often used to describe the force exerted by the environment upon living organisms that produces the changes we collectively term "evolution." *Id.* Here, the term is used to describe the force exerted upon young life science companies by the marketplace, such as availability of investment capital.

155. As stated, when venture capitalist firms make riskier investments they may also demand more control of the company. As these firms obviously expect to earn returns on their investments, they may show less patience with technology and product development and be more inclined to pull their support from young companies whose books do not rapidly ascend from red ink to black.

concentrated in the hands of the "winners." While this result can be wonderful for successful competitors, consumers will often end up paying higher prices as a result of a decrease in market competitors. For example, consider the price of a hot dog at a major league stadium. Because the number of hot dog vendors is contractually limited,[156] the overall level of competition is lowered. Vendors can charge a higher price for a hot dog inside the stadium than they could outside, where one could buy from any number of sources. As the number of competitors in the market is limited, vendors do not need to compete as hard as they would in a market teeming with hot dog suppliers, such as any place not within the confines of a major league ballpark. Fledgling biotechnology companies are not selling hot dogs, but regardless of the particular market involved, consumers generally benefit from competition between providers of goods. On the other hand, as the number of providers in an active market decreases,[157] consumers have less leverage with which to influence those providers. The threat of taking one's business elsewhere has little effect when there is no "elsewhere" to take it. *Enzo* may further this scenario by deterring venture capitalist investment in young life science companies as a result of the uncertainty caused by judicially relaxed written description standards. Alternatively, the same end result may arise as a consequence of *Enzo* by causing venture capitalists to demand increased concessions (to offset the increased risks of unclear DNA sequence patents) from young life science companies in need of capital; these increased concessions could make the young company more susceptible to the vagaries of the market, as well as cede more control of the company to venture capitalists than was the norm a few years ago. In either case, *Enzo* may make it harder for these young

156. This is not to imply any sort of conspiracy in the nation's stadiums, and there may be perfectly valid reasons why many stadiums have a single hot dog vendor (with multiple outlets, of course). In fact, the reason for the limitation on the number of vendors is often irrelevant. Whether it is a result of limited space, in the interest of efficiency, or through the evil intent of the worldwide hot dog cartel, most limitations on competition among providers of goods and services will result in increased costs to the consumer. For more information on hot dogs at the major league level, see Chris Corbellini, *2001: A Baseball Odyssey*, *at* http://www.mlb.com/NASApp/mlb/mlb/events/mlb_odyssey_story.jsp?type=notes&day=story_0906 (last visited Apr. 5, 2003), for one man's opinion on the best dogs in the majors.

157. This is true as long as the market does not crash. Assume ten companies each maintain a ten percent market share, and through competition the number of companies decreases to five, the market shares of at least some of the five companies will necessarily increase. Eventually, as the number of competitors falls, the amount of selective pressure the customer can apply through purchase decisions decreases because her choices decrease along with the number of players in the particular market. Ever wonder why there is no "value menu" at the fast food outlets inside major league stadiums? There is none because baseball fans do not have the leverage to force the supplier to provide one.

companies to amass capital sufficient to withstand the Darwinian pressures of the modern marketplace. Should that happen, medical and scientific progress may slow as fewer companies pursue the promise of breakthrough DNA technologies.[158]

3. The Impact on the Judicial System

The federal court system will also feel the impact of *Enzo*. The disclosure regime thereby enabled could very well result in increased patent litigation for the simple reason that, in the U.S. system, courts are the final arbiters of patent claims. As such, when patents blur at the margins, courts will increasingly be called upon to determine the exact scope of a given claim.

The judicial difficulty with a relaxed written description standard will most likely arise in the infringement context. Typically, courts analyze infringement using a two-step process.[159] First, the court compares the allegedly infringing item with the claims of the patent.[160] If the claims "read on" the infringing device, there is infringement unless the nonpatented device does not "do the same work, in substantially the same way, and accomplish substantially the same result."[161] Barring literal infringement, a device might still infringe by the doctrine of equivalents.[162] By this doctrine, a device will be found infringing if it

158. This view of the effects of marketplace competition is not the only one. Economist Joseph Schumpeter has written extensively on the *advantages* of monopolies in certain risky fields, especially in the area of innovation, because companies with monopolistic positions can better realize (because of the lack of competition) the rewards such risk can create. *See* JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY 87 (Harper Torchbooks 1976) (1942). In the patent context, the work of Edmund Kitch has followed a similar arc, recommending broad patents on basic research as incentive for further development of the patented device. *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276 (1977).

159. *See, e.g.*, Autogiro Co. of Am. v. United States, 384 F.2d 391, 428 (Ct. Cl. 1967).

160. *Id.*

161. Dominion Magnesium Ltd. v. United States, 320 F.2d 388, 396 (Ct. Cl. 1963). This requirement exists because "the law is to benefit the inventor's genius and not the scrivener's talents." *Autogiro Co. of Am.*, 384 F.2d at 399.

162. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 606 (1950). "One who seeks to pirate an invention, like one who seeks to pirate a copyrighted book or play, may be expected to introduce minor variations to conceal and shelter the piracy. Outright and forthright duplication is a dull and very rare type of infringement." *Id.* at 607. The doctrine of equivalents seeks to limit this loophole by preventing competitors from marketing functionally equivalent (though not identical) versions of the patented device. *Id.* at 608.

performs the same function in the same way with the same result.[163] Thus, because both literal infringement and infringement by the doctrine of equivalents involve a test of what function a device performs, in what way the device performs, and the end result achieved, anything that blurs this examination will make patent infringement issues even more problematic for courts. Patents that only satisfy the relaxed written description requirements indicated by *Enzo* might present problems in the "way the device performs" aspect of the infringement examination, because it will at times be difficult to determine the exact mechanism of a device's operation when the written description does not precisely describe the device. For DNA sequence patents, this issue could arise in various ways. To refer to an earlier example, if STD-Away continues their work and eventually markets an antisense gonorrhea drug, Enzo will almost certainly bring an infringement suit, because for all Enzo knows, STD-Away *is* infringing. By satisfying the written description requirement through a public deposit, Enzo was never forced to determine the exact structure of its sequence, so neither they, STD-Away, or the district court hearing the case will know the "way" in which the invention works.[164] As murky as the described situation would be, imagine if STD-Away had, like Enzo, made a public deposit to satisfy 35 U.S.C. § 112. Then, the court would have to determine the sequences of both Enzo's and STD-Away's inventions before they could even begin their infringement analysis. Thus, public deposits could impose upon courts the duty to map DNA sequence patent limits, thereby increasing both the temporal as well as monetary burdens of infringement suits.[165]

If courts should steer away from these sorts of determinations, unclear patents could still make patent litigation more uncertain[166] by turning infringement suits into contests between expert witnesses asserting that

163. *Id.* (quoting Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929)).

164. Of course, on a superficial level, the way Enzo's probes work is by binding to DNA, but the legal analysis goes beyond that. In the case of DNA sequences, the "way" aspect of the infringement analysis would presumably require determination of exactly where on the bacteria's genome the probes bind, and this determination is difficult, if not impossible, to make without knowing the sequence of the probes. *See supra* note 94 and accompanying text.

165. As stated, time (in the sense of a company racing to market a product) and money (with which to finance the race) can both operate as selective pressure. This makes litigation an even more attractive option for larger companies who are better able to cope with extended (and expensive) patent contests. *See supra* note 155 and accompanying text.

166. Infringement suits are notoriously unpredictable anyway because accused infringers have a wide array of defenses, including proving either that no infringement occurred or that the original patent was invalid because of failure to meet any of the guidelines specified in Title 35, such as utility, novelty, or nonobviousness. *See* 35 U.S.C. §§ 101–103 (2000).

the device in question does or does not perform in a certain manner. Further, as infringement is a question of fact,[167] many patent decisions will be only narrowly applicable, with little precedential value. Finally, this increase in uncertainty as to the direction courts may take could make it easier for larger firms to employ their patents strategically[168] by bullying smaller firms with the threat of expensive infringement suits. For example, Bristol-Myers, the world's fifth-largest pharmaceutical company, recently settled antitrust charges brought by the Federal Trade Commission (FTC) alleging the company had misused patent law to block generic competitors. According to FTC allegations, for over a decade, Bristol-Myers had filed "baseless" infringement suits to preserve its own monopoly position and frivolously listed new patents to delay FDA approval of competitors' generic versions of the company's drugs.[169]

In light of the uncertainty *Enzo* will engender, it seems likely that the threat of this sort of corporate behavior will increase; as patent applicants take advantage of the Federal Circuit's decision, infringement suits may grow in complexity and expense, thus favoring the side with deeper pockets. This threat of strategic litigation in the patent context has already been used in technical fields to eliminate competitors. In the 1980s, Eastman Kodak was forced to stop production of instant cameras in response to infringement litigation initiated by Polaroid.[170]

4. The Impact on the PTO

The yearly number of patents issued by the PTO has risen from less than 100,000 twenty years ago to almost twice that in 2001.[171] In

167. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996) (quoting Winans v. Denmead, 56 U.S. (15 How.) 330, 338 (1853)).

168. Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 WASH. U. J.L. & POL'Y 309, 310 (2002).

169. Bloomberg News, *Bristol-Myers Agrees to Halt Patent Tactics*, L.A. TIMES, Mar. 8, 2003, at C3. The charges concerned several anticancer drugs (Taxol and Platinol) as well as the antianxiety drug BuSpar. *Id.* Bristol-Myers earns almost $2 billion annually from the sale of these drugs. *Id.*

170. *See* Polaroid Corp. v. Eastman Kodak Co., 641 F. Supp. 828, 877–78 (D. Mass. 1985).

171. Typically, sixty-five percent of patent applications result in patents; logically, then the number of applications the PTO must process is much higher. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1498 (2001); *see also* United States Patent and Trademark Office, *Patent Counts*: *States and Countries of Origin Calendar Year 2001*, *at* http://www.uspto.gov/web/offices/ac/ido/oeip/

addition, recent advances in the life science industry have resulted in a flood[172] of patent applications relating to DNA sequences, further straining the ability of the PTO to adequately perform their screening function.[173] The *Enzo* result may add momentum to this flood, as the relaxed written description standards could encourage more applicants to strike while the iron is hot.

Even if the PTO can adequately cope with an ever-increasing number of DNA sequence patent applications, the lowered written description standards pose a further problem in the prior art[174] context. When a prospective patentee submits an application to the PTO, she is also obliged to turn in any prior art of which she is aware.[175] She is not, however, required to search for prior art.[176] This approach puts the burden for prior art searches entirely on the patent examiner, who will, for the average patent application, spend a total of eighteen hours examining it.[177] Historically, when considering the novelty[178] of an invention, patent examiners looked to scholarly publications as well as previously issued patents for prior art.[179] Patent examiners also use prior art to determine whether an invention is obvious.[180] It would seem that

---

taf/st_co_01.htm (last visited Apr. 8, 2004).

172. Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard-Setting*, 1 INNOVATION POLICY AND THE ECONOMY 3 (Adam Jaffe et al. eds., 2001), *available at* http://haas.berkeley.edu/~shapiro/thicket.pdf (last visited Apr. 5, 2003).

173. Lemley, *supra* note 167, at 1499–1500.

174. Prior art is "the entire body of knowledge from the beginning of time to the present." Walter J. Blenko, Jr., *Considering What Constitutes Prior Art in the United States*, J. MINERALS, METALS & MATERIALS SOC'Y, June 1991, at 45. Relevant prior art is that which bears some relation to the patentee's invention. ELIAS, *supra* note 65, at 278.

175. Patents, Trademarks, and Copyrights, 37 C.F.R. § 1.56 (2002).

176. *Id.* Many patent applicants (or more accurately, their attorneys) do conduct their own prior art search before filing their patent so as to better craft their own patent claims. *Id.* Presumably, the prior art turned up by the applicant is turned over to the PTO, as good faith is required from prospective patentees. *Id.*

177. Lemley, *supra* note 167, at 1500. These eighteen hours represent the entire time spent on an average patent application over the two to three years the patent is being considered by the PTO. *Id.*

178. *See* 35 U.S.C. § 101 (2000). Inventions must be novel to gain a patent. If the subject matter of the application is not novel, it adds nothing to the store of technology in the public domain, and thus there is no reason to award a patent.

179. MERGES ET AL., *supra* note 43, at 168.

180. 35 U.S.C. § 103. Inventions cannot be obvious improvements over that which is already in the public domain. If the improvement were obvious, there would be no reason to reward the effort with a patent. As stated by the Supreme Court, "Unless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention." Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 267 (1850).

if eighteen hours were insufficient[181] to conduct a thorough search of the prior art and determine the patentability of an application pre-*Enzo*, the burden upon examiners will surely mount as written descriptions increasingly refer to ATCC deposit numbers. While these deposits may convince one of ordinary skill in the art that an inventor possessed the invention as well as knew identifying characteristics as to the structure, deposits likely will not be as helpful to the average patent examiner.

B. Broad Impact of Enzo: *Problems Inherent to Patenting Basic Research*

While the impact of *Enzo* will certainly be felt in the short-term, it is perhaps the broader repercussions of the decision that pose the greatest risk. Because the case concerned a human DNA sequence, the decision could have a devastating effect on many "downstream" uses for the information, such as diagnostics and treatment. By making it easier for an applicant to obtain a DNA sequence patent, the Federal Circuit has enabled the patentee to make it more difficult, and thus more expensive, for everyone else to work with the particular sequence.

1. Transaction Costs

Just as the public benefits from the spread of technology promoted by our patent system, the public also incurs costs from it. Two of the costs commonly associated with patents are social costs and transaction costs. Social costs are the negative impacts caused by business operations,[182] such as noise or pollution. Transaction costs are those costs generated through the research, negotiation, and time investments associated with entering into contracts.[183] Transaction costs can vary greatly; obviously a merger between two multinationals will create higher transaction costs than purchasing a used car. Usual types of transaction costs include search and information costs,[184] bargaining costs,[185] and enforcement

181. This is a common complaint of the PTO's procedures. *See, e.g.*, John H. Barton, *Reforming the Patent System*, 287 SCIENCE 1933, 1933–34 (2000).
182. R.H. COASE, THE FIRM, THE MARKET, AND THE LAW 95 (1988).
183. Johnson, *supra* note 11.
184. Search and information costs include the expense of developing background information on technology, the market, and competitors. *Id.*
185. Bargaining costs include the time and finances expended during (as well as in preparation for) negotiations. *Id.*

costs.[186] By the Coase Theorem, *any* initial allocation of property rights will still result in the most efficient outcome, *as long as transaction costs are zero*.[187] However, if there are transaction costs, the Theorem suggests that the initial allocation of property rights will be critical to reaching the most efficient outcome.[188]

There are always transaction costs involved with patent licenses, often in all three of the categories (research, negotiation, and enforcement expenses) described above. Bargaining costs rise as the parties involved in the negotiation hammer out the terms of the agreement.[189] Enforcement costs may accrue as one side attempts to police the other to ensure compliance with the contract. Should a dispute arise, the expense of lawyers and litigation can quickly outweigh the benefits provided by the license.[190] Search and information costs are incurred through research of the prior art in the field (to identify the relevant players and scope) as well as the patent itself. Therefore, the initial allocation of property rights to the patentee is critical in achieving the most efficient outcome. In Coase terms, *Enzo* could increase transaction costs by requiring more investment in searches and information processing, while at the same time making the initial allocation of property rights more difficult.

Enzo could increase the costs of information to prospective licensees by making it harder to find relevant prior art. Just as the usual sources of prior art cited by the PTO are issued patents and scholarly writings,[191] licensees also utilize these sources. The problem facing licensees is the same one that post-*Enzo* examiners may face: How does one determine the exact scope of a patent that references a deposit number to satisfy the written description requirement? While licensees may not be under the same time and budget constraints as the PTO, their investment of time and money in hopes of determining the scope of the patent of interest

186. *Id.*

187. R.H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 15, 19 (1960). The theorem also assumes that the two parties desire an agreement. Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 82 (1994). However, this assumption may fail as parties behave strategically. *Id.* Of course, patent holders may indeed behave strategically, and the likelihood of this occurring would seem to increase as patent boundaries lose their precision. *Id.*

188. COASE, *supra* note 182, at 114–19.

189. Generic licensing agreements tend to reduce this aspect of transaction costs through the establishment of routine procedures and forms. In addition, as the players in a given field become familiar with the terms of the generic agreement, negotiations may be further streamlined. Interview with Owen Smigelski, Of Counsel, David R. Preston & Assocs., in San Diego, Cal. (April 19, 2004).

190. If the case goes to trial, much of the cost is an *externality* to the parties involved because the public pays much of the cost of the court system. Johnson, *supra* note 11.

191. MERGES ET AL., *supra* note 43, at 168.

will be reflected in transaction cost increases. These increases in the "cost of doing business" may discourage some licensees, and those that persist in their efforts to license will pass these increased costs on to their customers.

As transaction costs increase, the initial allocation of property rights rises in importance.[192] In our patent system, the PTO makes these initial allocations based on the submitted application as well as patent prosecution[193] in an attempt to balance the competing interests of the inventor, who wants expansive rights, and the public, who wants to limit monopolies. It is hard to imagine that the job of the PTO will be made any easier by a regime allowing inventors to gain monopoly rights with a lesser disclosure. Thus, *Enzo* may well have a snowball effect in the sense that the decision itself could trigger a rise in transaction costs for the reasons previously described. This rise in transaction costs will in turn make the initial allocation of property rights even more important. However, this initial allocation itself has become more difficult post-*Enzo* because of the relaxed disclosure standard. As the *Enzo* decision made the job of the PTO more difficult, it has also made it more important.

2. The Tragedy of the Commons or Anticommons

In 1968, Garrett Hardin published his seminal work on issues relating to commonly held resources.[194] In it he described what he termed the "tragedy of the commons," a situation where it is to one's benefit to overuse a commonly held resource, because the harm caused by the overuse is borne by others—that is, it is externalized relative to the over-user.[195] Further, as the resource at issue is commonly held, no parties have the right to exclude anyone else from exploiting it, and thus no one can protect the resource. In the situation before us, the commonly held resource is the genome, the sum of all the DNA that makes us human. By Hardin's theory, it would be rational for parties to attempt to overuse the resource[196] as the costs of such overuse are not borne by the over-

192. *See supra* note 188 and accompanying text.
193. Patent prosecution refers to the correspondence between an applicant and the examiner. BitLaw, *Patent Prosecution*, *at* http://www.bitlaw.com/patent/prosecution.html (last visited Apr. 5, 2003).
194. Hardin, *supra* note 30.
195. *Id.* at 1244.
196. In a genomic context, resource overuse is demonstrated by companies

user alone, but shared by us all. Though such exploitive behavior may be rational for the party benefiting, it ultimately leads to the tragedy of resource depletion.[197] Thus, one can see that commonly held resources are vulnerable to exploitation, so a mechanism to prevent such overuse is appropriate. In the context of the genome, one such protection mechanism is the patent system.

The PTO serves as a check on the ability of users to exploit the commonly held resource of our genome by limiting patentees to claiming only that which they have invented. However, there is a corollary to the "tragedy of the commons," the "tragedy of the anticommons,"[198] wherein many parties have the power to exclude. A resource can effectively become blocked as a result of the multitude of parties holding property rights in it, and as the number of parties to a negotiation increases, transaction costs can soar. This rise in transaction costs leads to resource under-use, as seen in land development evolutions in the United States[199] and elsewhere.[200] Typically, a tragedy of the anticommons results from resource "fragmentation" to the point where efficient use of the resource requires coordination or negotiation between the vast numbers of owners. In feudal societies, fragmentation could result from families (or the feudal lord) dividing the land as it passed to younger generations.[201] More analogous to the situation concerning DNA patents is the example of homesteading in the American West,[202] where vast numbers of people facing a large resource obtained exclusionary rights to small parts of it. As with the homesteaders, patentees holding small DNA sequences may find it economically unfeasible to develop their invention. Further, these patentees could lack the resources necessary to bear the large transaction costs of coordinating or negotiating with those holding neighboring sequences. Finally, due to the increased transaction costs, it is possible

---

patenting as much of the genome as possible.

197. Hardin, *supra* note 30, at 1244–45.

198. Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1166 n.8 (1999).

199. *Id.* at 1172. This problem arose from the small homesteads granted in some parts of the country. *Id.* The parcels were too small to farm effectively, and they could not be sold before the homesteader acquired complete ownership. *Id.* Further, even if the owner were able to sell, what would the buyer want with a plot of farmland too small to be effectively farmed? *Id.* The prospective buyer could also try to buy the neighbor's farm, and the next neighbor's, and the next, but as more participants enter the negotiations and transaction costs rise, this is less likely to happen. *Id.* Many of these homesteads were eventually abandoned. *Id.*

200. *Id*. at 1171 (describing the effects of "fragmentation," or dividing a resource to the point where it can no longer be used efficiently).

201. *Id.* at 1171 n.34.

202. *Id.* at 1171–72.

that no one will be willing to shoulder this task. This danger is inherent in the situation currently faced by the life science industry and would be difficult to overcome even if patent boundaries were crystal clear. Of course, patent boundaries have never been so precise, but consider the situation post-*Enzo*: Under the relaxed written description standards the Federal Circuit seemed to advocate, transaction costs are almost sure to increase as companies and researchers are forced to discern the limits of already issued patents. Coupled with the PTO practice of awarding patents on small DNA sequences,[203] these higher transaction costs seem to create an environment ripe for the "tragedy of the anticommons" discussed by Michael Heller.

Of course, the ultimate impact of *Enzo* upon the life science industry cannot yet be discerned, but history does provide a glimpse of what can happen with developing technology that evolves absent strong patent protection. In testimony before the Federal Trade Commission and the Department of Justice on the topic of competition and intellectual property law, Yale President Richard Levin described the differences in perception as to patent protection among various industries.[204] Levin noted that while firms in most industries believed their competitive advantages were best protected by being the first to market rather than through the patent system, certain pharmaceutical and chemical industries felt quite strongly that patents were the best protection of the fruits of their R&D efforts.[205] In part, this pro-patent outlook developed because, in these industries, the nature of the technology dictated discrete inventions such that patents on one molecule did not impact the

203. Ed Susman, *U.S. PTO to Allow Patents on Gene Fragments Called EST's*, BIOTECH. NEWSWATCH (Mar. 3, 1997). ESTs, or Express Sequence Tags, are short sequences that are of sufficient length to identify the specific gene of which they are a part. *See supra* note 93 and accompanying text. However, ESTs may be patented with no more stated utility than for use as probes. *Id.* Thus, one may patent an EST without knowing what the particular identified gene does. Susman, *supra*. This practice of allowing patents on small DNA sequences increases fragmentation of the resource, and thus fragmentation itself raises transaction costs by increasing the number of parties who have exclusionary rights. Beyond transaction cost issues, a further danger of fragmentation of resources is that, just as thermodynamics dictate, it is easier to break things up than it is to put them back together.

204. *FTC/DOJ Joint Hearings on Competition and Intellectual Property Law* (Feb. 6, 2002) (testimony of Richard C. Levin). Mr. Levin directed a 1980s Yale research program on the economic impact of intellectual property, and he currently co-chairs a National Academies' Board on Science, Technology, and Economic Policy committee on Intellectual Property Rights in the Knowledge-Based Economy. *Id.*

205. *Id.*

work of others—a patent on one chemical structure rarely prevented competitors from patenting others. However, in industries where progress tended to be cumulative, that is, building upon the work of others, strong patent protection on early research could actually function as a detriment to progress. In 1982, Levin described the nascent semiconductor industry[206] in which innovations in both basic research as well as more developed applications drove the evolution of the technology at a pace that would have been impossible to attain in an environment where basic research was quickly patented.[207] In light of the current state of the science industry, in which cumulative development has become the norm rather than the exception, does it make sense to lessen the requirements for patenting basic research?

V. PROPOSALS

As stated, *Enzo* created problems on two levels: First, by relaxing the written description requirement, the decision relieved patentees of the responsibility of determining the bounds of their claims. Because these bounds are crucial to both researchers in similar fields as well as to courts making infringement determinations, the boundaries will still have to be mapped, only now the patent holder will not bear the cost. The simplest solution to the *Enzo* problem is to reverse the decision and return to the regime established in *Lilly*. In *Lilly* the Federal Circuit indicated that satisfaction of the written description requirement entailed more than a demonstration of proof of possession; the inventor must describe the invention in detail.[208] A return to the *Lilly* standard would eliminate the written description loophole endorsed in *Enzo* and force inventors to delay patenting until they could adequately identify their inventions. In the case of DNA sequence patents, this degree of identification would require patentees to sequence the DNA, rather than forcing others to do so. Further, while the relaxed written description standards indicated by *Enzo* obviously apply to DNA sequence patents, in no way are they limited to that field. *Enzo* may enable patent applicants in diverse fields to circumvent the spirit of the written description requirement and patent their inventions with minimal disclosure, thus impairing the traditional quid pro quo inherent in the U.S. patent system. A recent Federal Circuit case has already applied *Enzo* beyond the life sciences. In *Moba, B.V. v. Diamond Automation,*

206. Richard C. Levin, *The Semiconductor Industry*, *in* GOVERNMENT AND TECHNICAL PROGRESS: A CROSS-INDUSTRY ANALYSIS 9 (Richard R. Nelson ed., 1982).

207. *Id.* at 82.

208. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).

Inc.,[209] the court cited *Amgen Inc. v. Hoechst Marion Roussel, Inc.*[210] (which cited *Enzo*'s written description criteria) to support the conclusion that the written description requirement was satisfied when the inventor has demonstrated possession of the invention.[211]

On a larger scale, *Enzo* added to the dangers inherent in granting patents on basic research by making it easier to patent inventions whose limits are unknown. These basic research patents can impede the development of entire industries by removing technology from public reach, making further study or development impossible or prohibitively expensive.

A similar situation arose almost a century ago, after the Wright Brothers' groundbreaking flights at Kitty Hawk. At the time of those initial powered flights, the Wrights stood poised at the threshold of a new technology, much like the DNA researchers of today. Subsequent to those flights, the Wrights applied for and were awarded patents on their aircraft technology. These basic research patents stifled the U.S. aircraft industry until the government finally intervened.[212] This

209. 325 F.3d 1306 (Fed. Cir. 2003) (addressing a patent dispute surrounding egg-sorting equipment).

210. 314 F.3d 1313, 1330 (Fed. Cir. 2003).

> More recently, in *Enzo Biochem*, we clarified that *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

Id. at 1332.

211. *Moba, B.V.*, 325 F.3d at 1320. "The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." *Id.* The court went on to state that in "*Enzo* and *Amgen*, the record showed that the specification that taught one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention." *Id.* at 1321. This seems to collapse the written description requirement to one of merely enablement (at least in some fields), which is an interpretation that is not entirely supported by precedent. *See supra* note 57 and accompanying text. This interpretation of § 112 does have its proponents, among them is Judge Rader, who concurred in *Moba*:

> The language of § 112, ¶ 1 indicates that a patent will contain an adequate description if it provides enough information to enable a person skilled in the art to make and use the invention. Any disclosure that enables one to make and use the invention also, by definition, also shows that the inventor was in possession of that full invention. Consequently, the erroneous written description requirement of *Lilly* case lacks both a statutory and a logical foundation.

Moba, B.V., 325 F.3d at 1323 (Rader, J., concurring).

212. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights*

illustrates the dangers that can manifest when basic research is "locked" through the patent system. In the Wright Brothers' example, the grant of a patent at the nascent stage of industry development crippled progress such that U.S. fliers in World War I flew British or French aircraft.[213] Only in Europe, where the U.S. patents had no legal authority, could a dynamic aircraft industry develop. Eventually, the U.S. government intervened, with the Secretary of the Navy urging the creation of an agreement providing for automatic cross-licensing.[214]

In the DNA sequence context, the U.S. government could establish compulsory cross-licensing arrangements whereby the patent holder's exclusionary rights were relaxed in return for a fee paid by those interested in working with the patented sequence. This would lessen the "tragedy of the anticommons" danger inherent to patents on basic research by maintaining public access to the raw materials of genetic research.

A similar solution has proven effective in the automobile industry, preserving competition as well as reducing transaction costs.[215] In the music field, the American Society of Composers, Authors, and Publishers (ASCAP) provides a blanket license that allows buyers access to all of the songs from the catalog.[216] While these sorts of arrangements can raise antitrust issues,[217] they provide an efficient mechanism to aid in the dissemination of technology, which was, after all, the goal of the patent system in the first place.

VI. CONCLUSION

The scientific profession has changed tremendously in the last few hundred years; no longer is it limited to the landed classes and bourgeoisie.[218] Just as the demographics of the profession have changed, perhaps the motivations have as well.[219] Though society has enjoyed countless benefits derived from the efforts of those pushing the

---

and the Norms of Science, 94 NW. U. L. REV. 77, 131–32 (1999).

213. EZRA BOWEN, KNIGHTS OF THE AIR 148–53 (1980).

214. George Bittlingmayer, *Property Rights, Progress, and the Aircraft Patent Agreement*, 31 J.L. & ECON. 227, 232 (1988).

215. *See* Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1950–51 (2002).

216. Michael J. Meurer, *Copyright Law and Price Discrimination*, 23 CARDOZO L. REV. 55, 111 (2001).

217. Lemley, *supra* note 215, at 1951.

218. *See generally* Krimsky, *supra* note 1.

219. *Id.* at 15. The author notes the increasing number of "associations" between academic researchers and industry, including research grants, private gifts, and confidentiality agreements between researchers and the funding companies. *Id.* at 28–31.

envelope of scientific knowledge, it must be careful to ensure that the fruits of scientific labor continue to benefit society as a whole, instead of merely profiting the latest version of the bourgeoisie described by Sheldon Krimsky.[220] In the context of the human genome, the PTO must act as trustee for the benefit of human kind by protecting the single thing that all humans share—our genetic heritage. By making it easier to obtain a patent, the Federal Circuit has shifted stewardship of our genetic heritage to parties whose motivations are subject to question[221] and effectively limited the power of the PTO to protect our most important resource.

Today, one can sequence a DNA sample quickly and inexpensively, sparing the would-be DNA patentee the "Herculean effort"[222] Judge Dyk feared in *Enzo*. However, the harm *Enzo* caused is not limited to diagnostic probes, but rather lies in the attenuated disclosure requirements the decision created. The Federal Circuit's lowering of the bar to patentability

220. *Id.* at 15. As an example of the differing end result achieved when a public organization owns a gene patent as opposed to a private entity, Krimsky describes two genetic screening tests. *Id.* at 37. One of the tests diagnoses Tay Sachs disease, and the gene patent is held by the Department of Health and Human Services. *Id.* A screening test for Tay Sachs costs around $100. *Id.* In contrast, a screening test for breast cancer involving the BRCA1 and BRCA2 genes (patent held by Myriad Genetics) costs $2400. *Id.*

221. In response to an increasing number of AIDS related deaths, South Africa passed legislation in 1997 that, in effect, allowed it to circumvent U.S. patent laws. Shawna Williams, *Innovation vs. Access: Two Epidemics Transform the Pharmaceutical Patent Law Debate into an International Controversy*, 8 J. YOUNG INVESTIGATORS (May 2002), *at* http://www.jyi.org/volumes/volume5/issue8/features/williams.html. The legislation allowed importation of drugs from countries that lacked drug patent protection as long as the patent holder was paid a fee. *Id.* Almost immediately, a U.S. pharmaceutical association began lobbying to persuade the Clinton Administration to pressure South Africa into changing the new laws. *Id.* The United States then warned South Africa that trade sanctions could result from the legislation. *Id.* In 1998, the trade association filed suit, naming Nelson Mandela as the "First Responder." *Id.* After two years of bad publicity regarding the lawsuit, the association dropped the action. *Id.*

It is currently estimated that by 2006 the number of AIDS-related fatalities in South Africa will be approximately 250,000 annually, rising to 500,000 annually by 2008. AIDS Foundation of South Africa, *AIDS in South Africa*, *at* http://www.aids.org.za/aids_in_south_africa.htm (last updated July 28, 2003). By 2008, the average life expectancy in South Africa will have plunged from approximately sixty years to approximately forty years. *Id.* In contrast, the Bush administration considered overriding the patent on the Anthrax drug Cipro after fewer than twenty cases were reported in the United States. Williams, *supra*. As of this writing, the Bush administration has indicated support for a change in World Trade Organization policy to allow countries facing public health emergencies to seek patent waivers. *Id.*

222. Enzo Biochem, Inc. v. Gen-Probe Inc., 285 F.3d 1013, 1026 n.2 (Fed. Cir. 2002), *vacated by* 323 F.3d 956 (Fed. Cir. 2002).

could hamstring the U.S. life science industry by inhibiting research and investment. The court's decision could also force consumers to bear ever-increasing health care costs by making basic research easier to patent. These basic research patents in turn drive up the cost of health care by creating a thicket of transaction costs that deter innovation by making the pursuit of new drugs and treatments in heavily patented fields prohibitively expensive.

Perhaps *Enzo* will not be the *Dred Scott*[223] of patent jurisprudence, a bitter reminder of the dangers of ignoring the forest for the trees. In such a dynamic field, the harm *Enzo* caused can be readily corrected. Hopefully it will be soon.

HAL GIBSON

223. Scott v. Sandford, 60 U.S. (19 How.) 393 (1856) (holding that Dred Scott was to remain a slave and that the Federal Government had no authority to prohibit slavery in new territories, thereby invalidating the Missouri Compromise and continuing the United States in its march towards the Civil War).