

Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation

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I. INTRODUCTION

In recent years, the major innovator pharmaceutical companies have experienced two pronounced and significant trends: a decreasing output of innovative new drugs and cutbacks in research and development (R&D) investment. The two phenomena probably are not unrelated and raise significant concerns for a society intent upon providing affordable health care for an aging population.

While the root causes of these trends are complex and diverse, we should not overlook the critical role patents play in creating the necessary incentives for the substantial investment required to develop pharmaceutically-interesting chemical compounds into actual drugs and to take them through the clinical trials necessary for Food and Drug Administration (FDA) approval. In a recent presentation, Robert Armitage, Senior Vice President and General Counsel for Eli Lilly and Co. (Lilly), identified the high level of unpredictability in today's patent law as a significant impediment to the development of new medicines.¹ This Article discusses various forms of unpredictability in patent law and how they impact innovators, particularly in the pharmaceutical sector, and provides some ideas for addressing the problem.

Part II of this Article summarizes the current R&D crisis confronting the pharmaceutical industry and the accompanying drop-off in innovative output from this important technological sector. Part III explains Mr. Armitage's "view from industry," which attributes a significant causative effect to unpredictability in the patent system. Part IV provides two Lilly case studies involving generic challenges to two of the company's important drugs, Gemzar and Strattera, in which the company has suffered as a result of this unpredictability. Part V identifies three distinct forms of unpredictability in patent law: unpredictability caused by the proliferation of loosely defined standards rather than bright line rules; unpredictability associated with long-delayed clarification of critical and identifiable ambiguities in patent law; and perhaps worst of all, unpredictability that occurs when courts adopt a new interpretation of legal doctrine and apply it retroactively, to the detriment of the investment-backed expectations of patent owners. Part VI discusses how Con-

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1. See *infra* Part III.

gress and the United States Patent and Trademark Office (PTO) can ameliorate problems of unpredictability by taking a more active role in instituting changes in patent law.

II. THE CRISIS IN PHARMACEUTICAL R&D

Pharmaceutical R&D is in crisis. The signs are all around us. For example, in early February 2011, the world's largest drugmaker, Pfizer, announced plans to slash R&D and close a major research facility in Sandwich, England, birthplace of important pharmaceutical innovations such as Viagra.² Layoffs and facility closures have become endemic in Big Pharma, resulting in the loss of an estimated 9000 R&D jobs in the first half of 2010 alone.³ These closures and job losses affected a broad swath of the innovative pharmaceutical sector, including: AstraZeneca, 3500 R&D jobs eliminated; Roche, 800 R&D jobs cut or transferred; Sanofi-aventis, Pennsylvania R&D facility closed, ending 400 jobs; and Takeda, 1400 U.S. jobs cut.⁴

The cutback in R&D coincides with an increasing reluctance among investors to support pharmaceutical R&D, based upon the emerging consensus that the expected payout in the current environment does not justify the risk and expense. A report by Reuters published on February 10, 2011, begins with the assertion that “[d]rug companies are drinking in the last-chance saloon and have just two to three years to prove to investors they can generate a decent return on the billions of dollars thrown annually at research and development.”⁵ A Bureau of National Affairs report, published one week earlier, arrived at a similar conclusion, noting that, “Wall Street analysts like Morgan Stanley have run the numbers and found powerful financial rationales for shutting down internal drug discovery and early development, and they are making this abundantly clear to pharma.”⁶ In the words of David Redfern, GlaxoSmithKline's head of strategy: “I am absolutely convinced that this will be the last generation of R&D spending unless a decent return is generated.”⁷

Unfortunately but inevitably, decreased investment in R&D translates into decreased output of innovative products from the drug pipeline. In fact, the number of approvals of innovative drug products already has decreased. For example, in 2008 only twenty-one New Molecular Entities (NMEs) were approved, a twenty year low.⁸ 2009 was only slightly better – the twenty-six

2. Ben Hirschler, “*Last Chance*” for Sickly Pharma to Deliver on R&D, REUTERS, Feb. 10, 2011, available at <http://www.reuters.com/article/2011/02/10/pharmaceuti-cals-rd-idUSLDE71912R20110210>.

3. Eleanor Herriman, *BNA Insights: The Biopharma-Contract Research Organization Ecosystem*, BNA BIOTECH WATCH, Feb. 3, 2011, at D3.

4. *Id.*

5. Hirschler, *supra* note 2.

6. Herriman, *supra* note 3.

7. Hirschler, *supra* note 2 (internal quotation marks omitted).

8. Herriman, *supra* note 3.

NMEs launched globally that year represented only slightly more than half the peak level in 1997.⁹ The decreasing productivity of pharmaceutical R&D only feeds into investor fears, creating a vicious cycle of decreased investment, more cutbacks, and ultimately less life-saving innovation, a particular concern as society struggles to contain healthcare expenditures while caring for an advancing army of aging baby boomers.

Not surprisingly, policymakers are concerned about the sharp drop-off in productivity plaguing pharmaceutical R&D. On January 22, 2011, the *New York Times* reported that “[t]he Obama administration has become so concerned about the slowing pace of new drugs coming out of the pharmaceutical industry that officials have decided to start a billion-dollar government drug development center to help create medicines.”¹⁰ The article notes that pharmaceutical companies are paring back on research and concludes that “[p]romising discoveries in illnesses like depression and Parkinson’s that once would have led to clinical trials are instead going unexplored because companies have neither the will nor the resources to undertake the effort.”¹¹ National Institutes of Health (NIH) Director Francis Collins was quoted as saying that pharmaceutical research productivity has been declining for fifteen years, “and it certainly doesn’t show any signs of turning upward.”¹²

Regrettably, this foray into drug R&D by the federal government will be expensive, and the *New York Times* article notes that researchers and NIH staff members are questioning the wisdom of the plan.¹³ For example, Mark Lively, a professor of biochemistry at Wake Forest University, is quoted as observing (correctly in my view) that, “NIH is not likely to be very good at drug discovery, so why are they doing this?”¹⁴ The NIH traditionally has played an important role in funding the early-stage research that is the starting point in drug development, but the public sector has demonstrated little success in taking these early-stage candidates through clinical trials and onto the market as FDA approved drugs.

The answer to Dr. Lively’s question appears to be that the move is borne largely out of frustration, if not desperation. The *New York Times* article points out that for years Director Collins has been predicting that “gene sequencing will lead to a vast array of new treatments, but years of effort and tens of billions of dollars in financing by drug makers in gene-related research has largely been a bust.”¹⁵ Director Collins is quoted as saying, “I am a little frustrated to see how many of the discoveries that do look as though

9. *Id.*

10. Gardiner Harris, *Federal Research Center Will Help Develop Medicines*, N.Y. TIMES, Jan. 23, 2011, at A1, available at http://www.nytimes.com/2011/01/23/health/policy/23drug.html?_r=2&hpw.

11. *Id.*

12. *Id.* (internal quotation marks omitted).

13. *Id.*

14. *Id.* (internal quotation marks omitted).

15. *Id.*

they have therapeutic implications are waiting for the pharmaceutical industry to follow through with them.”¹⁶ Government officials acknowledge that it is unclear whether government can succeed where private industry has failed, “but they say doing nothing is not an option.”¹⁷

III. A VIEW FROM INDUSTRY: THE PROBLEM OF UNPREDICTABILITY IN PATENT LAW

Policymakers could gain insight into the problem of decreasing pharmaceutical innovation by consulting with Robert Armitage, longtime Senior Vice President and General Counsel for Lilly. Were they to do so, Mr. Armitage likely would point to an unacceptably high level of uncertainty and unpredictability in the U.S. patent system as a major disincentive for the investment necessary to bring innovative new drug products to market.

Unfortunately, neither President Obama nor Director Collins was in attendance at a conference held at the University of Illinois on September 22, 2010, commemorating the thirtieth anniversary of *Diamond v. Chakrabarty*.¹⁸ If they had been, they would have witnessed Mr. Armitage’s presentation, entitled: “The Role of Patents in Ensuring Innovation: A View from Industry.”¹⁹ The Lilly vice president opened his talk with a PowerPoint slide dominated by this bullet point: “*Uncertain, unpredictable patent enforceability will destroy the ability to make the high-risk investments to create new medicines.*”²⁰ He explained how, from the perspective of an innovative pharmaceutical company, the current state of the U.S. patent system had rendered it extremely difficult for companies and their investors to predict with an adequate degree of confidence whether they will be able to successfully enforce their patents to maintain a sufficient period of protection from generic competition.²¹ He substantiated this point with a couple of recent examples in which key Lilly patents were invalidated unexpectedly in patent challenges launched by generic competitors.²² While there are clearly a number of factors contributing to the decrease in investment and innovation, we should take seriously concerns voiced by those within the industry since we as a society

16. *Id.* (internal quotation marks omitted).

17. *Id.*

18. See generally *30th Anniversary Celebration of Diamond v. Chakrabarty*, U. ILL. C. L., <http://law-www.law.uiuc.edu/faculty-admin/chakrabarty/default.asp> (last visited Feb. 21, 2011) (providing a description of the conference).

19. Robert Armitage, *A Fresh Start on Limiting Patent Eligibility: Barring Patents Where Information or the Exercise of Human Intellect is an Element of a Purported Invention*, U. ILL. C. L. (Sept. 22, 2010), <http://law-www.law.uiuc.edu/faculty-admin/chakrabarty/videos/armitage.html> (video of Mr. Armitage’s presentation).

20. *Id.* at 4:10.

21. *Id.*

22. *Id.* at 4:21.

rely upon this industry to generate continuing advances in medicine and healthcare.

Taking a promising drug candidate through development, clinical trials, and onto the market is a notoriously expensive and high risk gamble. Only a small fraction of the drug candidates in which pharmaceutical companies invest become commercially successful products. Drug companies spend millions, even hundreds of millions of dollars on a promising drug candidate only to find out that the compound lacks the safety and efficacy profile necessary to meet the stringent standards of FDA approval.²³

The process appears to have become more challenging in recent years. For example, the number of Phase III terminations during 2007-2009 was reportedly twice that of 2004-2006.²⁴ A recent study, covering 2004 through 2010, found that only 7% of traditional small molecule chemical drugs that entered human clinical trials obtained FDA marketing approval.²⁵ The problem is particularly pronounced with respect to the most critical drug categories – the success rate for cancer drugs was found to be “a mere 4.7%, with cardiovascular drugs second-worst at 5.7%.”²⁶ The low success rate for these drugs is attributed in part to the implementation of more demanding standards of proof by FDA regulators, such as requiring convincing evidence that cardiovascular drugs reduce heart attacks and strokes rather than just lower a risk factor, such as cholesterol levels.²⁷

Notably, these dismal statistics apply to drug candidates that were tested on human subjects.²⁸ Most drug candidates never make it that far; it typically requires millions of dollars of investment just to get to the point where the FDA will approve administering the drug to human subjects in Phase I clinical trials.²⁹

23. See, e.g., *id.* at 7:21 (discussing Eli Lilly’s recent abandonment of the trial of an Alzheimer’s drug).

24. Herriman, *supra* note 3. For a description of Phase III clinical trials, and the drug approval process, see generally Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362 (2001), available at <http://www.jabfm.org/cgi/reprint/14/5/362.pdf>.

25. Bill Berkrot, *Success Rates for Experimental Drugs Falls: Study*, REUTERS (New York), Feb. 14, 2011, <http://uk.reuters.com/article/2011/02/14/health-us-pharmaceuticals-success-idUKTRE71D2U920110214> (discussing a study conducted by the Biotechnology Industry Organization (BIO) and BioMedTracker, which found a somewhat higher success rate of 15% for biologics).

26. *Id.*

27. *Id.*

28. See *id.*; see also Lipsky & Sharp, *supra* note 24, at 365 (describing the stages of clinical trials and that human testing begins in Phase I).

29. See *Drug Discovery and Development*, PHRMA, <http://www.phrma.org/research/drug-discovery-development> (last visited June 28, 2011) (describing the average cost of taking a drug from investigation to market and the number of drugs researched that make it to market).

FDA approval of a new drug is a landmark accomplishment, but by no means a guarantee of commercial success and adequate return on investment. Innovative drugs are often subject to competition by other products used to treat the same indication. Profits can be relatively small in the case of orphan drugs, and more generally, in situations where the patient population is relatively small or impecuniary.

Even if a drug is a commercial success, the company is not out of the woods. Product liability suits, often based on unanticipated adverse side effects, are endemic and costly to defend. Some recent judicial decisions have gone so far as to hold a drug company liable for alleged injuries caused by a drug sold by a generic competitor.³⁰

In the face of these long odds, patents play a critical role in creating the necessary incentives for investment. In most cases, the prospect of adequate patent protection is a prerequisite for a pharmaceutical company's decision to try and develop a promising drug candidate into an approved drug product.³¹ While the Food, Drug, and Cosmetics Act (FDCA) provides drug innovators with five years of data exclusivity, most would agree that the period of market exclusivity afforded by this short data exclusivity period is insufficient to incentivize adequate investment.³² In practice, most new drugs enjoy the benefit of a de facto period of market exclusivity closer to eleven to thirteen years,³³ and patents have played a critical role in extending the period of market exclusivity well beyond the five years of data exclusivity.³⁴ These additional years are critical for providing the necessary profits to justify the expensive and risky investment.³⁵ Without the availability of adequate patent protection, drug companies will choose not to make the investment, resulting in many potentially life-saving compounds never being developed into drugs.³⁶

But as pointed out by Mr. Armitage, the unpredictable application of patent law to drug patents repeatedly has cut short the period of market exclusivity that the innovator had counted on when deciding to bring the drug to

30. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705-09 (D. Vt. 2010); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 320-21 (Cal. Ct. App. 2008); see generally Allen Rostrom, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123 (2011).

31. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 503 (2009).

32. See, e.g., *id.* at 565-67; Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REV. DRUG DISCOVERY 479, 487 (2008).

33. Henry C. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL AND DECISION ECONOMICS 491, 493 (2007), available at <http://fds.duke.edu/db/attachment/324>.

34. See Roin, *supra* note 31, at 565 n.332.

35. *Id.* at 565-67.

36. *Id.* at 503.

market.³⁷ Assuming that investors in drug development are rational, the level of investment will drop off as investors see the patents on which the last generation of investors depended upon for a recoupment of their investment unexpectedly torpedoed by the patent challenges of generic competitors. After witnessing repeated cases where a drug company has its patent rights negated based on unpredictable and unanticipated applications of the law, rational investors will discount the value of patents, which could in some cases result in a decision not to invest in the development of a promising drug candidate. The current unpredictable environment, wherein the investment backed expectations of investors are given short shrift, disincentivizes investment and thereby hampers innovation.

IV. TWO CASE STUDIES ILLUSTRATING THE PROBLEM FROM THE INDUSTRY PERSPECTIVE

At the time Mr. Armitage gave his presentation, Lilly was stinging from two recent judicial decisions invalidating key patents on innovative drugs that the company had developed and brought to market. In one of these decisions, *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, the Federal Circuit affirmed the invalidation of a patent on Gemzar, the only approved drug for the treatment of pancreatic cancer, a particularly lethal and intractable form of the disease.³⁸ The invalidation of this patent hastened market entry by generic competitors by nearly two years. In the other decision, *Eli Lilly & Co. v. Actavis Elizabeth LLC*, a district court invalidated Lilly's patent on Strattera, a drug used to treat attention deficit hyperactivity disorder (ADHD).³⁹

In order to provide the reader with a more concrete understanding of the problem of patent certainty from the perspective of a pharmaceutical innovator, this section summarizes the course of events leading to the development and approval of these drugs and the subsequent invalidation of the key patents. The decisions invalidating these patents illustrate two pernicious aspects of the current patent regime: prolonged delay in the clarification of long-standing and clearly defined ambiguities in the patent laws, coupled with unpredictable and retroactive judicial expansion of patent doctrine.

37. See Armitage, *supra* note 19.

38. 611 F.3d 1381, 1389 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2445 (2011); see also Armitage, *supra* note 19.

39. 731 F. Supp. 2d 348, 390 (D.N.J. 2010); see also Armitage, *supra* note 19.

A. Case Study #1: The Invalidation of Lilly's Gemzar Patent

In the early 1980s, Lilly began developing “nucleoside analogues” for use as antiviral agents.⁴⁰ The synthesis of these molecules was quite challenging, but after many attempts Lilly chemists succeeded in synthesizing a number of nucleoside analogues, including gemcitabine (the active ingredient in Gemzar).⁴¹ The compounds were tested and found to exhibit promising antiviral activity.⁴² On March 10, 1983, Lilly filed its original patent application relating to these compounds, which included the first documented reference to gemcitabine.⁴³ The application also disclosed the antiviral utility of the compounds.⁴⁴ The anticancer properties of gemcitabine were, of course, not disclosed since they were unknown at the time the application was filed.⁴⁵

Eight months after Lilly filed the original patent application, the scientist who synthesized gemcitabine submitted the compound to another Lilly scientist to be tested as a potential anticancer agent.⁴⁶ This testing, which began on November 1, 1983, revealed that the compound exhibited significant anticancer activity in cultured human cells and mice.⁴⁷ On December 4, 1984, twenty months after the filing of the original patent application, Lilly filed a second application disclosing and claiming use of gemcitabine for the treatment of cancer.⁴⁸

So far, so good – Lilly scientists had succeeded in synthesizing and isolating a difficult class of pharmaceutically interesting molecules and had identified one with promising anticancer activity.⁴⁹ These were two distinct inventions, made by different inventive entities at different points in time, and resulting quite naturally in two distinct patent applications.⁵⁰ The filing of the second application, directed toward the method of treating cancer, occurred more than a year and a half after the application disclosing gemcitabine, reflecting the time lag between synthesis of the compound and discovery of its anticancer activity.⁵¹

It was at this point that Lilly made a critical “mistake” in patent prosecution tactics, which resulted twenty-five years later in the invalidation of its

40. Brief of Defendant-Appellant Eli Lilly and Company at 7-8, *Sun Pharm.*, 611 F.3d 1381 (No. 2010-1105), 2009 WL 5422839 [hereinafter Brief of Defendant-Appellant Eli Lilly and Company, *Sun Pharm.*].

41. *Id.*

42. *Id.* at 8.

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.* at 9.

47. *Id.* at 9-10.

48. *Id.* at 10.

49. *Id.* at 7-10

50. *Id.*

51. *Id.* at 9.

Gemzar patent and the early market entry by generic versions of Gemzar. On December 4, 1984 (the same day it filed its anticancer method application), Lilly re-filed the original application as a continuation-in-part (CIP), including a single additional paragraph describing gemcitabine's anticancer activity.⁵²

At the time, Lilly's decision to supplement the original application with disclosure of the later-identified anticancer activity would not have appeared to have been a mistake, but rather prudent patent practice. It was to be ten years before the Federal Circuit decided *Transco Products Inc. v. Performance Contracting, Inc.*, finally resolving the important question of the extent to which an inventor is required to update the disclosure of best mode in a pending patent application.⁵³ Lilly now contends that the anticancer activity was added in order to ensure compliance with the best mode requirement,⁵⁴ which seems quite plausible. It also could be the case that Lilly added the anticancer activity in order to bolster the disclosure of utility in the application. To this day, substantial ambiguity exists with respect to the utility requirement for novel pharmaceutical compounds.⁵⁵

Faced with this uncertainty, Lilly erred on the side of disclosure and filed the updated application as a CIP.⁵⁶ This application ultimately issued as a patent claiming gemcitabine and methods of using the compound as an antiviral agent (the "composition of matter patent") on February 28, 1989, which expired on May 15, 2010.⁵⁷ The second application issued as a patent claiming the use of gemcitabine to treat cancer (the "method of treatment patent") on November 7, 1995, and was due to expire on November 7, 2012, two and a half years after expiration of the earlier gemcitabine composition of matter patent.⁵⁸ Gemcitabine, which Lilly marketed under the trade name

52. *Id.* at 10-11.

53. 38 F.3d 551, 558 (Fed. Cir. 1994).

54. Brief of Defendant-Appellant Eli Lilly and Company, *Sun Pharm.*, *supra* note 40, at 11-12.

55. *See, e.g.*, *Brenner v. Manson*, 383 U.S. 519, 529 (1966) (describing utility as "a simple, everyday word" that is "pregnant with ambiguity when applied to the facts of life"). Significantly, if the anticancer activity was necessary to establish patentable utility, Lilly would not have been able to rely on its original filing date. Brief of Defendant-Appellant Eli Lilly and Company, *Sun Pharm.*, *supra* note 40, at 2. Regardless, the PTO explicitly found that the antiviral activity disclosed in the original application as filed was sufficient to establish patentable utility for gemcitabine. *Id.* at 11-12.

56. Brief of Defendant-Appellant Eli Lilly and Company, *Sun Pharm.*, *supra* note 40, at 11-12.

57. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1383 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2445 (2011). The patent term was presumably extended under 35 U.S.C. to compensate for the delay in market entry caused by the time spent by Lilly obtaining FDA approval. *See* 35 U.S.C. § 156 (2006).

58. *Sun Pharm.*, 611 F.3d at 1383.

Gemzar, received its first FDA approved indication in 1996.⁵⁹ Currently, it is approved for four important indications: pancreatic cancer, metastatic breast cancer, ovarian cancer, and non-small cell lung cancer.⁶⁰

In 2006, Sun Pharmaceutical, a generic drug company, filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of Gemzar.⁶¹ On November 29, 2007, Sun filed a declaratory judgment action against Lilly, seeking declaratory relief that the method of treatment patent was invalid and not infringed.⁶² On August 17, 2009, the district court granted Sun's motion for partial summary judgment, holding that the asserted claims of the method of treatment patent were invalid for obviousness-type double patenting (OTDP) over the claims of the earlier composition of matter patent.⁶³ The district court based its decision upon the finding that the disclosure of anticancer activity in the composition of matter patent, which was only introduced after the initial filing date as a result of the amendment to the CIP application, and which was not claimed in that patent, rendered a second patent claiming the anticancer activity invalid as a matter of law.⁶⁴ A panel of the Federal Circuit affirmed on July 28, 2010, and Lilly's petition for rehearing en banc was denied, albeit over a vigorous dissent by four of the court's more senior judges, who argued that the decision was inconsistent with well-established legal precedent.⁶⁵ On January 26, 2011, generic drug companies Teva and APP announced the launch of a generic version of Gemzar, nearly two years before Lilly expected the patent to expire in November 2012.⁶⁶ The Supreme Court has denied Lilly's petition for certiorari.⁶⁷

Two aspects of the court's decision are troubling. First, Lilly's method of treatment patent was invalidated solely because Lilly chose to err on the side of disclosure and introduce the paragraph describing anticancer activity into the specification of the originally filed application.⁶⁸ In retrospect, it is clear that this additional disclosure was unnecessary and provided no benefit to Lilly. In 1995, ten years after Lilly made this fateful decision, the Federal

59. *Gemcitabine for Injection*, GEMZAR®, <http://www.gemzar.com/Pages/index.aspx> (last visited June 11, 2011).

60. *Id.*

61. *Sun Pharm.*, 611 F.3d at 1384.

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.* at 1383; *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 625 F.3d 719, 720-21 (Fed. Cir. 2010) (denying petition for rehearing en banc).

66. *Teva and APP Announce Launch of Generic Gemzar® Pursuant to Agreement*, BUS. WIRE (Jan. 26, 2011), <http://www.businesswire.com/news/home/20110126005936/en/Teva-APP-Announce-Launch-Generic-Gemzar%C2%AE-Pursuant>.

67. *Eli Lilly & Co. v. Sun Pharm. Indus., Ltd.*, *cert. denied*, 131 S. Ct. 2445 (2011).

68. *See Sun Pharm.*, 611 F.3d at 1389.

Circuit finally clarified the scope of the ongoing duty to disclose best mode, holding in *Transco Products Inc. v. Performance Contracting, Inc.* that there is no obligation to update the best mode in a continuing patent application.⁶⁹

Furthermore, the disclosure was not necessary to satisfy the utility requirement, as the PTO explicitly concluded that the antiviral activity disclosed in the originally filed application was sufficient in this regard.⁷⁰ Early and complete disclosure is to be encouraged, and a number of patent doctrines have been developed that incentivize early disclosure.⁷¹ Ironically, in this case, the court is punishing Lilly for engaging in behavior patent jurisprudence normally professes to encourage.

A second striking aspect of the decision is that the method of treatment patent would not have been invalidated if the two patent applications were not commonly owned. If the patents were owned by different companies, then OTDP would not have applied. If the patents were not commonly owned, the earlier patent specification could have been used as 102(e)/103 prior art,⁷² but since the anticancer activity was not introduced into the patent specification until the filing date of the invalidated patent, that crucial aspect of the disclosure would not have been available to establish obviousness. In fact, another district court in Indiana treated the earlier patent specification as 103 prior art and held that it did not render the method of treatment patent invalid.⁷³ Thus, it seems fairly clear that Lilly's patent would not have been invalidated if the earlier composition of matter patent was owned by another entity. This result is ironic since the PTO and courts have adopted a clear preference for commonly assigned patents over patents owned by separate entities, as embodied in the terminal disclaimer rules.⁷⁴

In reaching its decision, which seems to be at odds with sound policy, the district court appears to have ignored long-standing precedent that limits the OTDP inquiry to a comparison of the claims in the two patents.⁷⁵ The four Federal Circuit judges who dissented from the decision not to grant en banc rehearing correctly pointed out that, under long-established precedent of the Federal Circuit and its predecessor court, subject matter appearing in the specification but not the claims cannot be used to invalidate a second patent

69. 38 F.3d 551, 558 (Fed. Cir. 1994).

70. Brief of Defendant-Appellant Eli Lilly and Company, *Sun Pharm.*, *supra* note 40, at 11.

71. Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467, 541 (2008).

72. See 35 U.S.C. § 103(c) (2006).

73. *Eli Lilly & Co. v. Sisor Pharms., Inc.*, 705 F. Supp. 2d 971, 993 (S.D. Ind. 2010).

74. *In re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982) (upholding that PTO Rule 321 requires terminal disclaimers to contain a "non-alienation" agreement).

75. See *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 625 F.3d 719, 721-22 (Fed. Cir. 2010) (denying petition for rehearing en banc) (Newman, J., dissenting).

for OTDP.⁷⁶ As explained by the Federal Circuit in *General Foods Corp. v. Studiengesellschaft Kohle mbH*, “[d]ouble patenting is altogether a matter of what is claimed.”⁷⁷ The court went on to state that “[o]ur precedent makes clear that the disclosure of a patent cited in support of the double patenting rejection cannot be used as prior art.”⁷⁸ Nonetheless, the court in *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.* invalidated the second patent based on a disclosure of anticancer activity appearing in the patent’s written description but never mentioned in the claims.⁷⁹

This ill-advised expansion of OTDP in *Sun Pharmaceutical* traces its origin to two earlier Federal Circuit decisions, *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*⁸⁰ and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*⁸¹ In those cases, the Federal Circuit upheld the invalidation of method of use claims for obviousness-type double patenting based on disclosure of the method in an earlier patent,⁸² in apparent conflict with the precedent set forth in *General Foods*; however, the specific facts of those cases differed in crucial respects from the facts in *Sun Pharmaceutical*. As noted by the four dissenting Federal Circuit judges in the decision not to rehear *Sun Pharmaceutical* en banc, including the author of *Geneva*, Chief Judge Randall Rader, the factual differences between the cases were crucial and rendered *Geneva* and *Pfizer* inapposite for use as precedential authority in *Sun Pharmaceutical*.⁸³

The *Sun Pharmaceutical* panel made the fundamental error of treating *Geneva* and *Pfizer* as establishing a bright line rule that, as a matter of law, a patent claiming a method of use is invalid for OTDP if that use was disclosed in an earlier commonly assigned patent, regardless of when or how that disclosure was introduced into the first patent specification. In so doing, the panel ignored the factual predicates of *Geneva* and *Pfizer*, and the substantial policy concerns associated with blindly applying the outcome in those cases as a bright line rule in the very different factual context of *Sun Pharmaceutical*, in a manner showing complete disregard for Lilly’s investment-backed expectations in its patent.⁸⁴ The outcome in *Sun Pharmaceutical* is particularly problematic when one considers that OTDP is entirely judge-made law, finding no explicit support in the statute.

76. *Id.*

77. 972 F.2d 1272, 1277 (Fed. Cir. 1992).

78. *Id.* at 1282.

79. *See Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385-89 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2445 (2011).

80. 349 F.3d 1373 (Fed. Cir. 2003).

81. 518 F.3d 1353 (Fed. Cir. 2008).

82. *See Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1381.

83. *Sun Pharm.*, 625 F.3d at 722-23 (Newman, J., dissenting) (including Chief Judge Rader in the dissent).

84. *Id.*

B. Case Study #2: The Invalidation of Lilly's Strattera Patent

The second recent example of a court invalidating an important Eli Lilly patent occurred in *Eli Lilly v. Actavis Elizabeth LLC*, a challenge to Lilly's Strattera patent.⁸⁵ The drug's active ingredient is atomoxetine, also known as "tomoxetine," a compound originally discovered by Lilly in the 1970s and disclosed and claimed in a patent issued on October 2, 1982.⁸⁶

Lilly initially explored the potential for using atomoxetine in the treatment of depression, but after substantial investment and extensive studies in a large number of human patients, including Phase III clinical trials, they were unable to demonstrate a statistically significant effect.⁸⁷ For years, Lilly invested further in exploring the potential of the compound for treating other indications, including urinary incontinence, but repeatedly without success.⁸⁸

Eventually, collaboration between Lilly and non-Lilly scientists led to a proposal to try using atomoxetine for the treatment of ADHD.⁸⁹ On December 1, 1994, Lilly submitted an Investigational New Drug (IND) application to FDA seeking authorization to begin human clinical trials testing this hypothesis.⁹⁰ On January 3, 1995, FDA informed the researchers that their application had been approved, allowing clinical investigation to begin.⁹¹ Because the relative safety of the drug had already been well established in earlier trials, the investigators were not required to repeat Phase I studies for safety and were permitted to immediately commence Phase II trials for efficacy.⁹² On January 11, 1995, Lilly filed a patent application disclosing and claiming the use of atomoxetine for the treatment of ADHD.⁹³ The success of this patent application was critical if Lilly hoped to recoup its investment in developing atomoxetine as an ADHD drug since Lilly was just beginning clinical trials and less than five years remained on the patent claiming atomoxetine as a composition of matter.⁹⁴ A patent issued from the application on August 19, 1997, with claims reciting methods of using atomoxetine to treat ADHD.⁹⁵

85. 731 F. Supp. 2d 348 (D.N.J. 2010).

86. U.S. Patent No. 4,314,081 (filed Jan. 10, 1974) (issued Feb. 2, 1982); *see also Actavis Elizabeth*, 731 F. Supp. 2d at 351 n.1.

87. Brief of Plaintiff-Appellant Eli Lilly and Company at 22, *Actavis Elizabeth*, 731 F. Supp. 2d 348 (No. 2010-1500), 2010 WL 3758723 [hereinafter Brief of Plaintiff-Appellant Eli Lilly and Company, *Actavis Elizabeth*].

88. *Id.* at 23.

89. *Id.* at 23-24.

90. *Id.* at 24.

91. *Id.* at 25.

92. *Id.* at 6-7.

93. *Id.* at 12.

94. *Id.* at 6-7.

95. *Id.* at 28.

This time, the clinical trials were successful, with Lilly receiving positive Phase II results by May 1995.⁹⁶ Finally, on November 26, 2002, the FDA approved atomoxetine, marketed under the trade name Strattera, as a safe and effective treatment for ADHD.⁹⁷ By this point, the composition of matter patent had expired, rendering the method of treatment patent critical if Lilly hoped to maintain marketing facility beyond that provided by the FDCA's five-year data exclusivity period.⁹⁸ Were it not for the expectation that this patent would be enforceable, Lilly might very well have decided not to invest in the expensive clinical trials necessary to secure marketing approval for Strattera.

But, as inevitably happens with any successful innovative drug, a host of generic companies soon began challenging Lilly's patent, seeking approval to enter the market with generic versions of Strattera prior to the expiration of Lilly's patent.⁹⁹ Lilly responded in 2007 by suing these companies, alleging that marketing the generic drugs would infringe its method of use patent.¹⁰⁰ On August 12, 2010, after a bench trial, the district court issued an order invalidating Lilly's claim for lack of utility.¹⁰¹ The court's decision hinged on the fact that, as filed, the patent application did not contain data demonstrating the utility of atomoxetine as a treatment for ADHD.¹⁰²

During the trial, Lilly argued that under well-established case law and long-standing PTO practice, a utility asserted in a patent application can be established by the submission of evidence generated after the filing date of the patent.¹⁰³ In this case, Lilly had compelling evidence of utility shortly after the application was filed, in the form of positive human clinical test results, which ultimately led to FDA approval of the drug.¹⁰⁴ The district court, however, was unconvinced, essentially holding that Lilly was required to generate the data prior to the filing date and to include that data in the patent specification as filed.¹⁰⁵

The court noted the paucity of controlling precedent in this area, finding "little guidance in the case law as to whether utility for a medical treatment can be established absent test data."¹⁰⁶ However, the court concluded that a recent Federal Circuit decision, *In re '318 Patent Infringement Litigation*,

96. *Id.* at 25.

97. *See id.* at 26.

98. *Id.* at 6-7.

99. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 352 (D.N.J. 2010).

100. *See id.* at 353.

101. *Id.* at 390.

102. *Id.* at 389-90.

103. Brief of Plaintiff-Appellant Eli Lilly and Company, *Actavis Elizabeth*, *supra* note 87, at 41.

104. *Id.* at 25-26.

105. *Actavis Elizabeth*, 731 F. Supp. 2d at 384-85.

106. *Id.* at 380.

was “legally and factually similar” to the Lilly case, and that it dictated that subsequently-generated data could not be used to confirm an asserted utility.¹⁰⁷

The court interpreted *In re '318 Patent* as requiring that, in order to satisfy the enablement/utility requirement of 35 U.S.C. § 112 with respect to a claim to a method of treatment, the patent application as filed must provide one of two things: test result data as evidence of the asserted utility or an indication that a person of skill in the art would have a reasonable expectation that the claimed method would work.¹⁰⁸ Based largely upon arguments made by Lilly to establish the nonobviousness of the invention, the court reasoned that one having skill in the art, after reading the patent application, would not have come away with a reasonable expectation that the claimed method would work.¹⁰⁹ The court ruled that Lilly could not use the clinical trial data to establish utility, because that data was generated after the application was filed, and thus was not included in the application as filed.¹¹⁰ Lilly apparently never submitted the data to the PTO, presumably because the office had not required the data in order to allow the patent to issue.

In retrospect, Lilly might have saved its patent by waiting to file its patent application after it had generated sufficient human clinical data to establish the drug’s efficacy. However, Lilly probably decided to file early out of fear that if it delayed filing, intervening prior art might create a bar to patentability.

For example, Lilly had to be concerned that the clinical trials might someday be construed as patent-invalidating “public use” of the claimed invention under 35 U.S.C. § 102(b). At the time, the status of human clinical trials under section 102(b) was unclear, and even today the answer is not entirely unambiguous. In 2004, for example, the Federal Circuit held that clinical trials did constitute a public use under section 102(b).¹¹¹ In 2005, on different facts, another panel of the Federal Circuit found that clinical trials did not constitute a public use.¹¹² But in 1995, when Lilly faced this decision, it had no way of knowing whether the clinical trials would later be construed as public use invalidating their patent.

Beyond the issue of clinical trials, by 1995 atomoxetine had been publicly disclosed for many years, and has been the subject of other clinical tri-

107. *Id.* at 385.

108. *Id.* at 389-90.

109. *Id.* at 386-90.

110. *Id.* at 389-90.

111. *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1320 (Fed. Cir. 2004), *vacated en banc on other grounds*, 403 F.3d 1328 (Fed. Cir. 2005), *and superseded by* 403 F.3d 1331 (Fed. Cir. 2005).

112. *Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc.*, 134 F. App’x 425, 431 (Fed. Cir. 2005); *see also* *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006) (holding that a clinical trial does not constitute a public use).

als.¹¹³ Lilly could have been legitimately concerned that other concurrent research, perhaps conducted by non-Lilly researchers, might be creating prior art that could defeat its ability to obtain a patent if it delayed filing for too long. Lilly chose to err on the side of early filing and disclosure and filed its application prior to receiving the clinical data confirming that atomoxetine did have the asserted efficacy in humans for the treatment of ADHD.¹¹⁴

Alternatively, one might suggest that Lilly should have at least generated *in vitro* or animal test data to substantiate the utility of atomoxetine for the treatment of ADHD and included that data in the application as filed. Under *In re Brana*, decided shortly after Lilly filed its patent application, such data can be used to establish patentable utility even in the absence of human data.¹¹⁵ While this route is available for many drugs, such as most anticancer or cardiovascular drugs, at the time there was no suitable cell-based or animal-based test to establish the utility of atomoxetine for the treatment of ADHD.¹¹⁶ Not surprisingly, Lilly did not perceive monitoring the attention span of mice as a useful proxy for ADHD activity in humans.¹¹⁷ Thus, owing to the nature of the condition they sought to treat, Lilly was in the difficult situation of either having to file its patent application without any data to substantiate the assertion in the patent specification that atomoxetine is useful in the treatment of ADHD or delay filing until after it obtained human trial data demonstrating the drug's efficacy, but in doing so potentially generating section 102(b) art that would preclude patentability.

During the trial, the generic drug companies argued that Lilly had essentially filed a patent application on mere speculation that atomoxetine might have ADHD activity.¹¹⁸ Clearly, allowing inventors to obtain an early filing date based on the mere disclosure of potential uses of a drug without any substantiating data raises legitimate policy concerns. But to be fair, Lilly did not file its patent application claiming the use of atomoxetine to treat ADHD until after it already had sought and obtained FDA approval to begin conducting clinical trials for that indication.¹¹⁹ Getting to this point required substantial investment; use for ADHD was more than just a mere throwaway idea put into a patent, as suggested by the generic companies.

Note the close similarity between *Actavis Elizabeth* and *Sun Pharmaceutical*. In both cases, a clear ambiguity existed in the law: in one case the ambiguity prompted Lilly to file too early¹²⁰ and in the other to disclose too

113. Brief of Plaintiff-Appellant Eli Lilly and Company, *Actavis Elizabeth*, *supra* note 87, at 24-25.

114. *Id.* at 2.

115. *In re Brana*, 51 F.3d 1560, 1563 (Fed. Cir. 1995).

116. Brief of Plaintiff-Appellant Eli Lilly and Company, *Actavis Elizabeth*, *supra* note 87, at 11.

117. *Id.* at 7.

118. *Id.* at 31.

119. *Id.* at 52.

120. *Id.* at 8.

much.¹²¹ In both cases, the decision to err on the side of disclosure and early filing resulted ultimately in the invalidation of a key patent, permitting early market entry by generic competitors and disrupting the company's investment backed expectations in their drugs.¹²²

V. THREE CATEGORIES OF UNPREDICTABILITY

This section discusses three distinct but often overlapping areas of unpredictability in patent law that can act as disincentives to investment in innovation, particularly in the pharmaceutical sector. The first, and perhaps most widely discussed form of unpredictability, is that created by the proliferation of ambiguous standards instead of bright line rules, a situation driven in large part by Congress and even more so in recent years by the Supreme Court. A second, and arguably more problematic, aspect of unpredictability is the often prolonged delay before the courts resolve important and readily identifiable ambiguities in patent law. The third form, and perhaps most problematic, is the unpredictability that occurs when the courts apply a new interpretation of patent law doctrine retrospectively and in a manner that undercuts the investment backed expectations of patent owners. Note that it is primarily uncertainty of the second and third types that negatively impacted Lilly in the two case studies reported above.

A. Loosely Defined Standards Instead of Bright Line Rules

A major source of unpredictability in U.S. patent law stems from its heavy reliance on vaguely defined standards rather than bright line rules. This aspect of patent jurisprudence mirrors the patent statute itself, which in many respects bears more resemblance to a constitution than a code, setting forth broad, aspirational parameters, and leaving the courts to flesh out the doctrinal contours.

The Supreme Court has also demonstrated a marked predilection for flexible standards amenable to subjective judicial interpretation. The plasticity of these standards allows the courts to exercise substantial judicial discretion and thereby arrive at the "correct" outcome on a case-by-case basis. In a dissent to the Federal Circuit's en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, Chief Judge Rader criticized the subjectivity and unbridled judicial discretion inherent in the vaguely defined standards of patentability.¹²³ Rader characterized the Lilly written description requirement as an amorphous "wildcard" with which a court can invalidate a claim deemed "unworthy" of patent protection without having to conduct the (at least rela-

121. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1386 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2445 (2011).

122. *See id.* at 1384, 1389.

123. 598 F.3d 1336, 1361 (Fed. Cir. 2010) (en banc) (Rader, J., dissenting).

tively) more rigorous analysis necessary to establish invalidity under more established doctrines of patentability, such as the enablement requirement.¹²⁴ Despite Judge Rader's disapproval, the majority's embrace of the Lilly written description suggests that many Federal Circuit judges are not averse to relying upon vaguely defined criteria of patentability to arrive at the "correct" outcome in cases such as *Ariad* in expedited fashion.

While Judge Rader is correct in his observation that the Federal Circuit has failed to articulate a coherent standard for compliance with the Lilly written description requirement, the situation regarding enablement is only marginally better. Federal Circuit case law clearly establishes that the specification must provide adequate teaching with respect to making and using at least one embodiment of the claimed invention, sufficient to enable one skilled in the art to make and use the invention without undue experimentation.¹²⁵ At the same time, it is equally clear that the specification need not literally enable every species falling within a genus claim in order for the genus claim as a whole to satisfy the enablement requirement.¹²⁶

Composition of matter patents claiming drug active ingredients are a good example. It is black letter law that the inventor of a new chemical active ingredient may claim it as a composition of matter and that the patent can cover formulations and methods of use not specifically enabled by the specification. For example, a claim broadly reciting a "pharmaceutical formulation comprising Substance X" would cover later-invented pharmaceutical formulations comprising Substance X that are unquestionably not specifically enabled by the specification and that were never even envisioned by the original inventor of Substance X, such as a new timed-release formulation, a new combination product, or a later discovered method of using the drug to treat an indication. Federal Circuit precedent establishes that the fact that the composition of matter claims covers these non-enabled embodiments does not necessarily invalidate the claim for lack of enablement.¹²⁷

At the same time, there is a point at which a claim can be rendered invalid for violation of the enablement requirement if it encompasses too many non-enabled embodiments. The test is whether the scope of disclosure is "commensurate with the scope of the claims," a vague and amorphous standard that allows the court to arrive at what it considers the correct outcome on

124. *Id.* at 1366.

125. *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

126. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997).

127. *See* Christopher M. Holman, *Protein Similarity Score: A Simplified Version of the BLAST Score as a Superior Alternative to Percent Identity for Claiming Genuses of Related Protein Sequences*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 55, 70 (2004).

a case-by-case basis.¹²⁸ Beyond this vaguely defined standard, the case law provides little prospective guidance regarding the relationship between subject matter disclosed in the patent specification and the scope of claim protection permitted under the enablement requirement. This undeveloped aspect of enablement precedent was recently pointed out by Judge Richard Linn in a concurrence to *Ariad*.¹²⁹

The Federal Circuit also has fostered unpredictability in its test for compliance with the definiteness requirement. The permissive “insolubly ambiguous” standard promulgated by the Federal Circuit allows for claims that are often nonetheless highly ambiguous in scope, to an extent which seems unnecessary and at odds with the important notice function of patent claims.¹³⁰ In a petition for certiorari recently filed in the case of *Applera Corp. v. Enzo Biochem Inc.*, the Supreme Court has been asked to intervene and impose a more exacting requirement of definiteness on patentees.¹³¹ The Court has invited the Solicitor General to file a brief in the case expressing the views of the U.S. government.¹³²

Claim construction is another area in which Federal Circuit precedent has introduced what many perceive to be excessive unpredictability, as evidenced by the high rate at which the Federal Circuit reverses district court claim construction rulings.¹³³ Many observers had hoped that the Federal Circuit would address this concern when it decided *Phillips v. AWH Corp.*¹³⁴ en banc, but the consensus appears to be that *Phillips* has not remedied the

128. See Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 149 & n.120 (2008); see also U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENTING EXAMINER PROCEDURE § 2164.08 (8th ed., 8th rev. July 2010) [hereinafter MPEP], available at <http://www.uspto.gov/web/offices/pac/mpep/index.html>; Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 15 (2007) [hereinafter Holman, *Paper Tiger*].

129. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1381 (Fed. Cir. 2009) (Linn, J., concurring) (opining that the appropriate doctrinal total for policing claim scope is enablement, not written description, and bemoaning the fact that the Court has “left unresolved” the question of to what extent the enablement requirement constrains the ability of an inventor to claim “known and unknown” embodiments of the invention), *vacated*, 595 F.3d 1329 (Fed. Cir. 2009), and *superseded en banc*, 598 F.3d 1336 (Fed. Cir. 2010).

130. See *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347-48 (Fed. Cir. 2005) (discussing the Federal Circuit’s insolubly ambiguous standard) (internal quotations omitted).

131. Petition for Writ of Certiorari at 18, *Applera Corp. v. Enzo Biochem, Inc.*, 131 S. Ct. 847 (2010) (No. 10-426), 2010 WL 3777219.

132. 131 S. Ct. 847 (2010) (mem.).

133. David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223, 266 (2008).

134. 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

situation.¹³⁵ For example, in *Phillips* the Federal Circuit considered, but ultimately rejected, an approach that would rely more heavily on dictionary definitions for interpreting claim terms.¹³⁶ This approach could have introduced more predictability into claim construction, albeit at the expense of flexibility for inventors to achieve adequate claim scope for their inventions. This tension between predictability and fairness runs through much of patent jurisprudence, and in many cases, unpredictability in the doctrines of patent law reflects a conscious decision to promote fairness to inventors at the expense of certainty and public notice.

While the Federal Circuit has fostered the use of vague standards in some aspects of patent law, a notable feature of recent Federal Circuit jurisprudence has been its repeated attempts to introduce greater predictability into patent law by creating relatively bright line rules. Equally notable, however, has been the Supreme Court's response, repeatedly rebuffing those efforts by overturning bright line rules in favor of more flexible standards.¹³⁷ While the Supreme Court's approach allows the courts more freedom to finess the doctrines of patent law in a manner that achieves the correct outcome on a case-by-case basis, it does so at the expense of predictability, making it more difficult for inventors, investors, and potential infringers to plan their courses of action. It also poses challenges for the PTO, which must interpret these standards in a manner that can be applied as consistently and efficiently as possible by its large corps of patent examiners.¹³⁸

An example of this divergence between the Federal Circuit and the Supreme Court can be seen in their approaches to the doctrine of equivalents. In 1997, the petitioner before the Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* sought to eliminate the doctrine of equivalents, arguing that this judge-made doctrine, used to expand the scope of patent claims beyond their literal boundaries, runs contrary to the notice function prescribed by the peripheral claiming system as embodied in the modern patent statute.¹³⁹ The Supreme Court, however, rejected this argument and unanimously upheld the continuing vitality of the doctrine.¹⁴⁰ While the doctrine of equivalents is laudable in some respects, and arguably an appropriate doctrinal tool for ensuring fairness to inventors, it necessarily interjects substantial unpredictability in attempts by potential infringers to assess their freedom to operate.

A few years later, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, the Federal Circuit en banc attempted to attenuate the unpredictability of

135. See Schwartz, *supra* note 133, at 266.

136. *Phillips*, 415 F.3d at 1322-23.

137. See, e.g., Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 82 (2010); Kelly Casey Mullally, *Legal (Un)Certainty, Legal Process, and Patent Law*, 43 LOY. L.A. L. REV. 1109, 1109-10 (2010).

138. Mullally, *supra* note 137, at 1126-28.

139. 520 U.S. 17, 36-37 (1997).

140. *Id.* at 40.

the doctrine of equivalents by imposing a “complete bar” to the availability of the doctrine in any instance where an amendment had narrowed the scope of the claim for a reason related to patentability.¹⁴¹ The court explicitly rejected the so-called “flexible bar” approach used in some earlier Federal Circuit decisions, under which a narrowing amendment created a rebuttable presumption that the doctrine of equivalents had been waived.¹⁴² In doing so, the Federal Circuit referred to the flexible bar approach as “unworkable,” because it could not “be relied upon to produce consistent results and [did not] give rise to a body of law that provides guidance to the marketplace on how to conduct its affairs.”¹⁴³ In contrast, the court praised the complete bar for lending “certainty to the process of determining the scope of protection afforded by a patent.”¹⁴⁴ In effect, *Festo* sought to address the unpredictability associated with the doctrine of equivalents by creating a bright line rule that rendered the doctrine inapplicable in the large percentage of cases in which a critical claim limitation had been amended during prosecution.

However, the Supreme Court overruled the Federal Circuit and essentially reinstated the flexible bar approach that the Federal Circuit majority had characterized as “unworkable.”¹⁴⁵ Thus, the Supreme Court again demonstrated its overriding preference for loosely defined standards amenable to judicial discretion over bright line rules.

Similarly, over the years the Federal Circuit and its predecessor court had established something approaching an irrebuttable presumption that a prevailing patent owner will be granted a permanent injunction in cases where patent infringement has been established.¹⁴⁶ Under this standard, an injunction was virtually mandatory unless a compelling public policy interest would be negatively impacted by the injunction, such as the precipitation of a public health crisis.¹⁴⁷

In *MercExchange, L.L.C. v. eBay, Inc.*, the Federal Circuit enforced this rule when it reversed a district court’s decision not to enter a permanent injunction against eBay after finding the company liable for patent infringement.¹⁴⁸ On appeal, however, the Supreme Court reversed, rejecting the Federal Circuit’s de facto rule requiring automatic injunction and replacing it with a four-part test to determine on a case-by-case basis whether an injunc-

141. 234 F.3d 558, 574 (Fed. Cir. 2000) (en banc), *vacated by* 535 U.S. 722 (2002).

142. *Id.* at 574-75; *id.* at 625 (Rader, J., concurring in part and dissenting in part).

143. *Id.* at 575 (majority opinion).

144. *Id.* at 577.

145. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741 (2002).

146. *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005), *vacated by* 547 U.S. 388 (2006).

147. *See id.*

148. *Id.* at 1339.

tion is appropriate.¹⁴⁹ The inquiry requires the court to balance equitable considerations relating to both the parties and the public at large before deciding whether or not to enter a permanent injunction.¹⁵⁰ Once again, the Supreme Court had rejected a relatively bright line rule created by the Federal Circuit in favor of a more flexible standard, thus permitting the court more discretion to consider the fact-specific equities of the case at hand.

In *MedImmune, Inc. v. Genentech, Inc.*, the Supreme Court reviewed the Federal Circuit's test for establishing standing to bring suit in a declaratory judgment action.¹⁵¹ Previously, the Federal Circuit had held that in order to satisfy the case-or-controversy requirement, the plaintiff in a declaratory judgment action must establish a "reasonable apprehension of imminent suit."¹⁵² This test provided another relatively bright line rule for patent owners to assess whether conduct or communications with a putative infringer might trigger standing in a declaratory action, potentially subjecting the patent owner to a preemptive patent challenge in an undesirable venue. However, in *MedImmune*, the Supreme Court rejected the "reasonable apprehension of imminent suit" test, replacing it with a more flexible and amorphous approach that considers whether "under all the circumstances . . . there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."¹⁵³

With respect to patent exhaustion, sometimes referred to as the first-sale doctrine,¹⁵⁴ the Federal Circuit had instituted rules that tended to limit the doctrine in a manner that promoted predictability.¹⁵⁵ First, it had held that the doctrine only applies to product claims, not method claims.¹⁵⁶ Second, the Federal Circuit appears, at least implicitly, to have adopted an approach under which the doctrine only applies if the patent actually claims the product that was sold under the authority of the patent owner.¹⁵⁷ In *Quanta Computer*,

149. *MercExchange, L.L.C. v. eBay Inc.*, 547 U.S. 388, 390 (2006).

150. *Id.* at 391.

151. 549 U.S. 118, 120-21 (2007).

152. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005), *abrogated by* *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (emphasis removed).

153. *MedImmune*, 549 U.S. at 127 (2007) (quoting *Md. Casualty Co. v. Pacific Coal and Oil, Co.*, 312 U.S. 270, 273 (1941)) (internal quotation marks omitted).

154. *LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1369 (Fed. Cir. 2006), *rev'd sub nom.* *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008).

155. *See id.* at 1369-70.

156. *See id.* at 1370.

157. *Id.* (although the Federal Circuit decided the case based on its rule that exhaustion does not apply to expressly conditional sale or license, throughout the opinion, the court repeatedly emphasizes that the "patents asserted by LGE do not cover the products licensed to or sold by Intel; they cover those products when combined with additional components," and that "[n]otably, [the] sale involved a component of

Inc. v. LG Electronics, Inc., the Supreme Court overruled the Federal Circuit on both points, holding that patent exhaustion is triggered by method claims as well as product claims and that patent exhaustion is triggered by the sale of any product that “substantially embodies [the] patent,” even if the claims do not actually cover the product.¹⁵⁸

In *Graham v. John Deere Co. of Kansas City*, the Supreme Court promulgated a vaguely defined standard for assessing obviousness that directs the court (or PTO) to determine “the level of ordinary skill in the pertinent art” and ascertain the “differences between the prior art and the [claimed invention]” and then to decide whether the claimed invention would have been obvious to one of skill in the art in view of the prior art.¹⁵⁹ The Court provided little practical guidance as to what it meant for an invention to be obvious. Later, the Federal Circuit began to employ a “teaching, suggestion, or motivation” (TSM) test in order to provide more uniformity and consistency to the obviousness question. Under the TSM test “a patent claim is only proved obvious if . . . the prior art, [the problem’s nature], or the knowledge of a person having ordinary skill in the art” reveals some motivation or suggestion to combine the prior art teachings.¹⁶⁰

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court chastised the Federal Circuit for promoting predictability and objectivity at the expense of flexibility and subjectivity.¹⁶¹ While the *KSR* Court acknowledged that the TSM test can often provide helpful insights relevant to the question of non-obviousness, it faulted the Federal Circuit for implementing the TSM as a “rigid and mandatory formula[] . . . incompatible with [Supreme Court] precedents.”¹⁶² The Court found that the Federal Circuit had erred by transforming a “general principle into a rigid rule that limits the obviousness inquiry,”¹⁶³ and replaced the relatively predictable TSM test with a more subjective and flexible standard of nonobviousness,¹⁶⁴ the consequence of which has been increased uncertainty for inventors and patent owners,¹⁶⁵ not to mention increased patent prosecution costs.¹⁶⁶

the asserted patent invention, *not* the entire patent system,” implying that patent exhaustion only occurs when the sale involves a product covered by the claims) (emphasis added).

158. 553 U.S. 617, 629-38 (2008).

159. 383 U.S. 1, 17-18 (1952).

160. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

161. *Id.* at 418-20.

162. *Id.* at 419.

163. *Id.*

164. *See id.* at 419-20 (discussing the rejection of the Federal Circuit’s TSM test).

165. Emer Simic, *The Tsm Test Is Dead! Long Live the Tsm Test! The Aftermath of KSR, What Was All the Fuss About?*, 37 AIPLA Q.J. 227, 253 (2009).

166. *See* D. Christopher Ohly, Trevor Joike, Kelly L. Morron, & Melvin Robinson, *It Is Not So Obvious: The Impact of KSR on Patent Prosecution, Licensing, and Litigation*, 36 AIPLA Q.J. 267, 307 (2008).

The latest bright line rule versus flexible standard conflict involved the patent eligibility doctrine. In a series of cases dating back to the 1970s and early 1980s the Supreme Court established that “fundamental principles” such as physical phenomena, abstract ideas, and principles of nature constitute patent ineligible subject matter.¹⁶⁷ However, the Court provided little guidance with respect to what it meant for a claim to “patent” a “fundamental principle.” As a practical matter, by the turn of the twenty-first century the doctrine had become largely irrelevant to the vast majority of patent practice.¹⁶⁸

However, when the Supreme Court reinvigorated the doctrine by granting certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*,¹⁶⁹ the Federal Circuit en banc took up the issue in *In re Bilski* and created a more bright line criterion for patent eligibility, which became known as the “machine or transformation” test (MORT).¹⁷⁰ In explaining its decision to institute MORT as the exclusive test for patent eligibility, the Federal Circuit pointed to the ambiguity of the Supreme Court’s patent eligibility precedent and the practical difficulty lower courts face in attempting to apply the abstract standard to actual claims directed toward modern technology.¹⁷¹ Clearly, in creating MORT, the Federal Circuit sought to provide the lower courts and the PTO with a more objective and administrable test for patent eligibility.

However, following the consistent pattern set forth above, the Supreme Court intervened, granted *Bilski*’s petition for certiorari and held that while MORT can be highly probative of patent eligibility, it is not the sole and definitive test for patent eligibility.¹⁷² Significantly, the Supreme Court did not provide any further elucidation as to the proper standard for assessing the patent eligibility of claims, offering little more than a conclusory statement that the standard for patent eligibility remained unchanged since the *Benson-Flook-Diehr* trilogy.¹⁷³ In short, the Supreme Court rejected the Federal Circuit’s attempt to impose some sort of objectivity and predictability on the patent eligibility analysis, and reverted back to the Court’s original, vaguely defined standard.

167. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (holding that “laws of nature, natural phenomena, and abstract ideas” are excluded from patent protection); *Parker v. Flook*, 437 U.S. 584, 589 (1978) (holding that abstract principles, natural phenomena and mental processes are not patentable); *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972) (holding that ideas are not patentable).

168. Christopher M. Holman, *Patent Eligibility as a Policy Lever to Regulate the Patenting of Personalized Medicine*, U. ILL. L. REV. (forthcoming 2012).

169. 546 U.S. 975 (2005) (mem.).

170. *In re Bilski (Bilski I)*, 545 F. 3d 943, 959 (Fed. Cir. 2008), *aff’d but criticized sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

171. *Id.* at 954.

172. *Bilski v. Kappos (Bilski II)*, 130 S. Ct. 3218, 3227 (2010).

173. *Id.* at 3229-30.

But the Supreme Court does not bear sole responsibility for the proliferation of loosely defined standards in patent law. In some cases, the Federal Circuit has taken one of its own relatively bright line rules and transformed it into a vaguely defined standard. One example involves the so-called Lilly written description requirement, a judge-made requirement of patentability that appeared in the 1990s and was first applied to invalidate a claim in *Regents of the University of California v. Eli Lilly & Co.*¹⁷⁴

In *Regents*, the Federal Circuit held that an “adequate written description of a DNA . . . ‘requires a precise definition, such as by structure, formula, chemical name, or physical properties.’”¹⁷⁵ This holding was generally interpreted as creating a bright line rule “forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences, [the effect of which] is to narrow the scope of biotechnology patents – or at least DNA patents – rather dramatically.”¹⁷⁶

As first set forth in *Regents*, the newly-minted Lilly written description (LWD) requirement appeared to require an inventor to provide in the specification an explicit structural definition of a DNA molecule in order to claim it. Leading commentators interpreted the decision as limiting the scope of DNA genus claims to DNA sequences specifically disclosed in the patent specification.¹⁷⁷ The decision was widely lambasted, including by other judges on the Federal Circuit, for its effect of severely limiting the ability of biotechnology inventors to obtain adequate patent protection for their inventions.¹⁷⁸ But the decision at least appeared to set forth a relatively bright line test for patentability, based on the disclosure of DNA sequence information, and it was consistent with the bright line rule of nonobviousness, which *In re Deuel* appeared to have established two years earlier.¹⁷⁹

174. 119 F.3d 1559, 1568 (Fed. Cir. 1997). Although this was the first instance in which the doctrine was used to invalidate an originally filed claim, this new form of the written description requirement traces its origin to earlier Federal Circuit decisions in *Amgen v. Chugai* and *Fiers v. Revel*. See Holman, *Paper Tiger*, *supra* note 128, at 67.

175. *Regents*, 119 F.3d at 1566.

176. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653-54 (2003) [hereinafter Burk & Lemley, *Policy Levers*]; see also Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 649 (1998) (“In practical terms, *Lilly* may profoundly limit the scope of protection available for new gene inventions.”); Daniel P. Chisholm, Note, *The Effect of the USPTO’s Written Description Guidelines on Gene Patent Applications*, 35 SUFFOLK U. L. REV. 543, 567 (2001) (concluding that “narrow patents for gene inventions,” as required by *Lilly*, could provide insufficient incentives and impede genetic research).

177. Holman, *Paper Tiger*, *supra* note 128, at 4.

178. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1313-14 (Fed. Cir. 2004).

179. See *infra* note 191 and accompanying text.

In the first Federal Circuit decision after *Regents* to apply the LWD, *Enzo Biochem, Inc. v. Gen-Probe Inc. (Enzo I)*, the panel applied this bright line interpretation of LWD to the DNA claims at issue in the case and invalidated them for failure to disclose the specific nucleotide sequence of the claimed DNA molecules.¹⁸⁰ While this was clearly the outcome dictated by a literal adherence to *Regents*, it also highlighted the profound problems with LWD as articulated in *Regents*.¹⁸¹

On further reflection, however, after apparently coming to recognize the negative policy implications for biotechnology if the LWD bright line rule were to be applied literally, the Federal Circuit vacated *Enzo I* and superseded it with a second decision, *Enzo II*.¹⁸² *Enzo II* reversed the district court's decision and held that LWD *does not* require a specific recitation of DNA structure, so long as the claimed DNA sequence has been deposited into a publicly accessible depository.¹⁸³ The *Enzo II* Court also held that a broad genus claim directed toward polynucleotides defined in solely functional terms could comply with LWD.¹⁸⁴ This interpretation of LWD is entirely inconsistent with the literal holding in *Regents*, to say nothing of the spirit of the decision.

Shortly after *Enzo II*, a commentator correctly pointed out that *Enzo I* was decided in a manner consistent with *Regents*, and that if *Enzo I* were wrongly decided (as implied by the courts decision to vacate and reverse the decision), then logically *Regents* must also have been decided incorrectly.¹⁸⁵ Unfortunately, instead of acknowledging the deep flaws in *Regents*, and LWD in general, the *Enzo II* panel and subsequent panels of the Federal Circuit continued to maintain that LWD remains a viable doctrine of patentability.¹⁸⁶ But while *Enzo II* established that compliance with LWD does not necessarily require a disclosure of chemical structure, the Federal Circuit has never articulated a coherent statement of what exactly is required, beyond a vaguely defined and amorphous test of "possession."¹⁸⁷ Importantly, the Federal Circuit has never adequately explained how the "possession" test for compliance with LWD is to be distinguished from the enablement standard.¹⁸⁸

180. *Enzo Biochem, Inc. v. Gen-Probe Inc. (Enzo I)*, 285 F.3d 1013, 1018 (Fed. Cir. 2002), *vacated*, 323 F.3d 956 (Fed. Cir. 2002).

181. Holman, *Paper Tiger*, *supra* note 128, at 23.

182. *Enzo Biochem, Inc. v. Gen-Probe Inc. (Enzo II)*, 323 F.3d 956, 960 (Fed. Cir. 2002).

183. *Id.* at 964-65.

184. *Id.* at 964, 967-68.

185. MARTIN J. ADELMAN, 2A-2Pt2C PAT. L. PERSPS. § 2.9 (2d ed. 2004).

186. *See Enzo II*, 323 F.3d at 960.

187. Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party at 1-2, *Ariad Pharms. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed. Cir. 2009) (No. 2008-1248), 2009 WL 3711551.

188. Holman, *Paper Tiger*, *supra* note 128, at 23-24.

In an amicus brief filed with the Federal Circuit in connection with *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, I explained in detail why the decisions of different panels of the Federal Circuit applying LWD are generally incoherent and inconsistent with one another – a consequence of the lack of any principled definition of what is necessary for compliance with the requirement.¹⁸⁹ In a dissent to the en banc *Ariad* decision, Judge Rader derided this ambiguity when he characterized LWD as a doctrinal “wildcard” by which courts are able to invalidate patent claims deemed “unworthy” of patent protection, without engaging in the analytical rigor required by other doctrines of patentability, such as enablement.¹⁹⁰ In short, Judge Rader correctly points out that the Federal Circuit has effectively transformed what appeared to be a bright line rule in the *Regents* decision into an amorphous expedient with which to dispose of unpopular claims.

In *In re Deuel*, the Federal Circuit established what appeared to be a bright line (and remarkably permissive) test for the nonobviousness of newly cloned naturally occurring DNA molecules.¹⁹¹ After the Supreme Court decided *KSR*, however, the Federal Circuit revisited the test for obviousness with respect to this pharmaceutically important class of invention in *In re Kubin*, and effectively discarded the bright line rule that practitioners generally assumed had been created by *Deuel*, in favor of a standard that is more in line with the general approach to obviousness, but also less predictable.¹⁹²

Another example can be seen in connection with the test for whether an offer for sale has occurred under 35 U.S.C. § 102(b). Prior to the creation of the Federal Circuit, other circuit courts had created a relatively bright line test; an offer for sale only constituted a 102(b) statutory bar if at the time of the offer the invention had been reduced to practice.¹⁹³ Later, the Federal Circuit replaced this rule with a more unpredictable “totality of the circumstances” test, which was in turn supplanted by the current “ready for patenting” standard set forth by the Supreme Court in *Pfaff v. Wells Electronics Inc.*¹⁹⁴ The Supreme Court’s recent decision in *Quanta Computer, Inc. v. LG Electronics, Inc.* introduced even more ambiguity into the test for whether the on-sale bar has been triggered.¹⁹⁵

189. Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party, *supra* note 187, at 18-19.

190. *Ariad Pharms. v. Eli Lilly & Co.*, 598 F.3d 1336, 1366 (Fed. Cir. 2010) (en banc) (Rader, J, dissenting).

191. 51 F.3d 1552, 1558-59 (Fed. Cir. 1995).

192. 561 F.3d 1351, 1358 (Fed. Cir. 2009).

193. *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 60 (1998) (collecting cases).

194. *Id.* at 66 & n.12.

195. Shubha Ghosh & Lucas Divine, *The Sale of Patented Methods: Reconciling On-Sale Bar & Patent Exhaustion Doctrines in Light of In re Kollar & Quanta v. LG*, 39 AIPLA Q.J. (forthcoming 2011).

B. Delayed Clarification of Longstanding and Critical Ambiguities in Patent Law

A number of well-defined and important ambiguities in patent law have remained unresolved for many years, creating uncertainty and unpredictability that can create disincentives for investment in innovation. Some examples of this phenomenon can be seen in the two case studies of *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.* and *Eli Lilly & Co. v. Actavis Elizabeth LLC*, presented above.¹⁹⁶ For example, for many years it was unclear the extent to which a patent applicant was required to update the disclosure of best mode in a pending patent application.¹⁹⁷ In particular, there was some concern that a patent applicant might be required to update the disclosure in a continuation patent application in cases where a best mode of practicing the invention is recognized during the time between the filing of the original priority application and the continuation.¹⁹⁸ In 1995, in *Transco Products Inc. v. Performance Contracting, Inc.*, the Federal Circuit finally addressed this question, holding that the best mode requirement only requires that the disclosure in the CIP application be updated with respect to newly added subject matter and that there is no obligation to update the best mode with respect to originally filed disclosure.¹⁹⁹

But in Case Study #1, we saw that the resolution of this fundamental and important question occurred ten years too late for Lilly, which likely contributed to the ill-fated decision to unnecessarily update the best mode in a continuation application, which twenty-five years later resulted in the invalidation of a key patent.²⁰⁰

Alternatively, Lilly's decision to introduce the disclosure of gemcitabine's anticancer activity in the composition of matter application might have been motivated, at least in part, by a concern that the originally disclosed antiviral activity would be deemed insufficient to establish patentable utility for the claimed compound (although the PTO later found the antiviral activity sufficient to satisfy the utility requirement). This implicates another longstanding and highly relevant ambiguity in the patent law, i.e., what constitutes an adequate disclosure of putative pharmaceutical activity to satisfy the utility requirement with respect to a claim reciting a novel chemical compound? This is a critical question facing the pharmaceutical industry, and in some cases could make the difference between whether or not a company decides

196. See *supra* Part IV.A-B.

197. See Roy E. Hofer & L. Ann Fitzgerald, *New Rules for Old Problems: Defining the Contours of the Best Mode Requirement in Patent Law*, 44 AM. U. L. REV. 2309, 2338-40 (1995) (discussing ambiguity in the best mode requirement).

198. *Id.*

199. 38 F.3d 551, 557-58 (Fed. Cir. 1994).

200. See *supra* notes 61-69 and accompanying text (discussing the invalidation of Lilly's Gemzar patent because of an update to best mode).

to invest in attempting to develop a promising candidate into a new drug. Companies need to know how high the utility bar is set in order to know the amount of data it must generate prior to patent filing. As noted in *In re Brana*, it is important that the patentable utility bar be set substantially lower than the safety and efficacy requirement for FDA marketing approval, lest pharmaceutical companies be forced to invest heavily in human clinical trials prior to receiving patent protection.²⁰¹ Pharmaceutical companies are generally loath to make such investments, for reasons that are apparent in view of the discussion in earlier sections of this article.²⁰²

Ambiguity as to the level of disclosure necessary to satisfy the utility requirement for a pharmaceutical method of treatment was at the heart of Lilly's failure to obtain adequate patent protection for its ADHD drug, *Strattera*.²⁰³ As noted in Case Study #2, as recently as 2010 the district court in that case could find "little guidance in the case law as to whether utility for a medical treatment can be established absent test data."²⁰⁴ The lack of guidance with respect to a critical consideration in the decision to develop a drug contributes to the uncertainty and unpredictability of which Mr. Armitage complained.

Another well-defined but unresolved ambiguity in patent law that has generated quite a bit of interest lately is the question of whether isolated naturally occurring molecules, particularly isolated forms of naturally occurring DNA, are patent-eligible under 35 U.S.C. § 101.²⁰⁵ For years, courts have on numerous occasions upheld the validity of these sorts of claims, including claims to isolated naturally occurring DNA molecules,²⁰⁶ but apparently no court has ever addressed the specific question of the patent eligibility of the claimed subject matter.²⁰⁷ Nevertheless, the claims have withstood validity challenges based on allegations of lack of novelty, nonobviousness, and lack of enablement, and the consensus has been that isolation of naturally occurring molecules renders them patentable subject matter.²⁰⁸ The PTO officially

201. 51 F.3d 1560, 1568 (Fed. Cir. 1995).

202. See *supra* Part II.

203. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 384-90 (D.N.J. 2010).

204. *Id.* at 380; see *supra* Part IV.B.

205. See, e.g., Courtenay Brinckerhoff, *Judge Dyk Doubts Patent Eligibility of DNA Claims*, PHARMAPATENTS BLOG (Aug. 12, 2010), <http://www.pharmapatentsblog.com/federal-circuit-decisions/judge-dyk-doubts-patenteligibility-of-dna-claims/>.

206. *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J. concurring in part and dissenting in part) (listing cases in which the Federal Circuit has upheld the validity of gene patents).

207. *Id.*

208. See Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 311 (2007); see also Christopher M. Holman, *Gene Patents Under Fire: Weighing the Costs and Benefits*, in BIOTECHNOLOGY AND SOFTWARE PATENT LAW: A

took this position with respect to isolated DNA molecules in a guidance document published in 2001, and for thirty years the PTO has issued many hundreds, if not thousands, of patents directed toward isolated naturally occurring DNA.²⁰⁹ After initial reluctance, Europe and much of the rest of the world has joined the United States in recognizing naturally occurring DNA molecules in isolated form as patentable subject matter.²¹⁰

Then, in 2008, the American Civil Liberties Union (ACLU) and Public Patent Foundation challenged the tacit understanding that isolated naturally occurring compounds, including isolated DNA, are patentable subject matter in *Association for Molecular Pathology v. United States Patent and Trademark Office*.²¹¹ Two years later, in a decision that surprised many, the district court held that claims to isolated DNA molecules corresponding in sequence to naturally occurring genetic sequences are patent ineligible.²¹² The decision implicates a host of so-called “gene patents,” a category of patent that has played a central role in incentivizing investment in biotechnology over the last thirty years.²¹³

For example, the core patent claim asserted by Amgen to protect its franchise in recombinant erythropoietin (to date the most commercially significant product of biotechnology) in cases such as *Amgen, Inc. v. Chugai Pharmaceutical Co.* was a claim reciting the isolated erythropoietin gene,²¹⁴ a claim that is clearly invalid under *Association for Molecular Pathology*.²¹⁵ If upheld on appeal, the decision could have significant negative ramifications for biotechnology companies seeking to protect their innovative products with patents, which would in turn reduce the incentive for future investment in innovation.

The long deferred resolution of the important question of whether isolated DNA molecules, and isolated natural products in general, are patent eligible subject matter engenders uncertainty and unpredictability for biotechnology. Substantial investment in biotechnology has been based on an assumption that issued patents of this sort are valid, which has been the position of

COMPARATIVE REVIEW ON NEW DEVELOPMENTS 3-4 (forthcoming 2011) [hereinafter Holman, *Gene Patents Under Fire*].

209. Utility Examination Guidelines Notice, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

210. Holman, *Gene Patents Under Fire*, *supra* note 208, at 4.

211. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

212. *Id.* at 185.

213. Christopher M. Holman, *Maintaining Incentives for Healthcare Innovation: A Response to the FTC's Report on Follow-On Biologics*, 11 MINN. J. L. SCI. & TECH. 755, 762-63 (2010) [hereinafter Holman, *Maintaining Incentives for Healthcare Innovation*].

214. 927 F.2d 1200, 1206 (Fed. Cir. 1991).

215. Holman, *Maintaining Incentives for Healthcare Innovation*, *supra* note 213, at 771-72.

the PTO, to which the courts have implicitly acquiesced.²¹⁶ If the Federal Circuit upholds this aspect of *Association for Molecular Pathology*, it sends a message to investors that their investment-backed expectations in presumptively valid issued patents can be undercut at any time by a court retroactively applying a newly discerned bar to patentability to invalidate the patent.²¹⁷ And bear in mind, with respect to the specific question of whether gene patents are patent eligible, it seems well within the realm of possibility that the Federal Circuit could dispose of *Association for Molecular Pathology* on other grounds, particularly lack of standing for the plaintiffs to bring suit, which would defer indefinitely resolution of this important ambiguity in patent law.

This sort of prolonged delay in the resolution of clearly definable ambiguities in patent law has been endemic for years. As one more example, consider the many years it took for the courts to clarify what constitutes prior art for purposes of finding a claimed invention obvious under 35 U.S.C. § 103. As enacted in 1952, section 103 provides that an invention is unpatentable if “the differences between the subject matter sought to be patented and the *prior art* are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”²¹⁸ However, Congress never defined what constitutes prior art under section 103, a critical inquiry that is normally a prerequisite to analyzing a claim for compliance with the statute.

Today, the courts have clarified that prior art under section 103 is defined by sections 102(a), 102(b), 102(e), 102(f), and 102(g). But it took many years for the courts to provide this important clarification.²¹⁹ Section 102(a) art has always been assumed to constitute prior art under section 103, but it was not until 1965 that the Supreme Court held in *Hazeltine Research, Inc. v. Brenner* that 102(e) prior art also can be used to render a claim obvious under section 103.²²⁰ The result in *Hazeltine* could not have been assumed prior to the Supreme Court clarifying the issue since a reasonable argument could be made that “secret” prior art, not available to the public, is not the type of prior art that should be available to declare a patent claim obvious.²²¹ Indeed, in both Europe and Japan disclosures appearing in earlier filed applications are

216. See *supra* note 206 and accompanying text.

217. Christopher M. Holman, *The ACLU Gene Patent Decision from an Investor's Perspective: A Black Eye for the US Patent System*, HOLMAN'S BIOTECH IP BLOG (Apr. 1, 2010, 9:01 AM), <http://holmansbiotechipblog.blogspot.com/2010/04/aclu-gene-patent-decision-from.html>.

218. 35 U.S.C. § 103(a) (2006) (emphasis added).

219. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 763-64 (3d ed. 2002).

220. 382 U.S. 252, 254-56 (1965).

221. Section 102(e) prior art is “secret” because it takes effect as of the filing date of the prior art patent application, but disclosure of the application does not become public until it is published or issues as a patent.

used for purposes of anticipation but not obviousness analysis, i.e. these jurisdictions have come to the opposite position as that of the *Hazeltine* court.²²²

It was not until 1973 that the Court of Customs and Patent Appeals (CCPA) held in *In re Bass* that 102(g) prior art also falls within the realm of section 103.²²³ Like the decision in *Hazeltine*, the outcome in *Bass* was not reasonably foreseeable and is arguably counterintuitive, because it treats work that is not in the “public domain” as if it were available to render an invention obvious.²²⁴ The holding in *Bass* “created the rather anomalous situation that firms investing in research could find their own research was being used against them.”²²⁵ The effect was to chill collaborative research within companies and amongst participants in joint research ventures, a concern addressed by Congress with the enactment of 35 U.S.C. § 103(c).²²⁶

Finally, it was not until 1997 that the Federal Circuit clarified that 102(f) art also qualifies under section 103 in *OddzOn Products, Inc. v. Just Toys, Inc.*²²⁷ In that decision, the court stated in dicta that section 102(b) prior art is also prior art under section 103.²²⁸ As noted by Merges and Duffy, however, although modern courts behave as if section 102(b) references qualify as prior art under section 103, the question has never been addressed squarely by the courts, and the subtleties of using 102(b) references in this manner has yet to be explored.²²⁹ Again, the use of 102(b) in the context of section 103 is also arguably counterintuitive since it “seems to conflict with the language of section 103.”²³⁰ A section 102(b) reference is prior art as of one year after the filing date, while section 103 states that the relevant time for considering the obviousness of an invention is “at the time the invention was made.”²³¹

C. New Interpretation of Legal Doctrine Applied Retrospectively

Arguably some of the most problematic incidents of unpredictability have arisen when courts create new legal doctrine or adopt new interpretations of existing doctrine, and then apply it retrospectively and in a manner that undercuts the rights of patent owners, resulting in the disruption of legit-

222. MERGES & DUFFY, *supra* note 219, at 766.

223. 474 F.2d 1276, 1286-87 (C.C.P.A. 1973), *superseded by statute*, 35 U.S.C. § 103 (1984), *as recognized in* *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997).

224. *See id.* at 1359.

225. MERGES & DUFFY, *supra* note 219, at 776.

226. *Id.*

227. 122 F.3d 1396, 1401 (Fed. Cir. 1997).

228. *Id.* at 1402.

229. *See* MERGES & DUFFY, *supra* note 219, at 792.

230. *Id.* at 791.

231. 35 U.S.C. § 103(a) (2006).

imate investment backed expectations. The Federal Circuit has engaged in this behavior repeatedly in recent years.

A particularly glaring example of this can be seen in the recent expansion of obviousness-type double patenting (OTDP) in *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, as discussed above in Case Study #1.²³² To better appreciate the extent to which *Sun Pharmaceutical* departs from established precedent, it is informative to consider the roots of the OTDP doctrine.

According to *Chisum on Patents*, the first Supreme Court decision to explicitly set forth this judge-made doctrine was *Miller v. Eagle Manufacturing Co.*, decided in 1894.²³³ In that case, the Court was responding to perceived loopholes in the patent statute that could be exploited by an inventor to obtain a second patent on an obvious variation of subject matter claimed in an earlier patent, resulting in an unwarranted de facto extension of the patent term beyond the statutorily prescribed period.²³⁴ In *Miller*, the later invalidated patent and the earlier patent claimed priority to the same originally filed application.²³⁵ The drawings in the two patents were identical and their specifications “substantially the same.”²³⁶ The Court took pains to point out that “it distinctly appears that every claim of the 1881 patent could have been properly included and made a part of the claims of the 1879 patent.”²³⁷

Not only could the inventor in *Miller* have claimed the subject matter of the later patent in the earlier patent, but the Court also surmised that “[i]f the two patents in question had been granted to different parties, it admits of no question that the last would have been held an infringement of the first.”²³⁸ The nineteenth century terminology used by the Court is arcane, but clearly what the Court was getting at was that if different inventive entities had filed for these patents, the statute would have prevented the issuance of two patents claiming obvious variations of the same subject matter. In other words, the Court saw OTDP as a judicial stopgap to address a loophole in the statute that would permit the issuance of two patents to a single inventive entity – patents that would not have both issued if different inventive entities had applied for them. This implies that the doctrine is unnecessary, and I would argue inappropriate, in cases where this sort of disparate treatment under the statute does not exist, a point I will get back to shortly.

After *Miller*, OTDP became an established doctrine of patent law, implicitly sanctioned by Congress in the legislative history of certain amend-

232. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010), cert. denied, 131 S. Ct. 2445 (2011); see *supra* Part IV.A.

233. 3A DONALD S. CHISUM, CHISUM ON PATENTS § 9.02[6] (MB 2011); see *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894).

234. *Miller*, 151 U.S. at 202-03.

235. *Id.* at 189.

236. *Id.* at 196.

237. *Id.* at 202.

238. *Id.* at 200.

ments to the statute.²³⁹ But in order to constrain this non-statutory restriction on the ability of inventors to claim their invention, the courts have imposed certain limitations on the doctrine. In particular, until recently black letter law has stated that the analysis for double patenting is concerned solely with a comparison between the *claims* of the two patents.²⁴⁰ As correctly noted in *Chisum on Patents*, “[d]ouble patenting is concerned with attempts to claim the same or related subject matter twice. Thus, the standard for comparison for the second patent is *what was claimed in the first patent, not what was disclosed in the specification of the first patent.*”²⁴¹ In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, decided in 1992, the Federal Circuit stated that its “precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims.”²⁴²

The restriction of the double patenting inquiry to the claims is what distinguishes it from the use of an earlier patent as section 102(e) prior art for purposes of finding an invention obvious under section 103. If the subject matter claimed in a second patent was invented by a different inventive entity, and the two patents are not commonly assigned or the product of a joint venture, then the entire disclosure of the earlier patent is normally available as section 102(e) prior art in assessing the obviousness of the later claim.²⁴³ But if the patents involve different inventive entities and are not commonly assigned, then the earlier patent specification is not available as 102(e) prior art for purposes of assessing obviousness.²⁴⁴ In effect, OTPD is a judicial end-run around the statute that makes the earlier patent available as pseudo-prior art, but with the critical caveat that only the claims of the earlier patent are to be considered, not the specification as a whole. If a court were to base its OTPD inquiry on the entire specification of the earlier patent, it would essentially be treating the earlier filed specification as section 102(e) prior art, in direct contravention of 35 U.S.C. § 103(c).²⁴⁵

The challenge in performing the analysis for OTPD has been that it is conceptually very difficult to determine the obviousness of a claimed invention based on a comparison with an earlier *claim*. Obviousness under section 103 involves comparison of a claim to specific, tangible embodiments described in the prior art.²⁴⁶ In contrast, as observed in 1970 by the predecessor to the Federal Circuit, “[a] claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and

239. See, e.g., H.R. REP. NO. 108-425, at 5 (2004) available at <http://judiciary.house.gov/legacy/108-425.pdf>.

240. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

241. 3A CHISUM, *supra* note 233, § 9.03[1][a] (emphasis added).

242. 972 F.2d 1272, 1281 (Fed. Cir. 1992).

243. 35 U.S.C. § 102(e) (2006).

244. See *id.*

245. See *id.* § 103(c).

246. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary?"²⁴⁷ More recently, the Federal Circuit made a similar observation, noting that "a claim often does not describe any particular thing but instead defines the boundary of patent protection, and it is difficult to try to determine what is [or is not an] obvious variation of a legal boundary."²⁴⁸

For this reason, the courts have permitted some limited reference to the patent disclosure in analyzing claims for OTPD. For example, in *In re Vogel*, the CCPA stated that "in certain instances [the patent disclosure] may be used as a dictionary to learn the meaning of terms in a claim."²⁴⁹ In *In re Braat*, the Federal Circuit allowed that

[i]n determining whether one claim is patentable in view of the subject matter of another *claim*, it is useful to compare the one claim with a tangible embodiment which is disclosed and which falls within the scope of the other claim. *The patent disclosure must not be used as prior art.*²⁵⁰

In the 2003 *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC* decision, the Federal Circuit invalidated a second patent claiming a method of using a chemical compound as a pharmaceutical, based on the disclosure of this method of use in an earlier co-owned patent.²⁵¹ Significantly, the first patent only claimed the chemical compound as a composition of matter – the claims made no reference to the later-claimed method of use.²⁵² The decision seems to contradict the prohibition against looking beyond the claims in assessing OTPD but can arguably be rationalized by the specific facts of the case. In *Geneva*, the earlier patent disclosed only a single use for the chemical compound, and the Federal Circuit presumed that this method of use was hence necessary to establish the patentable utility of the compound.²⁵³ The panel cited a 1942 CCPA decision for the proposition that, since the earlier patent depended critically upon the disclosure of the single utility, that utility could not constitute a separate invention, but rather is "an essential part of a single invention."²⁵⁴

Two years later, in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, a different panel of the Federal Circuit cited to *Geneva* when it invalidated a second patent claiming a pharmaceutical method of using a compound, again

247. *In re Vogel*, 422 F.2d 438, 442 (C.C.P.A. 1970).

248. *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991).

249. *Vogel*, 422 F.2d at 441.

250. *Braat*, 937 F.2d at 594 n.5 (emphasis added) (citing *In re Vogel* 422 F.2d at 442).

251. 349 F.3d 1373, 1375, 1386 (Fed. Cir. 2003).

252. *See id.* at 1380.

253. *See id.*

254. *Id.* at 1385 (citing *In re Christmann*, 128 F.2d 596, 660 (C.C.P.A. 1942)).

based on disclosure of that method in an earlier patent claiming the chemical compound as a composition of matter.²⁵⁵ The facts in *Pfizer* differed substantially from *Geneva*, in that the earlier patent specification disclosed multiple uses of the compound.²⁵⁶ Thus, the *Geneva* panel's justification for looking beyond the claims of the first patent would not appear to be present in *Pfizer*. That is, at least some of the claims in the second patent invalidated for OTDP only claimed a subset of the methods disclosed in the first patent and therefore were not necessary to establish the patentable utility of the chemical compound. In effect, *Pfizer* further widened the door opened by *Geneva* in allowing the court to look beyond the claims of the first patent in the OTDP inquiry.

Against this backdrop, in 2010 the Federal Circuit took up the issue of OTDP in *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*²⁵⁷ In *Sun Pharmaceutical*, the court treated *Geneva/Pfizer* as having established a bright line rule that any method of using a pharmaceutical compound claimed in a second patent is invalid for OTDP if that method of use was disclosed in an earlier patent claiming the compound as a composition of matter, *regardless of the circumstances under which that disclosure entered the specification.*²⁵⁸ It then proceeded to woodenly apply this newly created bright line rule to invalidate Lilly's patent, resulting in early market entry by generic competitors and a two-year reduction in market exclusivity.²⁵⁹

Sun Pharmaceutical is problematic on a number of levels. Not only is it a clear departure from what appeared to be established precedent prohibiting the use of the earlier patent specification as prior art, it ignores the policy considerations upon which this judicially created doctrine is premised. In a dissent from the decision not to rehear the case en banc, which was joined by Judge Rader (author of the *Geneva* opinion),²⁶⁰ four Federal Circuit judges argued vigorously that the facts in *Geneva* did not support treating *Geneva* as creating a bright line rule, as interpreted by the panel in *Sun Pharmaceutical*.²⁶¹

OTDP is best rationalized as a judicial exception to the statutory prohibition against using an earlier patent as 102(e)/103 prior art in cases where the patents share a common inventor or common ownership.²⁶² Under such circumstances, OTDP permits the earlier patent specification to be treated as

255. 518 F.3d 1353, 1367 & n.8 (Fed. Cir. 2008) (citing *Geneva Pharms.*, 349 F.3d at 1386).

256. *See id.* at 1367; *Geneva Pharms*, 349 F.3d at 1380.

257. 611 F.3d 1381 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 2445 (2011).

258. *Id.* at 1385.

259. *See id.* at 1389.

260. *Geneva Pharms*, 349 F.3d at 1375.

261. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 625 F.3d 719, 723 (Newman, J., dissenting) (denying petition for rehearing en banc).

262. 35 U.S.C. §§ 102(e), 103(c) (2006).

a form of quasi-prior art. Until recently, this use was limited to a consideration of the claims of the earlier patent.²⁶³

Congress has recognized this relationship between section 103 and OTDP. For example, when Congress extended the section 103(c) safe harbor to include not only commonly assigned patents, but also patents assigned to different entities involved in a joint research venture, it noted that OTDP should apply to patents assigned to companies involved in a joint research venture falling under 103(c).²⁶⁴ In other words, Congress saw OTDP as a stopgap to be applied in cases where, under the statute, an earlier patent specification cannot be treated as 102(e)/103 prior art, either because of common inventorship or because of the section 103(c) exemption.

In stark contrast, in *Sun Pharmaceutical*, the earlier patent disclosure was available as 102(e)/103 prior art with respect to the later patent. In a parallel litigation involving the same patents, a district court in Indiana held that the earlier composition of matter patent is 102(e) prior art, with an effective filing date predating that of the second patent, but only as to the disclosure in the application as originally filed.²⁶⁵ The Indiana court concluded that the later patent was not obvious in view of the earlier patent because the disclosure of anticancer activity did not enter the specification until the effective filing date of the second patent application.²⁶⁶ In other words, the second patent would have been valid if they had not been commonly owned, since OTDP would not have applied, and the second patent was not invalid under section 103. Thus, the decision in *Sun Pharmaceutical* turns the policy underlying OTDP on its head by finding a patent invalid solely because it shared common ownership with the earlier patent.

Perhaps the most troubling aspect of *Sun Pharmaceutical* is that it retroactively invalidated an issued patent based on a newly devised requirement of patentability. The fact that the doctrine itself is entirely judge-made compounds the problem, as no statutory basis exists upon which one might have predicted this doctrinal shift. A bright line rule preventing a later patent from claiming subject matter disclosed in an earlier patent might arguably be justified on policy grounds, so long as users of the patent system were given ample notice of the rule. If Lilly had been aware of the rule in the 1980s, it would not have added the disclosure of anticancer activity to the first patent application, and could have easily avoided this outcome.

Alternatively, even if Lilly had included disclosure in the earlier patent, prior knowledge of the rule would have put it on notice that it would not be able to rely on the additional two years of market exclusivity, which the se-

263. See *supra* note 242 and accompanying text.

264. H.R. REP. NO. 108-425, at 5-6 (2004) available at <http://judiciary.house.gov/legacy/108-425.pdf>.

265. *Eli Lilly & Co. v. Sicom Pharms. Inc.*, 705 F. Supp. 2d 971, 989, 991, 995-96 (S.D. Ind. 2010).

266. See *id.* at 1007.

cond patent seemed to offer. This information might have altered the calculus in the decision to invest in bringing the product to market since it would have reduced the predicted profits for the drug. Even if Lilly had decided to bring the drug to market for the treatment of some forms of cancer, it might have decided not to invest in the clinical research necessary to secure FDA approval for use of the drug in the treatment of other cancers. A reduction in the period of market exclusivity reduces the incentive for this sort of follow-on research.

The point is, prospective knowledge of patent invalidity would have been important information in making these sorts of important investment decisions. The problem with decisions like *Sun Pharmaceutical*, which retroactively and without adequate notice destroy investment backed expectations in an innovator's patent, is that the lesson for companies and investors is that they must discount the value of their patents based on the very real possibility that at some point in the future, perhaps many years after the decision is made to invest in developing a drug, the patent might be invalidated based on a court's belated discernment of new legal doctrine.

Sun Pharmaceutical is by no means unique in this regard. Another recent example of the Federal Circuit creating a new interpretation of judge-made law and applying it retroactively to the detriment of patent owners can be seen with respect to the doctrine of equivalents and prosecution history estoppel. Like OTDP, the doctrine of equivalents is judge-made law, having no statutory basis. Nonetheless, the doctrine is well-established by numerous Supreme Court decisions dating back to the mid-nineteenth century.²⁶⁷ Patent owners have come to rely on the availability of the doctrine to supplement inadvertent deficiencies in claim drafting that only become apparent after the patent has issued. In 2002, the availability of the doctrine for patent owners seemed beyond question, in view of the Supreme Court's 1997 *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* decision rebuking the petitioner's attempt to eradicate the doctrine from patent law.²⁶⁸

But against this backdrop, an en banc Federal Circuit in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* created a new "complete bar" approach to prosecution history estoppel that would have precluded the availability of the doctrine of equivalents for any claim element that had been the subject of amendment during patent prosecution.²⁶⁹ This rule would have been quite detrimental for many patent owners since it is common for claims to be amended during patent prosecution,²⁷⁰ the practice is completely legiti-

267. See, e.g., *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

268. 520 U.S. 17, 21 (1997).

269. 234 F.3d 558, 569 (Fed. Cir. 2000) (en banc), *vacated*, 535 U.S. 722 (2002).

270. Kenneth D. Bassinger, *Allocating Linguistic Uncertainty in Patent Claims: The Proper Role of Prosecution History Estoppel*, 49 LOY. L. REV. 339, 387 n.249 (2003).

mate, and is in fact encouraged by the PTO.²⁷¹ The complete bar approach set forth in *Festo* would have had the effect of entirely precluding the availability of the doctrine of equivalents for many of the most important claim elements in a huge number of issued patents.

Particularly problematic was the fact that, at the time these claims were amended, patent applicants had no warning that their decision to amend their claims would result in a forfeiture of their rights under the doctrine of equivalents. If that notice had been provided, they would have had the option of avoiding claim amendment by appealing rejections or by filing continuation applications. They also could have drafted their claims differently at the outset in order to reduce the likelihood that claim amendment would even be necessary, thereby avoiding the deleterious effects of the *Festo* complete bar. *Festo* created a bright line rule but disregarded the consequential devaluation, without notice, of a host of issued patents, many of which were the basis for substantial investment.

Although a majority of the en banc Federal Circuit apparently did not recognize the problem of retroactivity, the Supreme Court certainly did, chastising the Federal Circuit for “destroying the legitimate expectations of inventors in their property.”²⁷² In overruling the Federal Circuit’s en banc *Festo* decision, the Supreme Court correctly observed that decisions in patent prosecution (such as the decision to amend the claim during prosecution) are made based on case law as it is understood at the time and that any subsequent change in the law applied retrospectively can unfairly disrupt the settled expectations of the inventing community.²⁷³ Not only do such changes undercut the incentive for future investment in innovation, but they “could very well subvert the various balances the PTO sought to strike when issuing the . . . patents.”²⁷⁴

The LWD is another relevant example of a newly discerned doctrine of patentability that was created by the Federal Circuit and has been applied retroactively in a manner that undercuts the expectations of patent owners. Although LWD has been around for many years, prior to 1997 it was used solely to police against the claiming of “new matter,” and hence was not applicable to originally filed patent claims.²⁷⁵ However, in *Regents of the University of California v. Eli Lilly & Co.*, the Federal Circuit created a new form of the written description requirement, applicable to originally filed claims. The court used it to invalidate important claims directed to the gene encoding human insulin, claims that appear to satisfy the other previously established

271. See, e.g., MPEP, *supra* note 128, § 2106 (“USPTO personnel should encourage the applicant to amend the claim to better reflect what applicant intends to claim as the invention.”).

272. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

273. *Id.*

274. *Id.*

275. Holman, *Paper Tiger*, *supra* note 128, at 4.

requirements of patentability.²⁷⁶ In particular, Lilly had never raised the issue of enablement in the district court or at the Federal Circuit, and it is generally assumed that the disclosure in the specification (i.e., the sequence for rat insulin cDNA, the protein sequence for human insulin, and a description of the methodology for isolating and sequencing human cDNA) provided adequate enablement of the claim to human insulin cDNA found invalid under this new interpretation of the written description requirement.

Since 1997, LWD has been applied retrospectively to invalidate other patent claims, primarily in the biopharmaceutical area.²⁷⁷ Because of its retroactive effect, the doctrine is impacting patents issued prior to *Regents*, and patents arising out of applications filed prior to the decision, wherein the disclosure and claims were drafted based on the assumption that the requirements of patentability were limited to the traditional, statutory-based doctrines of patentability such as enablement and nonobviousness.

VI. THE PROBLEM OF UNCERTAINTY MIGHT BE AMELIORATED BY GREATER INVOLVEMENT OF CONGRESS AND THE PTO

A certain degree of unpredictability in patent law is inevitable, and perhaps even desirable.²⁷⁸ In any event, there is a necessary trade-off between predictability and fairness, and overly rigid rules can be unfair not only to inventors, as exemplified by the wooden application of a bright line rule in *Sun Pharmaceutical*, but also to potential infringers and the public at large.²⁷⁹ It is difficult to anticipate ex ante all of the complex factual scenarios that can arise in the course of innovation and commercialization, and the Supreme Court and Congress have historically shown a marked preference for flexible standards that allow the courts sufficient discretion to arrive at the “correct” outcome on a case-by-case basis, at the expense of more bright line rules that favor predictability. In the majority of cases, it seems to me that the courts make appropriate use of this discretion.

Much more problematic is the unpredictability that arises out of the two other sources discussed above: delayed resolution of important and definable ambiguities in the law and retroactive applications of new interpretations of the law. This unpredictability, in contrast with the unpredictability inherent in the use of flexible standards, does not have any compensating positive attributes. In a better patent system, important questions of patent law, such as whether or not section 102(g) prior art can be used to render an invention

276. *Id.*

277. Brief of Amicus Curiae Law Professor Christopher M. Holman in Support of Neither Party, *supra* note 187, at 2.

278. See generally Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691 (2004) [hereinafter Burk & Lemley, *Biotechnology's Uncertainty Principle*].

279. See *supra* note 259 and accompanying text.

obvious under section 103, if the best mode must be updated in a continuing application, whether isolated biomolecules are patent eligible, or the quantum of data necessary to establish patentable utility for chemical compound, would all be answered sooner rather than later. And when patent law evolves, or new doctrines are developed, in many cases it would be better to only apply the change prospectively, in a manner that permits change but at the same time protects the investment backed expectations of patent owners.

Much of the problematic uncertainty in patent law stems from the fact that the courts, primarily the Federal Circuit, have taken on the leading role in creating U.S. patent law.²⁸⁰ While the courts are well-suited to creating standards and applying them fairly on a case-by-case basis in a manner that furthers public policy, they are often ill-equipped to resolve important questions in a timely manner, and by their nature changes in the law that originate in the courts are applied retroactively to patents prosecuted and issued prior to the change in law.²⁸¹ After all, courts can only address legal questions that are presented to them and are generally not permitted to issue advisory opinions.

Consider the ACLU's challenge to gene patents in *Association for Molecular Pathology v. United States Patent & Trademark Office*.²⁸² Without getting into the merits of the case, let us for the moment consider the possibility that, as a matter of policy, society would be better off if isolated genomic DNA sequences were ineligible for patent protection. The U.S. government took this position in its amicus brief filed with the Federal Circuit in connection with this case, and a sizable segment of the general population appears to share this view.²⁸³ Gene patents have played a critical role in incentivizing investment that launched the biotechnology industry, but perhaps the crucial need for these patents has passed, and moving forward their perceived negative impact on genetic testing and research might outweigh their utility.

The problem with the ACLU's court-based approach to the perceived problem of gene patents is that, if successful, it threatens to retroactively invalidate potentially thousands of issued patents, or at least to raise significant question as to the validity of these patents, which in turn creates serious harm

280. Ryan Vacca, *Acting Like an Administrative Agency: The Federal Circuit En Banc*, 76 MO. L. REV. 733, 734 (2011).

281. In some cases, courts do attempt to ameliorate the unfairness of retroactive application of new legal doctrine to the extent possible in the litigation context. See, e.g., *Bridgeport Music, Inc. v. Dimension Films*, 410 F.3d 792, 804-05 (6th Cir. 2005) (“[W]e realize we are announcing a new rule and because it is new, it should not play any role in the assessment of concepts such as ‘willful’ or ‘intentional’ in cases that are currently before the courts or had their genesis before this decision was announced.”).

282. 702 F. Supp. 2d 181, 183 (S.D.N.Y. 2010).

283. See Brief of the United States as Amicus Curiae in Support of Neither Party, at 27-37, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 2010-1406), 2010 WL 4853320.

for the legitimate expectations of those who have invested based on the expectation that these patents are valid. Some of these patents have no doubt already played a critical role in incentivizing important investment in biotechnology innovation. The unfairness of this outcome is compounded by the fact that, years ago, the PTO issued guidelines explicitly finding isolated DNA to be patent eligible.²⁸⁴

In effect, society is caught in a Catch-22 if it must rely solely on the courts to sort out the question of patent eligibility for isolated gene sequences. If the court declares this well populated class of patents invalid, it has undercut the expectations of patent owners and their investors. On the other hand, a balancing of policy considerations might counsel for the elimination of this sort of patent claim. The way to manage these important competing policy concerns would be to declare such subject matter patent ineligible, but only on a prospective basis. Unfortunately, the courts are not structurally positioned to modify the law in this way.

Furthermore, one could easily make the case that the judicial system is not the best institution to weigh the complex issues of science and technology policy that would lead to the optimal outcome in addressing tough questions of this sort. By its nature, litigation is primarily intended to resolve disputes between parties, and litigants generally approach the issue accordingly. For example, the task of Myriad's lawyers is to protect the interests of Myriad, not to assist the court in weighing the broader policy implications of a ban on the patenting of isolated biomolecules.²⁸⁵ In other contexts, such as the regulation of drugs and medical devices, the courts have recognized the heightened institutional competency of Congress and administrative agencies like FDA to weigh competing, technically complex policy concerns.²⁸⁶ Similar logic applies to administrative agencies like the PTO, which also has a greater institutional capacity to solicit input from shareholders and to balance competing policy considerations.

A. *An Expanded Role for Congress*

Now consider how Congress might address the perceived problem of gene patents. Instead of relying on litigation-driven arguments by lawyers representing a small genetic diagnostic testing company and a group of plaintiffs recruited by the ACLU to provide standing in a declaratory judgment action, Congress could have solicited broad input from numerous stakeholders who might be impacted by a decision to declare isolated DNA sequences

284. Utility Examination Guidelines Notice, 66 Fed. Reg. 1092 (Jan. 5, 2001).

285. Myriad is the primary defendant in *Association for Molecular Pathology v. United States Patent & Trademark Office*, discussed above. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 181.

286. Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2147 (2000).

(and by implication isolated naturally occurring products in general) patent ineligible subject matter. Then, if after weighing the policy considerations Congress decided to enact legislation barring “gene patents,” it could have done so in a manner that would only apply prospectively, thereby protecting the investment backed interest of the current owners of these patents.

In fact, in 2007, a bill was introduced in Congress that would have banned the patenting of many DNA-based inventions: HR 977, the Genomic Research and Accessibility Act.²⁸⁷ It seems reasonable to assume that Congress received substantial input from stakeholders, who would have explained the substantial negative unintended consequences likely to flow from such a ban on patenting DNA. Wisely, Congress never acted on the legislation. But note that at least HR 977 explicitly provided that its effect would only be applied prospectively to patents issued after enactment of the bill.²⁸⁸ This illustrates a compelling advantage of implementing changes to the patent law by statute rather than patent litigation: Congress’s ability to alter course prospectively without unduly harming the interests of current patent owners.

Frequently, statutory changes in the patent law are only applied prospectively. For example, when Congress amended the patent statute to require publication of some pending applications, the requirement applied only to applications filed after the change had been enacted.²⁸⁹ The same was the case when the patent term was changed from seventeen years from date of issuance to twenty years from date of filing.²⁹⁰

Congress has also applied statutes prospectively in order to protect the interests of parties other than patent owners, such as third parties that have been charged with infringement. For example, when Congress enacted the Cooperative Research and Technology Enhancement Act (CREATE) to expand the statutory safe harbor of 35 U.S.C. § 103(c) to include not only commonly assigned patents but also patents assigned to parties in a joint research venture, it specified that the safe harbor would not apply to patents already in litigation.²⁹¹

Another example of Congress ensuring that the expectations of third party potential infringers are respected can be seen in 35 U.S.C. § 252, which permits a patent owner to seek reissue of a patent.²⁹² Importantly, in order to

287. H.R. 977, 110th Cong. § 2 (2007).

288. H.R. 977.

289. District of Columbia Appropriations Act, 1999, Pub. L. No. 106-113, § 4508, 113 Stat. 1501, 1501A-567 (1999) *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ113.106 (last visited Aug. 10, 2011).

290. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4983 (1994) (codified as amended at 35 U.S.C. § 154 (2006)).

291. H.R. REP. NO. 108-425, at 2 (2004).

292. 35 U.S.C. § 252 (2006).

protect the interests of third parties, broadening patent claims are only allowed during the first two years.²⁹³ 35 U.S.C. § 252 also

gives a federal district court the discretion, to the extent that the court deems *necessary to protect business investments made before the reissue*, to permit the third party to *continue* to manufacture more of “the thing” made before the grant of the reissue (which “thing” did not infringe the original patent but now infringes the reissue), or to continue the manufacture of that which the patentee made “substantial preparation” to manufacture before the grant of the reissue.²⁹⁴

In general, Congress’s response to perceived problems in the patent system can be more measured and appropriate than changes to patent law arising out of litigation. Illustrative of this principle is the amendment to the patent statute in 1996 to address a concern that doctors might be in danger of being sued for infringing a patent in the course of performing a medical procedure. This fear was precipitated by an anomalous lawsuit filed in 1993 by one surgeon against another based on an allegation of infringement of a patent claiming a method of performing cataract surgery.²⁹⁵ The litigation ended in 1996 when the parties stipulated to the patent’s invalidity due to prior art uses of the claimed technique.²⁹⁶ “Nevertheless, the litigation caused a shudder in the medical community if only because it called attention to the PTO’s practice of allowing surgical patents.”²⁹⁷ In response to these concerns, a well-meaning public interest group such as the ACLU could have filed a declaratory judgment action against a doctor owning a medical procedure patent and sought a ruling declaring medical procedures patent ineligible. Alternatively, Congress could have addressed the issue by banning medical procedure patents.²⁹⁸

But Congress took a more measured and targeted approach to addressing the perceived problem by enacting 35 U.S.C. § 287(c) in 1996.²⁹⁹ This

293. *Id.* § 251.

294. JANICE MUELLER, PATENT LAW 310 (3d ed. 2009) (emphasis added) (footnote omitted).

295. *Pallin v. Singer*, 36 U.S.P.Q.2d 1050, 1051 (D.Vt. 1995).

296. *Pallin v. Singer*, Civ. A. No. 2:93-CV-202, 1996 WL 274407, at *1 (D.Vt. Mar. 28, 1996).

297. MERGES & DUFFY, *supra* note 219, at 182 & n.4 (noting that “while the *Pallin v. Singer* litigation was pending, a number of articles in the popular press fueled a steady interest in medical procedure patents”).

298. In fact, Europe has taken this approach, excluding medical procedures from patentability. The European Patent Convention, 14th ed. art. 53(c), Oct. 5, 1973, 1065 U.N.T.S. 254 available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar53.html>.

299. MERGES & DUFFY, *supra* note 219, at 183-84.

amendment to the statute did not ban the patenting of medical procedures, nor did it decree that it is not infringement for a doctor to perform a patented medical procedure.³⁰⁰ Instead, it eliminated the availability of remedies against medical practitioners and related healthcare entities for acts of patent infringement occurring during the performance of the medical activity.³⁰¹ Congress protected the investment backed expectations of current patent owners by including a provision that the “subsection shall not apply to any patent issued based on an application the earliest effective filing date of which is prior to [enactment of the statute].”³⁰²

The approach embodied in section 287(c) is preferable both to an outright ban on the patenting of medical procedures and to the alternative approach of exempting doctors from infringement. Patents on medical procedures are often important for companies that invest in the development of innovative new medical devices. In many cases a competing company would not infringe the method patent because it does not perform the surgery. Surgeons are the direct infringers, and their direct infringement is critical if the innovator company hopes to successfully sue a competitor under a theory of indirect infringement. If these patents were not available, or if Congress declared by statute that a doctor’s use of these patents does not constitute infringement, then this could have negatively impacted the ability of these innovators to obtain adequate patent protection for their products. 35 U.S.C. § 287(c) addresses the concern that doctors might be sued for patent infringement since, with no remedies available to the patent owner, there would be no reason for a doctor to fear being sued, but without unduly impacting the ability of innovators to protect their products.

B. Implementing Change at the PTO

The PTO could also play a role in promoting faster resolution of ambiguities in the patent laws and in amending the law in a prospective manner that respects the expectation interests of patent applicants and owners. Like Congress, the PTO is in a better position than the courts to solicit and balance the concerns of all stakeholders, through practices such as notice and comment rulemaking. It also has the ability to bring test cases to the courts, facilitating expedited resolution of ambiguities in the law. Importantly, the PTO generally institutes changes in a prospective manner, avoiding the problems associated with the retroactive application of new law.

Take, for example, *Diamond v. Chakrabarty*.³⁰³ The emergence of biotechnology in the 1970s brought to light a clear and important ambiguity in the law: to what extent are the products of biotechnology, particularly genet-

300. See 35 U.S.C. § 287(c) (2006).

301. *Id.*

302. *Id.* § 287(c)(4).

303. 447 U.S. 303 (1980).

ically modified living organisms, eligible for patent protection? The PTO could have simply assumed that genetically modified living organisms are patent eligible and begun issuing patents, analogous to the manner in which it handled the patenting of genetic sequences.³⁰⁴ Instead, the PTO decided to err on the side of patent ineligibility and to reject claims to living organisms, thus setting up the important test case of *Diamond v. Chakrabarty*. By cleanly setting the issue before the courts, the PTO provided clarity on this important issue, to which many people have attributed the investment in biotechnology that occurred after *Chakrabarty*.³⁰⁵ The PTO took a similar tack with respect to software patents, initially rejecting them until the Supreme Court stepped in and provided some clarity with respect to the patentability of software in *Benson, Flook, and Diehr*.³⁰⁶

In the 1980s and early 1990s, the PTO saw an influx of patent applications claiming newly cloned and sequenced cDNA molecules.³⁰⁷ These discoveries were often based on prior art knowledge of a protein of interest, knowledge used to isolate and characterize the cDNA encoding the protein.³⁰⁸ As the methodology became more routine, the question arose as to whether the resulting cDNA molecules were obvious and hence unpatentable. Once again, the PTO erred on the side of non-patentability and began rejecting such claims under 35 U.S.C. § 103, thereby prompting early judicial resolution of the issue.³⁰⁹

As a result, in *In re Deuel* the Federal Circuit established what was generally assumed to be a very low obviousness bar for DNA inventions.³¹⁰ The holding in *Deuel* was somewhat ambiguous, but by and large, patent practitioners and the PTO interpreted it as establishing that a cDNA molecule is not obvious unless the prior art discloses the DNA sequence or a substantially similar sequence.³¹¹ Significantly, under the dominant interpretation of the case, prior art knowledge of a protein was deemed insufficient to render the corresponding cDNA obvious, no matter how well-established the methodology for using a protein to isolate the corresponding cDNA.³¹² Of course, as noted above, the Federal Circuit recently in *In re Kubin* appears to have implicitly overruled this interpretation, essentially limiting that decision to its facts. Nonetheless, the example illustrates the potential for the PTO to pro-

304. See *supra* notes 212-13 and accompanying text.

305. Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. L. 318, 342-47 (2006).

306. See *supra* text accompanying notes 167-68.

307. See, e.g., *In re Deuel*, 51 F.3d 1552, 1553-54 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781, 782 (Fed. Cir. 1993).

308. *Deuel*, 51 F.3d at 1557; *Bell*, 991 F.2d at 781.

309. *Deuel*, 51 F.3d at 1559; *Bell*, 991 F.2d at 782.

310. See *Deuel*, 51 F.3d at 1559-60 (Fed. Cir. 1995).

311. See Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 278, at 704; Burk & Lemley, *Policy Levers*, *supra* note 186, at 1678-79.

312. *Deuel*, 51 F.3d at 1558.

mote early judicial review of important questions of patentability by implementing a policy of “when in doubt, reject.”

Another example can be seen with respect to expressed sequence tag (EST) sequences. The PTO implemented utility guidelines and began rejecting claims to EST sequences for which the patent specification failed to identify any “specific, substantial, and credible” utility.³¹³ This policy was challenged in *In re Fisher*, a decision in which the Federal Circuit sided with the PTO and backed its interpretation of the utility requirement, as applied to this important category of putatively patentable subject matter.³¹⁴ Again, the PTO facilitated early resolution of this issue in the courts.

The PTO also has some limited ability to affect change in the patent laws by issuing rules and guidelines, as stakeholders are allowed input through the mechanism of notice and comment. Importantly, the PTO can and does implement these changes prospectively, thereby avoiding the unfairness of retroactive application of the laws.

For example, in 2009 the PTO attempted to address what it perceived to be an abuse of continuation practice by instituting its now infamous “continuation rules.”³¹⁵ These rules were flawed in many respects, and stakeholders wasted little time before challenging their legitimacy in district court.³¹⁶ The district court struck down the rules, holding that they were substantive and thus exceeded the scope of the PTO’s rulemaking authority.³¹⁷ In response to this negative ruling in the courts, as well as the strong backlash from the patent community, the PTO rescinded the rules.³¹⁸

Although the substance of the continuation rules was problematic, there is still something to commend the use of PTO rulemaking to accomplish changes in patent law. For example, at least the continuation rules took into account the problem of retroactivity, by specifying that some of the rule changes would not be made applicable to certain patent applications filed prior to enactment of the rules.³¹⁹ When first proposed, the rules were open to public comment, which the PTO considered, at least facially.³²⁰ Further-

313. Utility Examination Guidelines Notice, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).

314. 421 F.3d 1365, 1370-71 (Fed. Cir. 2005).

315. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716-843 (Aug. 21, 2007) (codified at 37 C.F.R.).

316. *See, e.g.*, *Tafas v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) (dismissing appeal of the district court decision as moot given that the PTO had rescinded the challenge to continuation rules), *vacated in part sub nom. Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *vacated by* 328 F. App’x 658 (Fed. Cir. 2009) (per curiam).

317. *Id.*

318. *See Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009).

319. Changes to Practice for Continued Examination Filings, 72 Fed. Reg. at 46716-17.

320. *Id.* at 46717.

more, the availability of judicial review allowed stakeholders the opportunity to compel the PTO to rescind the rules in a relatively expedited manner.

A major stumbling block to the PTO taking a more active role in the evolution of patent law is that the patent statute limits the PTO's rulemaking authority to matters of procedure.³²¹ An earlier version of patent reform legislation would have provided the PTO with substantive rulemaking authority.³²² After the continuation rules fiasco, many pointed to it as evidence that the PTO is not to be trusted with such authority, and the current patent reform legislation does not include any such provisions.³²³

However, one must bear in mind that, in its continuation rules, the PTO appears to have been attempting to address the very real policy concerns associated with "late claiming," i.e., the practice of adding claims directed to previously unclaimed subject matter years after the effective filing date of a patent application.³²⁴ Knowing that it lacked statutory authority to make substantive changes in the patent laws, I suspect that the PTO issued the continuation rules in an attempt to rein in "late claiming" under the guise of a procedural change to continuation practice.³²⁵ The resulting rules were highly flawed, but perhaps if the PTO had the authority to implement statutory change, it could have addressed the matter head-on, and more competently. Furthermore, if Congress were to give the PTO the statutory authority for substantive rulemaking, the PTO might very well evolve the institutional competency to better tackle its important new role.

VII. CONCLUSION

One cannot lay the blame for decreasing investment in pharmaceutical R&D entirely on the doorstep of the patent system. For example, the closure of R&D facilities and loss of R&D jobs is, in part, a reflection of globalization and restructuring in the industry. But patents have historically played an important role in incentivizing drug innovation, and if leading drug companies are warning us that deficiencies in the patent system are contributing to a reluctance to invest in certain R&D activities, we should pay attention. Some degree of unpredictability in patent law is inherent, and many would argue desirable, but we should be concerned when excessive unpredictability acts to

321. 35 U.S.C. § 2(b) (2006); *Tafas*, 541 F. Supp. 2d at 816.

322. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 14 (2007) (as introduced in House, Apr. 18, 2007).

323. See Bring Jobs Back to America: Strategic Manufacturing & Job Repatriation Act, H.R. 5980, 111th Cong. § 8 (2010).

324. Chris Holman, *Recent Developments in Japan and Europe Regarding Continuation Practice and Late Claiming*, HOLMAN'S BIOTECH IP BLOG (Dec. 3, 2007, 5:37 PM), <http://holmansbiotechipblog.blogspot.com/2007/12/recent-developments-in-japan-and-europe.html>.

325. *Id.*

undermine the incentives for innovation, and attempt steps to ameliorate the concerns.

Of course, one potentially powerful means for addressing problems associated with our current heavy emphasis on patent protection is incentivizing pharmaceutical innovation to provide more substantial non-patent incentives. This could take the form of a longer period of data exclusivity for small molecule drugs, along the lines of the twelve years provided for biologic drugs under recently enacted biosimilar legislation.³²⁶ Alternatively, the market exclusivity granted to the developers of orphan drugs under the Orphan Drug Act could be expanded and made available to all drug innovators.³²⁷ It is worth considering whether the value to society of a bountiful drug pipeline is too high to continue to rely so heavily on the vagaries of the patent system.

326. See David E. Adelman & Christopher M. Holman, *Misplaced Fears in the Legislative Battle Over Affordable Biotech Drugs*, 50 IDEA 565, 570 n.21, 586 (2010).

327. M. ANGELES VILLARREAL, CONG. RESEARCH SERV., RS 20971, ORPHAN DRUG ACT: BACKGROUND AND PROPOSED LEGISLATION IN THE 107TH CONGRESS (2001), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS20971.pdf>.