

PATENT SYSTEM MEETS NEW SCIENCES: IS THE LAW RESPONSIVE TO CHANGING TECHNOLOGIES AND INDUSTRIES?

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I. INTRODUCTION

Faced with new sciences and emerging technologies, does the existing United States patent system remain competent to provide incentives for innovation and promote industrial application of scientific discoveries? The answer may not be too sanguine, as one takes a first glance at the administrative and judicial applications of patent law in recent years.

The United States Patent and Trademark Office (“PTO”), the administrative agency with patent examination and grant authority, has grappled with evolving technologies with little success. It has been widely criticized for the vast number of improvidently issued patents.¹ Bad quality patents exacerbate the problem of patent thickets,² which in turn threaten efficient market exploitation of patented inventions and thereby undercut a recognized object of the patent system.³ The quality and quantity problems associated with granting patents bring to focus certain problems in the PTO’s application of patent law standards. For one thing, each PTO Tech-

1. See, e.g., Cecil D. Quillen & Odgen H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1, 3 (2001) (showing a grant rate of approximately 90% in the PTO during the five-year period of 1993–1998, when corrected for continuation applications, compared with a rate of about 60% in the European and Japanese Patent Offices); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63 (2004) (detailing issues concerning the grant of continuation applications in the United States, which the authors argue represent a principle area negatively affecting the quality and quantity of American patents).

2. Many patents include claims of overlapping scopes, due in part to the inadequate prior art search in the PTO’s pre-grant examination. Licenses to multiple patents are frequently required for the freedom to operate in a specific technology market covered by overlapped patents. Competitors often find themselves engaged in intricate cross-licensing schemes. Carl Shapiro coined the term “patent thicket” to illustrate this phenomenon and its implications in the market. See Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam Jaffe et al. eds., 2001).

3. See *infra* section IV.

nology Center⁴ applies the patentability standards in its designated technology area with little regard to the approaches taken by others, making it difficult to assure coherent application of the law to diverse technologies within the PTO. The lack of coherence may also be caused by (i) the discrepancy in individual examiners' technical skills and patent law proficiency, (ii) the collective inadequate understanding within the agency of new technologies, and (iii) the want of clear judicial guidance.⁵ The quality of patent examination in the PTO must be improved in order for the patent system to retain credibility in the inventorship society and the commercial world.

Courts have similarly struggled in recent years to apply the age-old doctrinal framework to unfamiliar developments in science and engineering.⁶ The changing landscape of innovation calls into question the soundness and consistency of infringement and validity determinations relating to different kinds of inventions.⁷ The Court of Appeals for the Federal Circuit (the "Federal Circuit"), the appellate court with exclusive jurisdiction over patent appeals, has been faulted for its over-focus on fact-finding⁸ and lackluster interest in guiding the application of law to new fields of science.⁹ Some commentators, however, have noted a considerable shift, with negative economic consequences, toward a system of generous validity allowance but modest enforcement since the creation of the Fed-

4. The PTO manages its patent examination processes in eight separate Technology Centers. Biotechnology and Organic Chemistry inventions are examined in Technology Center 1600; Chemical and Materials Engineering inventions are examined in Technology Center 1700; Computer Architecture, Software, and Information Security inventions are examined in Technology Center 2100; Communications inventions are examined in Technology Center 2600; Semiconductors, Electrical and Optical Systems and Components inventions are examined in Technology Center 2800; Transportation, Electronic Commerce, Construction, Agriculture, National Security and License and Review are examined in Technology Center 3600; Mechanical Engineering, Manufacturing, and Products inventions are examined in Technology Center 3700; and Designs for Articles of Manufacture inventions are examined in Technology Center 2900.

5. *See infra* section II.

6. *Id.*

7. *See infra* sections III and IV.

8. *See, e.g.,* Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035 (2003).

9. *See, e.g.,* Craig A. Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 HOUS. L. REV. 667 (2002). This tendency was also manifested most recently by the Federal Circuit's repeated refusal to resolve en banc the question whether the written description requirement is separate from and independent of the enablement requirement set forth in the first paragraph of 35 U.S.C. § 112 (2000). *See infra* section II.B.

eral Circuit,¹⁰ a shift that has been attributed to the Federal Circuit's judicial activism.

Paralleling the critical scholarship on the performance of judicial and administrative tribunals, numerous proposals for reforming various aspects of the United States patent system have been advanced. Examples of such proposals include: shifting the "first-to-invent" system to a "first-inventor-to-file" system,¹¹ abolishing the continuation practice,¹² reforming post-grant reexaminations and establishing a post-grant opposition procedure,¹³ reducing the evidentiary burden for challenging patent validity,¹⁴ and even creating a harmonized international patent filing and enforcement regime.¹⁵ Particularly relevant to the challenges facing the existing doctrinal framework in today's dynamic, technology-based economy is Dan Burk and Mark Lemley's proposal that courts specifically apply patent "policy levers" tailored for specific industries.¹⁶ Burk and Lemley made an empirical observation that, contrary to the theoretical uniformity of the patent system, the judicial application of patent law has been technology-specific.¹⁷ They advocate the systemic implementation of a technology-specific

10. Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1 (2004) (showing, based on a statistical summary of patent infringement cases pre- and post-creation of the Federal Circuit, a shift to a routinely valid and narrowly enforced system from a rarely valid and broadly enforced system).

11. See generally A PATENT SYSTEM FOR THE 21ST CENTURY: REPORT BY THE NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES OF SCIENCE (Stephen A. Merrill, Richard C. Levin & Mark B. Myers, eds. 2004), available at <http://www.nap.edu/html/patentsystem>.

12. See Lemley & Moore, *supra* note 1.

13. See, e.g., Biotechnology Industry Organization, Letter re: Patent Quality Improvement: Post-Grant Opposition, to Lamar Smith and Howard Berman, House Subcomm. on Courts, the Internet and Intellectual Property, July 8, 2004, available at <http://www.bio.org/letters/ip>; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Oct. 28, 2003 [hereinafter *FTC Report*], available at <http://www.ftc.gov/opa/2003/10/cpreport.htm>; and Qin Shi, *Reexamination, Opposition, or Litigation?: Legislative Efforts to Create a Post-Grant Patent Quality Control System*, 31 AIPLA Q. J. 433 (2003).

14. See FTC Report, *supra* note 13 (recommending that validity challenges be sustained on the basis of a preponderance of evidence, rather than clear and convincing evidence).

15. Paul E. Geller, *An International Patent Utopia?*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 582, 590 (2003).

16. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1630 (2003) [hereinafter *Burk & Lemley (2003)*].

17. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002) [hereinafter *Burk & Lemley (2002)*].

framework of levers responsive to the needs of innovation in specific industries.¹⁸

Focusing on the tension between the old doctrinal framework and the new sciences, this article inquires into the fitness of the existing patent law framework in serving today's dynamic, technology-based economy. The article attempts to answer the following questions: (1) Has the current framework been so strained and broken, applied to new technology developments, that it needs to be tweaked for better technology-responsiveness?; and (2) Should technology-specific standards or policy levers be instituted as Burk and Lemley have proposed?

The article begins its inquiry with a survey of several patent doctrines in section II, outlining the confusion surrounding the utility standards, the divide on the disclosure requirement, and the recent evolution of the doctrine of equivalents. In section III, the article seeks to better understand the nature and process of discovery in evolving technology fields. The article takes a closer look in section IV at the operation of the factors that modulate the efficiency of commercialization. In section V, the article discusses the issue of neutrality versus specificity raised by Burk and Lemley. As will be shown, patent law by design applies to specific technologies, and the debate over whether the law is technology-neutral or specific is merely normative.¹⁹ Section V distinguishes (i) the special tailoring of patent standards and rules for specific industries from (ii) the specific application of established standards and rules to specific industries. It will be shown that the former, albeit well-intended, may be counterproductive and wasteful, while the latter provides a more robust solution that anticipates changes in diverse technologies and industries.

A series of emerging as well as maturing technologies is examined in section VI, including systems biology, pharmacogenomics, nano-machines and molecular manufacturing, regenerative cloning, biotechnology, and software. This section offers an analysis of a set of unique patent issues in each technology area under the established patent law framework. The article concludes that, under the existing doctrinal framework, the judicial as well as administrative applications of patent law may be improved and better technology-responsiveness and more sensible technol-

18. Burk & Lemley (2003), *supra* note 16, at 1638.

19. The styling of the debate around specificity versus neutrality highlights the normative system of patent law prescribed with a plurality of rules and standards. It does little to inform the underlying substantive inquiry on the technology responsiveness of the law.

ogy-specificity may be achieved, as courts and the PTO undertake to learn about each new field of science and the dynamic market forces underlying its industrial application. Specially tailored patent standards or policy levers for specific industries will do little to ease the strain on the patent law framework. To the contrary, they may elevate the rigidity of the system and trap the attention of the courts and the PTO in an unproductive morass of technology classification.

II.

NEW SCIENCES STRAIN OLD DOCTRINES

Rapid advances in science and technology have spurred many discoveries and innovations that were unfathomable in the recent past. The established patent law system seems attenuated as applied to such discoveries and innovations. This section samples a number of patent doctrines and discusses the issues that have surfaced in the administrative and judicial applications of such doctrines to recent technology developments.

A. *Utility Requirement: Specific, Substantial, and Credible Utility*

Usefulness is the first prompt of qualifying a patent. The utility requirement finds its origin in the United States Constitution, which confers on Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”²⁰ The statutory authority for the utility requirement appears in 35 U.S.C. § 101, which provides that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is entitled to a patent.²¹ Thus, constitutionally and statutorily the usefulness requirement for patenting is basic and the threshold is low. To be sure, the legislative history evidenced Congress’ intent that “anything under the sun that is made by man” be eligible for patenting.²² The courts—including the Supreme Court—have heeded the legislative intent in construing the usefulness standard, and have held that the “useful process, machine, manufacture, or composition of matter” en-

20. U.S. CONST. art. I, § 8, cl. 8.

21. 35 U.S.C. § 101 (2000).

22. S. Rep. No. 1979, 82d Cong., 2d Sess., at 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., at 6 (1952).

compasses diverse subject matters from computer algorithms²³ to genetically engineered microorganisms.²⁴

The statutory term “useful” has been interpreted by courts to not require present commercial value or marketability,²⁵ but only a practical benefit to the public—something more than a mere assertion of intrinsic value and possible uses.²⁶ This guidance in applying the utility doctrine was apparently deemed inadequate by the PTO, which proposed its own Utility Guidelines in 1999 and adopted the same in 2000 (the “Guidelines”).²⁷ The Guidelines require that a patent disclosure provide a well-established utility, which is defined as a utility that can be immediately appreciated by an ordinarily skilled artisan, and that is specific, substantial, and credible.²⁸ Other than stating that “throw-away,” “insubstantial,” or “nonspecific” utilities are excluded and that credibility should be assessed based on the disclosure and other evidence of record from the perspective of an ordinarily skilled artisan,²⁹ the Guidelines do not provide clear guidance on how much utility would meet the tripartite test of specificity, substantialness, and credibleness. Insofar as the tripartite test steps beyond the utility requirement imposed by the statute as interpreted by the courts, the Guidelines appear to lack substantive legal support.³⁰

The application of the Guidelines also raises procedural issues. For example, the Guidelines expressly disclaim any force and effect of law.³¹ The PTO does not require its examiners to use the Guidelines. When an examiner does so and subsequently issues rejec-

23. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that algorithms for banking and financial analysis are useful for the purposes of 35 U.S.C. § 101 and are statutory patentable subject matters).

24. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that “non-naturally occurring manufacture or composition of matter—a product of human ingenuity” is patentable subject matter).

25. *In re Langer*, 503 F.2d 1380, 1393 (C.C.P.A. 1974).

26. *Brenner v. Manson*, 383 U.S. 519 (1966). *See also* *Diamond v. Diehr*, 450 U.S. 175 (1981) (analyzing cases construing 35 U.S.C. § 101 and the categories of possibly patentable subject matter).

27. The Guidelines for Examination of Applications for Compliance with the Utility Requirement set forth the requirement for a patent application to disclose or otherwise establish a specific, substantial, and credible utility of the claimed invention. *See* United States Patent and Trademark Office, *MANUAL OF PATENT EXAMINING PROCEDURE* § 2107 (2004) [hereinafter *MPEP*].

28. *Id.*

29. *Id.*

30. The Guidelines have not been tested in the courts.

31. *MPEP* § 2107, *supra* note 27.

tions based on the Guidelines, the rejections are deemed to be made under the substantive law.³² The inventor or applicant cannot appeal the application of the Guidelines other than appealing the rejection based on the substantive law. Conversely, if the examiner failed to use the Guidelines and the inventor or applicant believes that the Guidelines should have been applied favorably to his claims, the inventor or applicant is not permitted to appeal their non-use. Such a one-sided and non-committal approach is not conducive to establishing a clear, consistent framework for administering the utility requirement, a goal that the PTO had in mind when it undertook to promulgate the Guidelines.³³

The substantive and procedural issues surrounding the Guidelines are unsurprising in light of the backdrop of events leading to their creation. Indeed, the effort to implement the Guidelines may have been misdirected from the start. The Guidelines were largely a response to the increased filing of gene-centric patent applications in the early- and mid-1990's,³⁴ which strained the quantitative and qualitative examination capacity of the PTO. Many patents were issued based on lean disclosures and prophetic assertions of physical and functional properties of genes (and proteins they encode).³⁵ Along with poor quality business method patents, these problematic gene patents signaled to many observers serious problems with the PTO's patent examination practice.³⁶ As the initial genomic discovery hype subsided, and companies and institutions scaled back from their quantity-driven filings,³⁷ the PTO took

32. 35 U.S.C. § 101 (2000).

33. See also section V.B. *infra*.

34. Public and private institutions and technology companies accelerated their patenting efforts as the race to sequence the human genome intensified, computing power multiplied, and DNA full length cloning techniques improved. Such aggressive and competitive patenting was also propelled by the optimistic outlook on growth among investors and business owners at the time in the genomic biotechnology sector.

35. For example, thousands of patent applications were filed and patents issued on expressed sequence tags (ESTs), which are essentially fragmented DNA sequences (typically 300–500 bases) that may or may not belong to a gene or a functional regulatory region (e.g., for transcription or translation). Many of those patent applications were produced using templates describing projected properties and uses of claimed genes or gene fragments. The questionable validity of patents issued from these applications was evidenced in certain high-profile court battles at the time. See, e.g., *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

36. See *supra* note 1.

37. The number of patent applications filed in the genomics area drastically decreased. A simple search in the PTO's databases demonstrates similar trends in the patent filing practices of companies such as Celera Genomics and Human

its own corrective action by putting in place the Guidelines that it hoped would more effectively enforce the utility requirement.

The Guidelines targeted exclusively biotechnology and pharmaceutical applications related to genes and proteins,³⁸ although their language does not prescribe this limitation. A de facto technology-specific approach as such raised more issues than it resolved. The Guidelines did not provide clarification and guidance as hoped; rather, they further complicated and confused the application of the established utility doctrine (in biotechnology or otherwise). Albeit largely inconsequential,³⁹ the Guidelines marked wasted efforts based on the unsound premise that the problem of dubious gene patents is due to a weak utility standard non-responsive to genomic technologies. In fact, the gene patent problem has more to do with the industry's and the PTO's then-rudimentary understanding of genomics inventions and their mode of, and value in, commercialization. The feeble administration of the utility standard does not mean that the standard itself needs to be beefed up. A more productive approach is for the PTO to direct its efforts to better informing itself of the nature and characteristics of the art in applying the utility requirement as enacted by the Congress and construed by the courts.

B. Disclosure Requirement: Written Description and Enablement

A patent is a grant of legal monopoly under which the patentee can exclude others from making and using its invention. The quid pro quo⁴⁰ of this monopoly is the patentee's disclosure of the invention in the patent document, known as "specification." The patent statute requires that the specification contain "a written description of the invention, and of the manner and process of

Genome Sciences. Likewise, the National Institutes of Health (NIH) reduced its patent filings related to gene fragments and sequences.

38. As of the time of this writing, the author has heard of no practitioners who received a utility rejection pursuant to the Guidelines on a subject matter other than biotechnology or pharmaceutical chemistry. The public comments received by the PTO on the earlier versions of the Guidelines concern only biotechnology and gene-related subject matters. See Public Comments on United States Patent and Trademark Office Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 71,440 (Dec. 21, 1999); 65 Fed. Reg. 3425 (Jan. 21, 2000).

39. The Guidelines do not have the effect of law and are only sporadically invoked in practice.

40. See, e.g., *Pfaff v. Walls Elecs., Inc.*, 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”⁴¹ The statutory language points to the “written description” and “enablement” of the invention, both of which are generally understood to be required of a patent disclosure in the United States. In recent years, however, the question of what is adequate written description in a given technology area beyond that which enables has caused much confusion as more diverse and new subject matters found their way into patent suits. This confusion stems from an unsettling debate over another, related, question: whether the written description requirement is independent of and separate from the enablement requirement.

The Federal Circuit is sharply divided on that question. A number of Federal Circuit judges, including Judges Rader, Linn, and Gajarsa, hold the view that written description is coupled with enablement and that an enabling written description is necessarily an adequate written description.⁴² This article denominates that view the “for-enablement written description” theory. Other Federal Circuit judges, including Judges Lourie, Newman, Bryson, and Dyk, believe that the written description requirement must be separately evaluated and satisfied, independently of the enablement requirement.⁴³ This article denominates that view the “independent written description” or “beyond-enablement written description” theory. Both theories are advanced by their advocates on the basis of statutory construction, lines of cases, hypotheticals, and public policy arguments.⁴⁴ Many variously-sided stakeholders and commentators urged the Federal Circuit to resolve the question en banc.⁴⁵ The court left the question open, however, when it declined in July 2004, by a 7–5 margin, to rehear en banc a decision

41. 35 U.S.C. § 112 (1994).

42. See *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting); *id.* at 1325 (Linn, J., dissenting); *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting); *id.* at 987 (Linn, J., dissenting).

43. See *Enzo Biochem.*, 323 F.3d 956; *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); and *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

44. See generally *Univ. of Rochester*, 358 F.3d 916; *Univ. of Rochester*, 375 F.3d 1303; and *Enzo Biochem.*, 323 F.3d 956.

45. See amici briefs filed in *Univ. of Rochester*, 358 F.3d 916, by Eli Lilly and Co. and the Regents of the University of California and amicus brief filed in *Enzo Biochem.*, 323 F.3d 956, by the United States. See also *Univ. of Rochester*, 375 F.3d 1303, 1314 (listing in appendix to Judge Rader’s dissenting opinion post-*Eli Lilly* commentaries and law reviews discussing the written description standard).

issued earlier in the year⁴⁶ that invalidated a patent owned by University of Rochester for lack of written description.⁴⁷ The unresolved question on patent disclosure standards creates uncertainties for innovators, competitors, and investors in the technology-oriented marketplace.

The invalidation of biotechnology-related patents in a series of recent Federal Circuit cases⁴⁸ left many observers with the impression that the written description standard is heightened for biotechnology inventions.⁴⁹ Some perceive, rightly or wrongly, a sign of hostility towards protecting innovations in the fledgling fields of new sciences from these cases. Manifested as a seemingly biotechnology-specific problem, the disclosure debate exposes fundamental issues that concern all technologies.

The independent written description theory requires an inventor to describe what the invention is, in addition to what it does or how to make and use it. This may not be possible for certain evolving technologies or new sciences where discoveries are conceived, made, and taught only in terms of “what it does,” not “what it is.” In those cases it is the function and application that lends the identity to the invention and defines its newness,⁵⁰ non-obviousness,⁵¹ and usefulness.⁵² Courts appeared to have recognized the inherent connections between function and identity and have, at times, relaxed the beyond-enablement written description requirement and permitted “diverse forms of description” including functional features.⁵³ Indeed, delineating the line between the function and identity of a new concept is better left for the cognitive sciences and philosophy than the patent law.⁵⁴

46. *Univ. of Rochester*, 358 F.3d 916.

47. *Univ. of Rochester*, 375 F.3d 1303. The United States Supreme Court denied certiorari in this case. 125 S. Ct. 629 (2004).

48. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and its progeny invariably relate to biotechnology inventions.

49. *See, e.g.*, *Univ. of Rochester*, 375 F.3d 1303, 1314 (listing in appendix to Judge Rader’s dissenting opinion post-*Eli Lilly* commentaries and law reviews discussing the written description standard); Burk & Lemley (2002), *supra* note 17, at 1173–74; R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003).

50. 35 U.S.C. § 102 (2000).

51. 35 U.S.C. § 103 (2000).

52. 35 U.S.C. § 101 (2000).

53. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997–1002 (Fed. Cir. 2000).

54. As a field evolves and matures, inventions it spurs will naturally enrich in identity and will encompass more information than functions and applications.

However, the for-enablement written description theory remains a minority position. This theory offers a simpler and to some, more sensible, alternative for measuring the sufficiency of patent disclosures. The sufficiency of written description under this theory hinges on enablement, an approach similar to that taken in Europe.⁵⁵ This approach would save lay juries from the amorphous exercise of assessing what amounts to adequate written description beyond that which enables, an indispensable exercise under the independent written description theory. Courts have not yet provided clear guidance for such an exercise.

A “possession” standard was first articulated in *Vas-Cath Inc. v. Mahurkar*,⁵⁶ which holds that, beyond teaching how to make and use an invention, an applicant must convey to one skilled in the art that, as of the filing date, he was “in possession of the invention.”⁵⁷ Although it is not immediately clear how much description is required to evidence “possession,” the *Vas-Cath* “possession” standard was adopted in some subsequent cases,⁵⁸ and embraced by the PTO.⁵⁹ Yet other cases disavow its application. For example, *Enzo* provides that application of the written description requirement is not subsumed by the “possession” inquiry and that a showing of “possession” is only ancillary and does not of itself establish adequate written description.⁶⁰ This contradiction in judicial precedents highlights the impracticability of measuring beyond-enablement description in the real world, and casts doubt on the soundness of the independent written description requirement, whether for treating new or matured technologies.

C. Scope of Protection: Doctrine of Equivalents

Patent claims define the metes and bounds of the patentee’s invention and the scope of his rights to exclude.⁶¹ The scope of protection under United States patent law extends from what is recited literally in the claims to the equivalents thereof. The Doctrine

55. The European Patent Convention requires that the applicant “disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.” European Patent Convention, art. 83 (2002).

56. 935 F.2d 1555 (Fed. Cir. 1991).

57. *Id.* at 1563–64.

58. *See, e.g., Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998).

59. MPEP §§ 2161 and 2163, *supra* note 27.

60. 323 F.3d 956.

61. 35 U.S.C. § 112 (2000). *See also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention.”).

of Equivalents (“DOE”) is an equitable principle that prevents others from copying a patented invention and escaping liability for infringement by making “insubstantial changes.”⁶² The operation of DOE may be undercut by the Prosecution History Estoppel (“PHE”), another legal doctrine rooted in equity. PHE operates to bar the benefits conferred by the DOE with respect to a claimed feature when the patentee amended the claim during its prosecution to narrow its scope in order to overcome patentability rejections.⁶³

In recent years, the Federal Circuit has shown increased reluctance to find infringement under the DOE and, correspondingly, increased willingness to apply PHE. In 2000 it ruled en banc in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*⁶⁴ that a narrowing amendment that affects the patentability of the amended claims completely bars application of the DOE on such claims. This decision was reversed on appeal in 2002 by the Supreme Court, which held that a narrowing amendment does not create a complete bar,⁶⁵ only a presumption that features otherwise covered under the DOE are surrendered.⁶⁶ On remand, the Federal Circuit generally restricted the ability of a patentee to rebut such presumption, leaving in effect a nearly complete bar.⁶⁷ Most recently, the Federal Circuit effected another blow to the DOE in *Honeywell International Inc. v. Hamilton Sunstrand Co.*,⁶⁸ where it explicitly held that cancel-

62. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 726–27 (2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), which reaffirmed that a patent protects its holder against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention).

63. *Festo*, 535 U.S. at 727

(“When the patentee responds to the rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent. Competitors may rely on the estoppel to ensure that their own devices will not be found to infringe by equivalence.”).

64. 234 F.3d 558 (Fed. Cir. 2000).

65. *Festo*, 535 U.S. 722.

66. *Id.*

67. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369–1372 (Fed. Cir. 2003) (discussing three grounds on which the presumption of surrender can be rebutted: unforeseeability (“whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment”), tangentialness (“whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent”), and some other reason (“suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question”)).

68. 370 F.3d 1131 (Fed. Cir. 2004).

ing an original independent claim and rewriting it in dependent form constituted a narrowing amendment if the scope of the independent claim is thereby narrowed to secure the patent.⁶⁹ The qualification as a narrowing amendment in this situation opens the door for the operation of PHE to bar the application of the DOE to the amended claims.⁷⁰

The recent interplay of the PHE and DOE has practically eliminated the benefits of the DOE in patent enforcement. The current law is such that prosecutors are left with little room to preserve the benefit of the DOE, as rarely does a patent issue on the original filed claims. In almost all cases, an amendment responsive to an office rejection addresses substantive rather than formal issues and would qualify under *Festo* and *Honeywell* as a narrowing amendment made for patentability reasons.

The de facto abolition of the DOE in the Federal Circuit's jurisprudence may have a bigger impact across multiple fields on early-stage technologies than matured technologies. This is because claims in early-stage technology patents often are not as comprehensive as those found in late-stage technology patents. Thus, early-stage technology inventions tend to rely on the DOE as the last resort for effective protection. It appears that, if the DOE is to be maintained as a viable instrument to enlarge the literal scope of protection where such protection is desirable,⁷¹ careful reconsideration of judge-made law is due in this area.

III.

DYNAMIC INNOVATION PROCESS IN NEW AND MATURED TECHNOLOGIES

In the recent years of technology development and industry growth, the United States patent bar has been experiencing fierce debates over numerous patent doctrines.⁷² The parallel between the successes in science and technology and the difficulties in the

69. *Id.* at 1141.

70. *Festo*, 344 F.3d at 1366 (citing *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) and stating: "If the amendment was not narrowing, then prosecution history estoppel does not apply. But if the accused infringer establishes that the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability.").

71. Detailed analysis of the DOE and arguments in support of limiting or enhancing its use are beyond the scope of this article.

72. The last five to ten years have seen a myriad of technological events that are of historical importance. Examples of such events include the sequencing of the entire human genome, the global expansion of high-connectivity broadband

application of patent law suggest a connection, if not causal, between the two. A legitimate question is whether the doctrinal framework of the United States patent system remains capable of dealing with new sciences and evolving technologies. It is useful, in answering this question, to bifurcate the inquiry pursuant to the generally accepted dual goals of the patent system: provide incentives for innovation and promote industrial application of scientific discoveries. This section considers the first part of the inquiry, and section IV discusses the second part of the inquiry.

The grant of a legal monopoly that excludes others from making and using the patented invention gives the inventor an edge in exploiting the invention for commercial gain. The economic benefits operate to enhance moral satisfaction; they reward past inventive contributions and provide incentives for future inventions. To assess whether the patent system provides effective incentives for inventors to invent further, it is useful to understand the nature and process of innovation and the factors affecting the motivating forces of patent grant on prospect inventors.

Innovations—or discoveries and inventions as expressly provided in the patent statutes as the subject of patent grant—are made in diverse scientific, technological, and engineering disciplines, some age-old and others new. In any given field, the discovery trajectory may become flatter over time, as the field evolves from a cutting-edge and uncertain discipline to an established, richly-defined area. Following such a trajectory, innovations change in character from groundbreaking discoveries to incremental improvements. At the beginning of the discovery trajectory, the discoveries tend to be “self-centric,” in that their very identities define the field. Thus, characteristically these early discoveries focus within the field. Towards the later part of the discovery trajectory, however, the inward focus of the discoveries diffuses as the field interacts with other fields and more inventions and improvements are made from applying the early discoveries in the related fields. In the course of this continuous discovery process, new fields may emerge at the intersections of two or more related fields. Ample examples may be drawn where areas of embryonic experimental science or amateur engineering transformed into multimillion-dollar

digital networks, the rapid evolution of wireless technologies, and the application of biometrics and digital signatures in commercial and governmental operations.

industries.⁷³ Over time, inventions in those fields also changed in kind and significance.

Therefore, the discovery process is dynamic in nature. Innovative fields, while concerning different and diverse technologies, track a similar discovery trajectory as inventions are made and applied. The common features of the discovery process (vertical parallelism) suggest that the patent system is most efficient in providing incentives for innovations when it treats different and diverse technologies and industries consistently (horizontal consistency). Technology-specific incentives may appear attractive at first, but as the technology evolves, the incentive specifically instituted may become out-of-sync with the discovery process, obviating its incentive appeals.

Making it easier to obtain patents for one technology than another does not make it so that those who invent in the first technology will have incentives to make more inventions than those who invent in the second technology. Depending on a range of factors, a prospective inventor may or may not alter his inventive behavior according to whether he had been issued patents before and, if so, how often, or whether it is easier for him to obtain a patent in a given field. Such factors include, *inter alia*, the inventor's own interest in and means for industrial application, the ripeness of the invention for commercial exploitation, the profit margin of the relevant market, and the difficulty and competitiveness of the art. The correlation between (i) the number of patents issued to an inventor or in the inventor's field and (ii) the likelihood that he will further invent, is nonlinear. Systematically adjusting patent standards to issue larger numbers of patents in specific fields in the hope of increasing incentives for prospective inventors is therefore an unpredictable and wasteful exercise.

IV.

DYNAMIC COMMERCIALIZATION PROCESS IN NEW AND MATURED INDUSTRIES

Retrospectively, the patent system serves to reward inventors and provide incentives for innovation. Prospectively, the patent system serves to promote efficient industrial application of the pat-

73. Consider the development of the biotechnology industry following the discovery of the DNA double-helix, and the growth of the computer industry after the first personal computer was built.

ented inventions. The latter is at the core of the prospect theory.⁷⁴ To evaluate the patent system's ability to promote industrial application, this section analyzes the nature and process of commercialization and explores factors affecting efficient commercial exploitation.

Commercialization requires (i) the rights to and knowledge of the invention, (ii) the means—human, financial, or otherwise—for developing, manufacturing, and marketing the products embodying the invention, and (iii) suitable market conditions.⁷⁵ Under a grant of patent, the patentee is guaranteed a monopoly profit that exceeds the competitive profits available in a free market under ordinary competitive forces, if he chooses to engage in commercial exploitation of the invention. Such secured profits operate to promote industrial application and commercialization of the invention by the patentee. Naturally, the patentee possesses the requisite rights and knowledge, and occupies an advantageous position for marshalling various means to develop, manufacture, market, and sell the patented products. For example, the patentee may initiate negotiations and cement research collaboration and profit-sharing partnerships to secure and sustain the commercial success of patented products. The patentee may presumably better lead, coordinate, and promote the efficient use, exploitation, and future improvement of the invention.⁷⁶ Achieving macroeconomic efficiency as such in the commercial exploitation of inventions serves a public good.

Just as the process of discovery is dynamic, so too is the process of industrial application and commercialization. The mode of commercialization, the relevant market forces, and the profitability structure will change as a field evolves from an exploratory discipline to a technology engine of marketable products. For example, companies that own platform technologies tend to orient their businesses around the provision of research services for product companies. They generally do not out-license patents covering research tools or platform technologies because it is difficult to obtain reach-through royalty payments on those kinds of patents. By contrast, companies whose patent estate covers elements of innovative combination products may seek partnership arrangements with companies having complimentary technologies or products. Partners may

74. See generally Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

75. Suitable market conditions include, for example, the existence of a market for the product and a reasonable profit margin in the market.

76. See Kitch, *supra* note 74.

share profit, cost, and risk under such arrangements, and collect royalties on licensed patents, if any are included. Companies whose market dominance is secured by lines of patent families covering salable goods are of course free to harvest monopoly profits under their patents. They may form distribution agreements with others to expand their markets.

Although commercialization activities in different industries may differ in focus and industry organization, the dynamic and evolving characteristics are common across industries. The incentives that patents offer to center commercialization activities around the patentee and his partners or affiliates operate in the same manner without regard to the kinds of technologies involved in a given industry.

Similar to the nonlinear correlation between the number of patents issued in the field of a prospective inventor and the likelihood that he will invent, the relationship between the number of patents and the effect patents have on promoting commercialization is nonlinear. Patents promote commercialization of inventions by optimally allocating resources and by giving the patentee a monopoly power to profit for a limited term, within a limited scope. Unrestrained increases in the number of patents covering small and incremental inventions, however, may over-encumber a field and exert mixed, or negative, effects on commercialization.⁷⁷ This problem is illustrated by the anticommons theory, which highlights the need to aggregate fragmented property rights in order to effectively use the property.⁷⁸ Distributed and fragmented patent rights pose negotiation and transaction costs for industry-wide commercial exploitation, although anticommons alone do not necessarily lead to lowered commercialization efficiency. A free and efficient market may internalize such negotiation and transaction costs, as well as the costs for procuring such patents. That is, if these costs do not justify the benefits to a rational market player, such patents will lose their appeal as in-license targets or out-license revenue earners, and will no longer issue as companies will stop paying for their prosecution or maintenance.

Yet, the transaction overheads of anticommons can be exacerbated by the problem of patent thickets.⁷⁹ Fragmented patent rights covering overlapping claim scopes create a perilous environ-

77. See generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698 (1998).

78. See generally Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).

79. See *supra* note 2.

ment for commercial developments, especially when patents are of questionable quality. Ambiguities and uncertainties in the scope of ownership rights inevitably lead to conflicts among stakeholders. They further burden intellectual property transactions and thereby impede efficient commercialization of proprietary technologies. To correct or prevent such peril, it seems that, as a first step, the quality of patents must be improved in every technology field for every industry.

V.

SPECIAL TAILORING VERSUS SPECIFIC APPLICATION

Whether in new or matured technologies and industries, innovation is dynamic, as is commercialization. With an understanding of the nature and process of innovation and that of commercialization, sections III and IV reveal that, if the patent system fails to effectively incentivize innovation or promote commercialization, this is not a technology- or industry-specific problem. Certainly it is not a problem specific to new and emerging technologies. Such technologies have, however, uncovered tension in the application of patent law.⁸⁰ Where does the solution lie for the strained doctrinal framework? Burk and Lemley answered this question in an incisive article which proposes that technology-specific patent standards or policy levers be adopted.⁸¹

A. *Patent Standards Specially Tailored*

Declaring the current system “unworkable and ineffective” for handling new technologies, Burk and Lemley faulted the system for its “undifferentiated” treatment of diverse technologies.⁸² They then, sought, however, to demonstrate technology-specificity in the judicial application of law, particularly with respect to biotechnology and software.⁸³ Dismissing this approach as ad-hoc specificity, Burk and Lemley proposed, instead, the systematic institution of specific policy levers for specific industries to better incentivize innovation.⁸⁴ A comprehensive critique of Burk and Lemley⁸⁵ is of-

80. *See supra* section II.

81. Burk & Lemley (2002), *supra* note 17.

82. *Id.* at 1155.

83. *Id.* at 1183.

84. Burk and Lemley advocate for “macro” and “micro” policy levers while disapproving “industry-specific legislation.” Burk & Lemley (2003), *supra* note 16, at 1630-40. For example, a “macro” policy lever according to Burk & Lemley represents “a blanket rule for one set of cases.” *Id.* at 1646.

ferred by Wagner,⁸⁶ in which he charged that the kind of technology-specificity Burk and Lemley advocated—termed “macro technology exceptionalism”—is unsound. This section is not intended to provide a deep analysis of, or rebuttal to, Burk and Lemley. Rather, it discusses a number of potential problems associated with tailoring patent rules and standards. Section V.B. next discusses, by contrast, specific applications of established rules and standards to diverse technologies.

As an increased number of subject-based (technology-based, in the case of patent law) exceptions are introduced, the value of a body of law to provide wide-ranging guidance, and its robustness in responding to the world (the technology world, in the case of patent law), likely diminishes. Specially-tailored patent standards and rules would disturb the rubric of patent law and transform it into a collection of *sui generis* laws for arbitrarily carved technology and industry fields. Such a transformation seems degenerative and backwards in terms of the development of patent law.

Building differentiated standards and rules into the patent system for different technologies creates a number of problems, chief among which is technology classification. Who should be given the authority to make such classifications? Because under this approach patent standards and rules differ from one technology area to another, whoever has the authority to make technology classifications would essentially determine the substantive law applied to a given invention. It seems that such significant authority should be vested in the judiciary. With only a few exceptions in the patent bar, however, most judges are laypersons.⁸⁷ A lay judge may not be best situated to evaluate the nature and characteristics of an invention and to classify it based on its perceived technical features. As technologies are increasingly interdisciplinary and multidisciplinary, technology classification becomes an inexact science, posing even greater challenges. Another twist in this dilemma is that classification involves heavily factual and technical inquiries and judges seem poorly suited for the task. Should, then, experts be enlisted?

85. Burk & Lemley (2003), *supra* note 16; Burk & Lemley (2002), *supra* note 17.

86. Wagner, *supra* note 49.

87. Typically judges receive systematic education in social, not natural, sciences, and thus are deemed laypersons in the technology arena. However, a number of judges (e.g., Judges Newman and Lourie of the Federal Circuit) in the patent bar hold advanced degrees in science and engineering in addition to law degrees.

Is it prudent to charge a technical expert with the responsibility of making the choice of law?

Because technology classification determines which specially-tailored standards or rules would apply, the opportunity to “forum shop” in search of technology-specific patent laws may lead parties to dispute classifications proposed by their adversaries in support of their respective positions. Battles over technology classification shift the focus away from the real dispute between the parties. They consume parties’ resources and divert the attention of the courts and the PTO. Thus, technology classification, the linchpin of a regime of technology-specific patent laws, will be costly to stakeholders as well as judicial and administrative tribunals. It may overshadow analyses based on relevant substantive laws and, with respect to resolving the real dispute between the parties, represent an unproductive overhead.

Synchronization is another problem associated with specially-tailored standards or rules. A vaunted benefit of tailoring rules and standards for specific technologies is that the law is responsive to, and in-sync with, changes in technology. While well-intentioned and theoretically desirable, in reality tailored rules and standards will never truly synchronize with changing technologies. By the time the rules and standards are adjusted or made anew in response to a change in technology, additional technological changes may occur that would render the newly-adjusted rules and standards obsolete.⁸⁸ It is a losing strategy to always play catch up.

In essence, specially-tailored patent standards or rules may be counterproductive. A more sensible approach is to retain the rules and standards under the existing doctrinal framework and specifically apply them to particular industries.

B. Doctrinal Framework Specifically Applied

Unlike the special tailoring of patent standards and rules for different industries, the specific application of the doctrinal framework is based on the established rules and standards, which do not change from industry to industry. The former represents a regime of technology-specific patent laws, whereas the latter embodies the existing patent doctrines specifically applied to diverse industries.

Patent law deals with technology by design and it has intrinsic technology-responsive hinges. For example, patentability and/or

88. This approach agrees with Burk and Lemley’s position against industry-specific patent legislation. However, this approach disfavors the “macro” level tailoring promoted by Burk and Lemley.

patent validity turns on the state of the art and the level of ordinary skill, both of which are specific to a given technology and industry. The debate over neutrality versus specificity of the patent system vis-à-vis technology underscores a fundamental question concerning the patent system's role in serving knowledge industries that are coming of age. That is, how can the system assure that rules and standards are responsive to new and changing technologies and the results of the application of patent law are consistent in promoting innovation and industrial application across multiple disciplines? As discussed above, "technologically responsive" does not necessarily require "technologically different." Paradoxically, a system that applies different rules for different technologies does not afford the technology responsiveness necessary for the patent system to carry out its dual missions.⁸⁹

By contrast, under the alternative approach proposed by this article, technology-responsiveness is achieved by requiring, in the application of patent standards and rules to a given technology industry, a specific understanding of the nature, the inventive processes, and the relevant market forces thereof.⁹⁰

Better understanding of a given technology field will enable the courts and the PTO to clarify the applicable laws and provide guidance on how standards and rules apply in the relevant technologies. To be sure, much of the difficulties in the application of certain patent doctrines may be alleviated as technology and business professionals, courts, and the PTO become better educated concerning the technologies and industries involved. For example, the filing of gene-centric applications—which inundated the PTO and led to the issuance of a great number of problematic gene patents and which triggered the implementation of the PTO's Utility Guidelines⁹¹—decreased dramatically as the companies and institutions understood better the nature of genomic discoveries, their functional implications, and the related value propositions.⁹² The "gene-patent crisis" partly took care of itself. Patent examiners grew more comfortable and confident in assessing the usefulness of inventions in this multidisciplinary field as they become more knowl-

89. *See, e.g.*, Semiconductor Chip Protection Act of 1984, 17 U.S.C. §§ 901–914 (2000). This Act provides protection to mask works in semiconductor chip circuit design, but it has not often been used. As technology evolved, the protection it provides become irrelevant.

90. Providing incentives for innovation and promoting commercialization are the dual missions of the patent system. *See supra* Section V.A.

91. *See supra* section II.A.

92. *See supra* notes 34 and 35.

edgeable in genomics, molecular biology, and bioinformatics, and better understood the relationship of such fields to pharmaceutical chemistry and bioengineering. The PTO's efforts to weather the crisis by imposing standards beyond the statutory utility requirement turned out to be unnecessary and misplaced.⁹³ A lesson is therefore learned that the means of the patent system to meet technology challenges lie not in tweaked standards and rules but in the improved understanding of relevant technologies and industries.

Similarly, with respect to the patent disclosure requirement, guidance is required from the courts for different technologies on how much written description is required beyond that which enables, as the doctrine of beyond-enablement written description is applied.⁹⁴ Such guidance should be offered as the courts learn about and carefully consider the specific nature and characteristics of each different technology. The Supreme Court or Federal Circuit en banc could also resolve the disclosure debate by simply adopting the written description for enablement theory⁹⁵ as the law of patent disclosure in the United States.

In sum, it is important to understand the art, the inventions, and the issues specific to patent protection in the art in applying established patent doctrines to each different technology field. Specifically applying established patent standards and rules represents a better approach to anticipating changes in diverse technology industries, compared to the tailor-making of patent standards and rules for every technology and industry.

VI.

A CLOSER LOOK AT EMERGING AND MATURING TECHNOLOGIES

Issues unique to patent protection in diverse technology areas, whether emerging or maturing, may be readily dealt with under the established doctrinal framework with a better understanding of the relevant technologies and industries. Technology-responsiveness of the patent law stems from specific attention to and specific understanding of each technology and industry, and based on that, specific application of a consistent legal framework.

93. *See supra* section II.A.

94. *See supra* section II.B.

95. *See supra* section II.B.

A. Emerging Technologies and Industries

This section identifies certain patent issues of import to a number of newly emerged technologies and industries and provides a starting point for analyzing these issues under the existing patent framework.

1. Systems Biology: Qualifying Relevant Art

Systems biology emerged in the last ten years as an exploratory science where a number of established disciplines intersect. Steps have been taken in recent years to apply results from systems biology research in the commercial world.⁹⁶ Systems biology takes a systemic approach to study living organisms. Engineering principles are utilized to dissect biological processes and track biological states. This field also features the employment of high-powered computers and other high-throughput instruments for, *inter alia*, generating and analyzing large datasets that relate to system states reflecting various target conditions.⁹⁷ Simulation of biological reactions, modeling of regulatory and metabolic pathways as well as normal and diseased states, and comparative genomic analyses of related species all fall under the rubric of systems biology.

A challenging issue for patent protection in systems biology is qualification of the relevant art. The state of the art, together with the level of ordinary skill in the art, marks a threshold of patentability and/or validity, for purposes of anticipation⁹⁸ as well as obviousness⁹⁹ analyses. In general, the richer the art, the higher the bar for patentability. The required disclosure to enable the invention may be thinner, however, because an applicant is not required to disclose in the specification what is well-known in the art.¹⁰⁰ The scope of the relevant art is therefore of great importance for determining the scope of protection under the patent system. A cross-disciplinary field, systems biology merges biology, medicine, and

96. For example, the Institute for Systems Biology is a non-profit research institute located in Seattle, Washington that is dedicated to the study and application of systems biology. It formed a partnership, the Accelerator Corporation, with a number of life science venture firms to commercialize cutting-edge ideas in systems biology. The Institute also spun off a series of early-stage companies in the last few years. *See generally* www.systemsbiology.org.

97. Genome-wide expression analysis, for example, may be carried out to compare a normal condition and a treatment condition.

98. 35 U.S.C. § 102 (2000).

99. 35 U.S.C. § 103 (2000).

100. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1998) (stating that “[a] patent need not teach, and preferably omits, what is well-known in the art.”).

chemistry with mathematics, physics, engineering, and computer sciences.¹⁰¹ Thus, the state of the art for a systems biology invention should reflect general teachings in all of these well-established disciplines. Certain inventions in systems biology may have one or more dominant features in further specialized areas, such as expert systems, artificial intelligence, and electrical physiology. Depending on the particular subject matter of the invention, these specialized areas may also constitute the relevant art.

It will be an intensely fact-based inquiry to qualify and evaluate the relevant art for systems biology inventions. For a new, dynamic, and intricate field like this, which draws from a series of theoretical and experimental sciences and which offers a myriad of applications, there is simply no short cut. Efforts must be made in the courts and the PTO to inform any patent law decisions related to subject matters of systems biology—whether in enforcement actions or patent examinations—with a reasonable understanding of the field.

2. Pharmacogenomics: The Challenge of Information Products

Pharmacogenomics concerns the application of genomics discoveries in the development of pharmaceuticals. The field was born on the heels of the completion of the human genome project. That project delivered the sequence of the entire human genome.¹⁰² Pharmacogenomics is defined by the International Society of Pharmacogenomics (ISP)¹⁰³ as “the influence of the human genome on response to medication.” It covers drug response markers that link individual genomic variations (DNA polymorphisms) to drug target, drug metabolism, clinical responses, and side effects. Pharmacogenomics thus intrinsically relates to the promise of personalized medicine. It is hoped that, for example, a large number of drug compounds that fell through late-stage clinical trials may be resurrected, based on pharmacogenomics information, as effective and safe therapeutics for a subset of patient populations having a certain genomic profile.

101. For example, see illustrations of the compositions of systems biology at www.systemsbiology.org.

102. See International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001); J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304 (2001).

103. The ISP is a non-profit organization formed in 2001 and dedicated to science, policy, and education in the fields of pharmacogenomics. See generally <http://149.142.238.229/isp/>.

Insofar as the principal asset derived from pharmacogenomics research is information on the relationships between individual genomic variations and individual responses to a particular drug compound, the field poses interesting questions on the desirability and strategy of protecting such information. Seemingly new and unfamiliar, these questions nonetheless can be dealt with under the existing doctrinal framework.¹⁰⁴ Information per se is not one of the four statutorily patentable subject matters¹⁰⁵ and does not meet the usefulness test under 35 U.S.C. § 101. However, information that is packaged in certain “useful” forms and that provides a practical benefit to its users may satisfy the utility requirement. The key, therefore, is to find a nexus in pharmacogenomics applications that transforms information into information products. This requires a comprehensive understanding of the field. Protection for valuable pharmacogenomics information may also be sought in connection with other patentable subjects, including, for example, methods of statistical analysis of genomic or expression data, methods for identifying biomarkers for drug responses, biomarkers and biomarker kits, and methods of use related to biomarkers.

3. Nano-Machines and Molecular Manufacturing: Size Matters

Nanotechnology is another new area that has experienced rapid growth in recent years.¹⁰⁶ The area comprises numerous specialty applications and is highly variegated. The vision of nanotechnology was first articulated by Dr. K. Eric Drexler in a landmark paper published more than two decades ago.¹⁰⁷ One principal focus of this area is nano-machines and molecular manufacturing. Molecular manufacturing uses nano-machines to make products on an atomic scale.¹⁰⁸ These technologies and related applications turn on many established scientific and engineering disciplines, including physics, chemistry, computation, systems engineering, and biology. Researchers and businesses have been actively pursuing patent protection for inventions in this field. Vari-

104. A full treatment of this topic is outside the scope of this article.

105. 35 U.S.C. § 101 (2000) (specifying four patentable subject matters: process, machine, manufacture, and composition of matter).

106. See generally Foresight Institute website at www.foresight.org/NanoRev/index.html and Zyvex website at www.zyvex.com/nano/.

107. K. Eric Drexler, *Molecular Engineering: An Approach to the Development of General Capabilities for Molecular Manipulation*, 78 PROC. NAT'L ACAD. SCI. USA 5275 (1981).

108. While offering many benefits, this field also has environmental, medical, and security implications. Detailed analysis of these various aspects is beyond the scope of this article.

ous aspects of these inventions can be protected under the established patent framework as process, machine, manufacture, and composition of matter.¹⁰⁹

One unique question for nano-machines and molecular manufacturing systems is how to effectively define and protect a feature solely based on size and/or dimension. Not infrequently, the difference in size is found to be the only distinguishing feature between an innovative nano-machine and a prior art machine. The law contemplates a number of scenarios. For example, if the nano-machine and the prior art machine have the same structure and make-up, serve identical functions, and operate in substantially the same way, then the nano-machine probably would be obvious in view of the prior art machine, assuming that building the nano-machine does not involve undue experimentation. But if the difference in size lends the nano-machine certain characteristics and functions that are wholly missing from the prior art machine, then the nano-machine probably will pass muster under the obviousness test.¹¹⁰ The nano-scale in this situation brings about qualitative changes in the machine that warrant patent protection. Therefore, seemingly unique to nanotechnology, this question may be analyzed and resolved following the established patent doctrines based on the factual and technical specifics in a given case.

4. Regenerative Cloning: Patentable Subject Matters Revisited

Regenerative cloning is one kind of therapeutic cloning that enables protein engineering for use in regenerative medicine. It relates closely to tissue engineering, which is directed to long-term repair and replacement of failing human tissues and organs.¹¹¹ Cells—often stem cells—are cloned, cultured in the laboratory, and harvested, e.g., on a proper scaffold, and stimulated using certain growth or cell-signaling factors to form a type of tissue that mimics the structure and physiology of a natural tissue of interest, such as bone, nerve, and liver tissues. These engineered tissues or tissue cells can then be placed into a patient through tissue or organ implantation or cell injection.

Regenerative cloning and tissue engineering marks another new multidisciplinary field that promises to directly benefit peo-

109. 35 U.S.C. § 101 (2000).

110. *See* 35 U.S.C. § 103 (2000) (concerning non-obvious subject matter).

111. *See generally* McGowan Institute for Regenerative Medicine website at http://www.mirm.pitt.edu/programs/tissue_biomaterials/index.htm and the Imperial College London Tissue Engineering & Regenerative Medicine Centre website at <http://www1.imperial.ac.uk/medicine/about/divisions/is/tissue/>.

ple's health and well-being. It draws from material sciences, molecular biology, genetics, physiology, and biomedical engineering and obviously provides a rich soil for innovation. The field is also poised to become a significant profit center for healthcare, medical device, and biopharmaceutical industries. Patent protection may naturally play a role in the development and growth of this field. It should be noted, however, that the technologies and applications of regenerative cloning and tissue engineering are tied to stem cell research. Many issues concerning morality, ethics, religion, and privacy are implicated, beyond questions of patent law. Such a complex backdrop offers an opportunity to rigorously evaluate and test patentability and other patent law questions. Careful studies of the technologies and industrial applications in the field, and the related societal impact, will permit the PTO, the judiciary, and the legislature to make sound decisions on applications and reforms of patent law. Regenerative cloning is a cutting edge technology-based industry that will be at the forefront of the development of patent law.

B. Maturing Technologies and Industries

Section VI.A. above discusses the exciting developments in some of the cutting-edge technologies and their promising industrial potential. The established patent framework provides useful guidance and instruments for analyzing, understanding, and resolving issues specific to each new field. To promote continued innovation and efficient commercialization in these areas, it is clear that courts and the PTO, in applying patent rules and standards, ought to make special efforts to stay informed of technology advances and their commercial implications. Given the dynamic evolving nature of these technologies and their intricate multidisciplinary reach, any attempt to implement different patent standards for each of these fields will be an undertaking with impracticable means serving an unproductive end¹¹²—one destined for frustration and failure. By contrast, a winning recipe for the patent system to serve diverse technology industries is a consistent, tried and tested legal framework coupled with a seasoned understanding of relevant technologies and industries, whether emerging or maturing. This section further elaborates on the issue of technology-specificity in the application of patent law using two examples of more matured areas: biotechnology and software.

112. See *supra* sections III, IV, and V.A.

1. Biotechnology and Software: Much-Touted Differences

The treatment of biotechnology and software by the patent system has been the focal point of much research, which spawned the notion that patent law is applied unevenly to various technology fields.¹¹³ Some perceived that whereas for biotechnology inventions, the non-obviousness bar is very low and the disclosure requirement is stringent,¹¹⁴ by contrast, for software inventions, the non-obviousness bar is very high and the disclosure requirement is quite relaxed.¹¹⁵ This perception is not completely accurate.

To begin, the seemingly high non-obviousness bar in software makes sense because software patents protect underlying methods and architecture of software, not the specific coding or implementation. The latter is a subject of copyright protection. Given proper documentation of a requirement analysis, a system specification, and/or pseudo code, a skilled programmer can readily implement a software system.¹¹⁶ That is, programming details are generally transparent to those who are trained in the field of computer science and software engineering. For the same reason,

113. See generally Burk & Lemley (2002), *supra* note 17, at 1183; Wagner, *supra* note 49.

114. See, e.g., Imran Khaliq, *Defining and Defending Intellectual Property in Biotechnology*, 8 NO. 1 INTELL. PROP. L. BULL. 15 (2003) (quoting Burk and Lemley that: [i]n biotechnology cases, the Federal Circuit has repeatedly held that uncertainty in predicting the structural features of biotechnological inventions renders them non-obvious, even if the prior art demonstrates a clear plan for producing the invention. At the same time, the court claims that the uncertain nature of the technology requires imposition of stringent patent enablement and written description requirements that are not applied to patents in other disciplines.)

See also Amir A. Naini, *Convergent Technologies and Divergent Patent Validity Doctrines: Obviousness and Disclosure Analyses in Software and Biotechnology*, 86 J. PAT. & TRADE-MARK OFF. SOC'Y 541, 544–55 (2004).

115. Burk & Lemley (2002), *supra* note 17, at 1170–71 (stating that: [t]he Federal Circuit's treatment of software validity issues suggests that while the court will find relatively few software patents nonobvious, those that it does approve will be entitled to broad protection. The Federal Circuit's decisions strongly suggest that a patent is nonobvious only if it is the first program to perform a given function. Most patents will not meet this test, of course, but those that do will not be constrained by prior art to claim only their particular implementation of a function. They can claim the function itself. And the fact that they give little or no description of how to achieve this function will be no bar to the broad claims because the Federal Circuit has proven remarkably unwilling to require software patentees to disclose details.).

See also Naini, *supra* note 114, at 555–60.

116. Consider the rampant outsourcing practice where software development is contracted out to, for example, Eastern Europe and India.

software patent applications are not required to disclose coding details. Hence the seemingly low disclosure requirement. In sum, the perceived high non-obviousness bar and low disclosure requirement reflect nothing more than an inevitable consequence of sensible applications of the statutory framework in the software technology. Patent standards are not unduly bent or unevenly applied in this area.

Similarly, in biotechnology the level of disclosure required and the non-obviousness bar are and should remain only a function of the state of the art and the level of skill among bioengineers and scientists. The perceived stringent disclosure requirement for biotechnology inventions is an artifact due largely to a present divide in the patent bar concerning the statutory interpretation of the patent disclosure standard.¹¹⁷ The much-touted differential application of patent standards to software and biotechnology inventions reflects nothing more than the application of the law to each of these fields based on their respective state of the art and the skill level of ordinary engineers or scientists.

Notwithstanding some commentators' observations on the disparity in the application of the law,¹¹⁸ the ongoing scrutiny of biotechnology and software patent law tends to demonstrate that the same patent doctrines are adaptable to treat diverse technologies in a sensible and responsive manner.

VII. CONCLUSION

Today, as in the past, patent law is faced with new sciences and must deal with both emerging and mature technologies. The existing doctrinal framework, though it may appear strained, affords certain flexibility to treat innovations in diverse technology areas, whether incremental improvements or groundbreaking discoveries.

It is a normative debate whether patent law is or ought to be applied in a technology-neutral or technology-specific manner.¹¹⁹ Patent law by design deals with technologies. Whether in patent examinations, litigation, or transactions, a given set of facts identifies the technology to which patent law is specifically applied. Just as it is a truism that law is applied in a fact-specific manner, it is a truism that patent law is applied in a technology-specific manner.

117. A discussion of the disclosure standards for biotechnology inventions is included in section II.B *supra*.

118. *Supra* notes 113 and 114.

119. *Supra* note 19.

However, the patent statutory framework does not require specially-tailored rules or standards for specific technologies.¹²⁰

If there is a need to reform the United States patent system,¹²¹ it is not in injecting technology-specificity in patent rules or standards. Specially-tailored rules or standards would reduce the robustness of the patent framework. The rate at which such rules or standards are promulgated would never equal the rate of technology advances, leaving uncertainty and confusion in fledgling fields of science. Specially-tailored rules and standards may be quickly rendered obsolete by technology advances.¹²² Albeit well-intentioned, tailoring patent rules or standards for specific technologies may be counterproductive or even wholly wasteful.

It would be wise, however, for courts and the PTO to focus their efforts on understanding the nature and processes of discovery in various evolving technologies, as well as their industrial applications. Adhering to the established statutory framework and keeping informed by such understanding, the judicial and administrative applications of patent law would better cohere across multiple disciplines and better anticipate the advent of new sciences.

120. A special obviousness provision, with limited exceptions, was created for biotechnology. *See* 35 U.S.C. § 103(b) (2000). This provision is rarely used in practice. Also, a first-use defense to infringement is provided for business methods. *See* 35 U.S.C. § 273(a)(3) (2000).

121. Reform may be desirable in many areas. *See supra*, sections I and II. The merits of various proposals are outside the scope of this article.

122. *See, e.g.*, Semiconductor Chip Protection Act of 1984, 17 U.S.C. §§ 901–914 (2000).

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