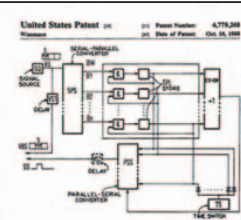
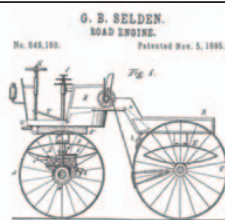
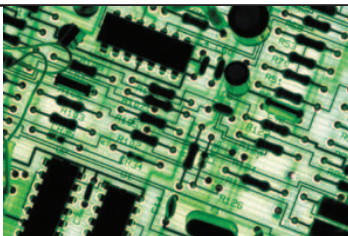




To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy

A Report by the Federal Trade Commission
October 2003



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Patent No. 4,805,654 - Sun Shield for Automobiles

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CHAPTER 4

COMPETITION PERSPECTIVES ON SUBSTANTIVE STANDARDS OF PATENTABILITY

Patent quality influences much of how the patent system and competition interact. The substantive standards and procedural criteria that govern patent rights have potentially significant and diverse competitive effects. In different settings, these patent rules may promote entry or give rise to market power. They may foster initial innovation, yet impede follow-on efforts. They may confer economic benefits or cause net economic harm.

Consequently, more patents in more industries and with greater breadth are not always the best answers for maximizing consumer welfare. A questionable patent can raise costs and prevent competition and innovation that otherwise would benefit consumers.¹ As Chapter 3 details, many panelists in knowledge-based industries such as biotech, computer hardware, and software asserted that, because of questionable patents, they must steer their innovative efforts away from potentially productive areas, accede to possibly unjustified licensing terms, or enter into cross-licensing agreements that effectively “contract out” of the patent system.

To understand patent quality, we look first to the substantive standards of patentability. They govern when to grant and uphold a patent as valid and how to determine the proper scope of a patent’s claims. The substantive standards of patentability manage the patent system’s “careful balance between the need to promote innovation and the recognition that

imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. . . .”²

We bring a competition perspective to bear on these issues. A competition perspective assumes consumer welfare over time as the goal of both competition and patent policy and reflects the application of economic analysis to patent issues.³ From a competition perspective, the standards for patentability should achieve four major policy objectives: (1) provide efficient incentives for innovation; (2) safeguard the patent system’s disclosure functions; (3) avoid unnecessary restraints on competition;⁴ and (4) minimize the sum of error and process costs and the detrimental effects of uncertainty.⁵

I. STATUTORY STANDARDS OF PATENTABILITY

A brief review of the statutory standards of patentability suggests that they are generally well-suited to achieve these

² *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

³ See *supra* Ch. 1.

⁴ For example, to avoid unnecessary restraints on competition, substantive patent standards should tend to support patentability only for those inventions that, “but for” the prospect of a patent, would not have been forthcoming as soon (or for which disclosure or commercial development would not have occurred as soon). See *supra* Ch. 1(I)(C)(1)(a).

¹ See generally Chs. 1-3.

⁵ See *supra* Ch. 1(IV)(B)(5).

four policy objectives.⁶ An invention must be novel⁷ – that is, “[t]o obtain a patent, you must do something *new*.”⁸ This requirement tends to exclude from patentability inventions that already exist and may be subject to competition. The requirement thus sets proper incentives for innovation – rewarding that which is new, not imitative – and avoids unnecessary restraints on competition.⁹ On the other end of the spectrum, the requirement that a claim must be “useful” tends to exclude areas of basic

research from patentability, thus leaving such matters available for the development of competing inventions.¹⁰

A claimed invention also must be nonobvious. Some describe the nonobviousness doctrine as “the heart of the patent law.”¹¹ It establishes a patentability step – a level of development beyond the prior art – that must be accomplished before a patent can issue.¹² As codified by Congress:

A patent may not be obtained . . . 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. . . .

35 U.S.C. § 103. A leading text explains, “Nonobviousness asks whether a development is a significant enough technical advance to merit the award of a patent”; it “can accurately be described as a

⁶ See also Box 4-1 for a summary of the statutory standards for patentability.

⁷ Section 102 of the Patent Act sets forth a variety of tests for novelty, such as whether “the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, . . .” 35 U.S.C. § 102(a). One eminent nineteenth-century treatise writer described “novelty” as the consideration that an inventor provides to society to obtain a patent:

An inventor does not become entitled to a patent merely by exercising his creative faculties in the production of an art [*i.e.*, process] or instrument. *The consideration for the grant of his exclusive privilege is the benefit which he confers upon the public by placing in their hands a means through the use of which their wants may be supplied.* If the same means has already been made available to them by the inventive genius of a prior inventor, . . . , no benefit results to them from his inventive act and there is no consideration for his patent. (Emphasis added).

1 WILLIAM ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 22 at 305 (1890), *cited in* ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 361 (3d ed. 2002).

⁸ MERGES & DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* at 361.

⁹ Novelty was not a major point of discussion during the Hearings and is not further addressed in this chapter. Thus, we do not discuss the complexities that can arise in the evaluation of whether a claimed invention is “novel.” See generally *id.* at 361-539.

¹⁰ 35 U.S.C. § 101. See generally MERGES & DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* at 254-58; ROGER E. SCHECHTER & JOHN R. THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK* §§ 15.1-15.3 at 315-21 (2003). See also *infra* Ch. 4(I)(D).

¹¹ *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Herbert C. Wamsley Testimony July 10, 2002, at page 20 (hereinafter, citations to transcripts of these Hearings state the speaker’s last name, the date of testimony, and relevant page(s)).

¹² See Stoner 3/36 at 117; Scotchmer 4/10 at 60-61, 69; Ted O’Donoghue, *A Patentability Requirement for Sequential Innovation*, 29 RAND J. ECON. 654, 657 (1998).

‘nontriviality’ requirement in patent law.”¹³ The requirement that an invention be nonobvious preserves the public domain by creating a patent-free zone around the existing state of the art.¹⁴

Properly applied, the “nonobviousness” requirement can ensure that the patent system avoids patents that “hav[e no] social benefit[,] because . . . others would have developed the idea even without the incentive of a patent.”¹⁵ The “nonobviousness” requirement also can

patents and avoiding royalties on obvious inventions,¹⁶ and can avoid the costs of granting obvious patents, which “may create a proliferation of economically insignificant patents that are expensive to search and to license.”¹⁷

A patent application also must meet certain disclosure requirements. A patentee must disclose the invention clearly enough so that one skilled in the art can understand it well enough to make and use it without having to undertake undue

Box 4-1. The Statutory Standards for Patentability

Patent law establishes the standards of patentability against which the PTO measures a patent application. These standards ask whether the claimed invention is:

- **patentable subject matter** under 35 U.S.C. § 101 (basically processes, machines, manufactures, and compositions of matter);
- **novel** under 35 U.S.C. § 102, which requires that the invention not be wholly anticipated by prior art or public domain materials;
- **nonobvious** under 35 U.S.C. § 103, which requires the invention to be beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field;
- **useful** under 35 U.S.C. § 101, which means the invention must be minimally operable towards some practical purpose; and
- whether the application meets the **disclosure requirements** under 35 U.S.C. § 112 by: (i) so completely describing the invention that skilled artisans are enabled to practice it without undue experimentation; (ii) providing a description sufficient to ensure that the inventor actually has invented what the patent application claims; and (iii) containing distinct, definite claims that set out the proprietary interest asserted by the inventor. *See generally* ROGER E. SCHECHTER & JOHN R. THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS* § 13.1 at 282 (2003).

provide undiluted incentives for inventors to create nonobvious inventions, by prohibiting

experimentation.¹⁸ This “enablement” requirement tends to safeguard the patent system’s disclosure function by ensuring relatively swift dissemination of technical information from which others in the art can

¹³ See MERGES & DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* at 644.

¹⁴ See Thomas 2/8 (Patent Session) at 57; SCHECHTER & THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK* § 17.1 at 370-71.

¹⁵ MERGES & DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* at 646 (citations omitted).

¹⁶ See *id.* at 646-47.

¹⁷ *Id.* at 647. See generally *supra* Ch. 3(IV) and (V).

¹⁸ See 35 U.S.C. § 112.

learn.¹⁹ The disclosure also must include a “written description” sufficient to show that the applicant was in possession of the claimed invention as of the applicant’s filing date.²⁰

Apart from some misgivings about the written description requirement,²¹ no one at the Hearings disputed the usefulness or analytical aptness of these statutory criteria for patentability. Rather, the Hearings record tends to support a conclusion that the statutory standards for patentability account for competitive issues and do not require changes.²² Panelists did not perceive the statutory standards of patentability themselves as sources of problems with patent quality or adverse competitive effects.

¹⁹ See generally MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 259-60. See *supra* Ch. 1(I)(A)(2) and (IV)(B)(2) and *infra* Ch. 4(II)(B).

²⁰ 35 U.S.C. § 112.

²¹ See, e.g., Janis 4/10 at 119-20 (stating that the written description requirement has been very difficult for the Federal Circuit to characterize in any meaningful way and that efforts to elucidate this requirement detract attention from enablement, which could be used more effectively); Thomas 4/10 at 128-30 (questioning the administrability of the written description requirement).

²² See *infra* Ch. 4(II); American Intellectual Property Law Association (AIPLA), *AIPLA Testimony* (Public Comment) 16, at <http://www.ftc.gov/os/comments/intelpropertycomments/aip la.pdf>; Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 16, at <http://www.ftc.gov/os/comments/intelpropertycomments/ipo .pdf> (hereinafter IPO (stmt)).

II. THE INTERPRETATION AND APPLICATION OF THE STANDARDS OF PATENTABILITY

Hearings participants did raise questions and concerns about the interpretation and application of certain statutory standards, however. This Section considers these topics in turn, discussing the competitive implications of each doctrine and summarizing and examining testimony to identify both areas of harmony and points of concern. When the system is functioning well, from a competition perspective, the discussion highlights the reasons for harmony. When problems are evident, it offers recommendations for taking better account of competition considerations within the patent system. When difficulties may be emerging, it identifies relevant issues and suggests appropriate precautions.

A. The Interpretation and Application of the Nonobviousness Requirement

1. Significance for Innovation and Competition

The nonobviousness doctrine establishes a patentability step – a level of development beyond the prior art – that must be accomplished before a patent can issue. The interpretation and application of this doctrine can have a variety of effects on innovation and competition. To begin, the size of the required patentability step affects the innovation incentives of both initial and follow-on innovators. For the initial innovator, the size of the required patentability step affects the extent to which

it must share revenues with independent improvers; if the required step is too small, for example, an initial inventor must split royalties with improvers that otherwise could not patent in the “obvious” area around the initial patent.²³ For follow-on innovators, the size of the step required for patentability affects the choice between seeking ambitious or niche improvements.²⁴

Second, a lax nonobviousness standard can generate proliferation or clutter problems — the thickets, minefields, royalty stacking, anti-commons, and flooding problems identified by various panelists.²⁵ A profusion of minor patents can significantly limit freedom of operation and require costly licensing negotiations.²⁶ In some settings, such as in semiconductors, these hurdles may be inevitable to some degree,²⁷ but in other

contexts the choice of obviousness standard may affect whether proliferation evolves.²⁸

Box 4-2. Nonobviousness and Potential Competitive Concerns

The nonobviousness standard defines the *level of development beyond the prior art* required for a patent to issue — that is, *the size of the required patentability step*. The size of the required patentability step can affect:

- innovation incentives of initial and follow-on inventors (who gets what rewards in what proportions?);
- the extent of patent proliferation problems (*e.g.*, if only a small step is required for patentability, a profusion of minor, “obvious” patents may require costly licensing negotiations and limit future firms’ freedom of design); and
- the extent of any patent-related market power (a patent on a technically trivial development sometimes can create significant market power, but withholding patent protection from entrants through an overly rigorous nonobviousness standard may delay their contribution to competition).

²³ See generally Duffy 7/10 at 113 (lax nonobviousness doctrine “not pro-inventor . . . because it can decrease the royalties to . . . people who really did invent”) and Duffy 10/30 at 110 (stating same principle).

²⁴ See Scotchmer 4/10 at 70. Follow-on innovators may be less likely to develop inventions that clearly fall short of that patentability step; without their own patent rights, such trivial improvers could face appropriation of their inventions by the initial innovator. See Scotchmer 4/10 at 69-70. Of course, to the extent that other appropriability mechanisms, such as first-mover advantages, are effective, the improver retains some incentive to develop follow-on inventions.

²⁵ See, *e.g.*, Duffy 10/30 at 63; Stoner 10/30 at 58; *supra* Chs. 2 and 3.

²⁶ See, *e.g.*, Duffy 7/10 at 110 (swarm of paltry patents may constitute a minefield). For discussion of issues that may be raised by a profusion of patents within a given industry, see *supra* Chs. 2(III)(C) and 3(IV) and (V).

²⁷ Several panelists indicated that technological limitations, the high ratio of patents to products, and the incremental nature of the innovation process all would contribute to the development of thickets in semiconductors irrespective of particular patent policies. See, *e.g.*, Detkin 2/28 at 668-70 (technological advance has led to

Third, either an overly lax or overly restrictive nonobviousness standard may result in unwarranted market power. A patent on a technically trivial development can sometimes create significant market power.²⁹ When market power already is

consolidation of multiple functions on single chips and “[t]here’s only a certain number of ways that you can connect transistors together,” resulting in “unavoidable overlap”); Poppen 2/28 at 712 (semiconductor thickets largely a result of the technology); Lemley 2/25 at 39 (noting high ratio of patents to product); Fox 2/28 at 714-15 (stressing incremental inventions).

²⁸ See, *e.g.*, Barton 2/26 at 223. Indeed, the ability to surround a competitor’s initial patent with technically trivial variants is a key element in flooding strategies. See *supra* Ch. 2(III)(C)(6).

²⁹ See, *e.g.*, R. Levin 2/6 at 102 (warning that market power can be a potentially serious consequence of a low threshold for patenting); Duffy 7/10 at 110-13

present, rather trivial patents may help to maintain or extend it. Thus, some panelists explained, portfolios of patents might be used to add breadth to an existing patent, creating a fence around its zone of exclusion.³⁰ Others suggested that existing market power may be extended beyond the life of the initial patent through an accumulation of minor improvement patents,³¹ although such an extension would require some reason why competitors offering the now-unpatented core product could not adequately constrain pricing of the slightly improved version still protected by patents.³² An overly rigorous nonobviousness standard may have its own market power effects; to the extent that withholding patent protection delays competition from entrants, an initial innovator's dominance may be extended.³³

("technical triviality does not at all equal economic triviality," citing the example of the Selden patent on the automobile).

³⁰ See, e.g., Cohen 2/20 at 31 and Wesley M. Cohen, *Patents: Their Effectiveness and Role* (2/20/02) (slides) at 14 (patents used to block substitutes by creating fences around core innovations), at <http://www.ftc.gov/opp/intellect/cohen.pdf>; Merges 2/26 at 162-65 (portfolios can add breadth); *supra* Ch. 2(III)(C)(5) (discussing patent fences).

³¹ See, e.g., Coffin-Beach 3/19 at 204-05; Scherer 7/10 at 180.

³² See *supra* Ch. 2(III)(C)(5) (discussing patent extensions).

³³ See Merges 2/28 at 581-82; Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* (Public Comment) 2 (under a strong nonobviousness requirement "[c]ompeting proprietary technologies take longer to accumulate so the patent holder's profits are larger and last longer"), at <http://www.ftc.gov/os/comments/intelpropertycomments/nonobviousness.pdf> (hereinafter Hunt (Nonobviousness stmt)); O'Donoghue, 29 RAND J. ECON. at 656.

2. Analytic Tools to Balance Patent and Competition Concerns

In the context of nonobviousness, "but for" thinking may be useful to better align patent law with competition policy. The concept is simple: to ask whether an invention likely would emerge in roughly the same time frame – that is, without significant delay – "but for" the prospect of a patent. Analogously, one can ask whether disclosure and commercial development of the invention would have occurred as soon "but for" the prospect of a patent. As a theoretical matter, if, even without the prospect of a patent, the invention would emerge (and would be disclosed and commercially developed) without significant delay, then the invention does not warrant a patent.³⁴

This test has roots in patent law: when a patent elicits little social benefit – such as when the invention could be expected anyway – patent law recognizes that withholding the patent and avoiding any costs to innovation and competition will maximize consumer welfare over time.³⁵ The test also accords with long-established

³⁴ See *supra* Ch. 1(I)(C)(1)(a). See Glynn S. Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363, 386 (2001); F. M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 443 (2d ed. 1980).

³⁵ See *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966) ("The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."); Edmund W. Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUP. CT. REV. 293, 301 (stating – prior to developing his prospect theory – "the basic principle on which the non-obviousness test is based: a patent should not be granted for an innovation unless the innovation would have been unlikely to have been developed absent the prospect of a patent"); 1 ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22 at 305, cited in MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 361; see generally *infra* Ch. 6.

modes of antitrust analysis: antitrust law is accustomed to comparing the world with and without a suspect transaction.³⁶ To the extent that patent law confers its right to exclude only if necessary to create, disclose, or develop an invention, congruence between patent and competition policy is more likely.³⁷

As noted earlier, application of the “but for” principle generally will not work in individual cases.³⁸ Some advances may be

³⁶ In evaluating mergers, the Antitrust Enforcement Agencies consider only merger-specific efficiencies, *i.e.*, only the efficiencies that are unlikely to be accomplished without either the merger or some other means having comparable anticompetitive effects. Federal Trade Commission and U.S. Department of Justice, Horizontal Merger Guidelines § 4 (1992), *available at* <http://www.ftc.gov/bc/docs/horizmer.htm>. In evaluating competitor collaborations under the rule of reason, “the central question is whether the relevant agreement likely harms competition by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of the agreement.” Federal Trade Commission and U.S. Department of Justice, Antitrust Guidelines for Collaborations Among Competitors § 3.1 (April 2000), *available at* <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

³⁷ Some tensions could still persist. The “but for” test states at most a necessary, not a sufficient, condition for patentability. An invention worth developing solely because of competitive advantages conferred by its patent rights could raise exclusionary concerns, yet would pass through a “but for” screen.

³⁸ The panelists widely recognized the standard’s unsuitability for practical application. *See, e.g.*, Banner 10/30 at 71-72 (giving the concept a “D” as a practical test in light of the difficulties that it would pose for judge or jury); Myrick 10/30 at 60 (“unworkable”); John Love 2/28 at 635 (concern with imposing another level of uncertainty and complexity on examiners); Stoner 10/30 at 58 (need a “more practical sieve”); Kitch 10/30 at 51 (“but for” thinking not a test for application “on a retail basis” to individual innovations); *see also* Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L. J. 1, 19 (1992) (describing the “but for” test as “the conventional ideal standard of patentability” but concluding, “It would be impossible in most cases to apply

ripe due to underlying technological or regulatory change and would flow without patent protection.³⁹ Other inventions may require substantial fixed costs and would not be forthcoming without the shelter from imitation that patent protection affords.⁴⁰ Distinguishing these situations through case-by-case inquiry would be costly, time-consuming, and prone to error. Indeed, sorting out the need for any given patent might prove impossible when multiple inventions flow from a single research program. Moreover, if the cost of invention is much less than the subsequent cost of developing a commercial product, a “but for” test would have to consider whether the innovation would be commercially developed absent the patent.⁴¹ “But for”

this standard”); *supra* Ch. 1(I)(C)(1)(a).

³⁹ *See* Duffy 7/10 at 113-15 (suggesting that some methods may have become obvious once the Internet developed and that a combination of ibuprofen and a common cold remedy could be expected once ibuprofen became an over-the-counter drug); Fox 2/28 at 715 (constantly seeing multiple inventors independently coming up with the same invention once the “logical bases for that invention come into place”).

⁴⁰ *See, e.g.*, Merges 2/28 at 580-81 (noting that “though something is extremely straightforward technically, it may be very very expensive to achieve” and urging that the nonobviousness standard take that into account); Merges, 7 HIGH TECH. L. J. at 48-50 (urging a relaxation of nonobviousness standards when R&D is very costly, in order to compensate for effects of risk aversion that might otherwise make innovation less likely). Any cost analysis would have to consider risks of failure, as well as cost in an individual case, lest only the cost of the one success in a field be counted. *See* Scherer 7/10 at 127-28; Duffy 7/10 at 132. The analysis also should not penalize the efficient inventor, whose cost will be less than the norm. *See* Kitch 10/30 at 51-52.

⁴¹ *See, e.g.*, Sobel 7/10 at 124-26; Scherer 7/10 at 126-27; Burk 7/10 at 129; Lunney 7/10 at 130-31; Dreyfuss 7/10 at 141-42 (adjust test to focus directly on risk of development). *But cf.* Duffy 10/30 at 133 (questioning whether patent system is really intended to encourage investment following the granting of the patent and

thinking also can account for the patent system's disclosure objectives, but further adjustments would be necessary.⁴²

Yet the Hearing record as a whole showed very substantial support for “but for” thinking as an idealized, foundational principle⁴³ that can be a useful tool for shaping general policy analysis.⁴⁴ We will return to it after a review of current interpretations and applications of the nonobviousness doctrine.

3. Nonobviousness: Interpretation and Application in the Courts

Participants generally perceived a

suggesting that post-invention investments can be protected by subsequent patents).

⁴² In fact, the patent system's disclosure function is reflected in the Supreme Court's language in *Graham* describing “the inherent problem” in formulating standards of patentability as “develop[ing] some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.” *Graham*, 383 U.S. at 11 (emphasis added). See Lunney, 7 MICH. TELECOMM. & TECH. L. REV. at 385-86 (phrasing a “but for” standard in terms of whether the invention “would have been developed, commercialized and disclosed even without a patent”) (emphasis added). If the patent system is viewed as a mechanism for increasing the efficiency of post-invention development, neither the “but for” test nor the obviousness standard may have a logical role. See Kitch 2/20 at 84-85; Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. LAW & ECON. 265, 284 (1977) (urging “substantial novelty” as the standard for patentability under the prospect theory).

⁴³ Herbert Wamsley summarized, “I suspect that everybody on this panel agrees that we should have a . . . test, one that finds nonobvious only inventions that wouldn't have been made otherwise or for which there's some incentive needed.” Wamsley 7/10 at 139.

⁴⁴ As James Pooley concluded, “The ‘but for’ standard strikes me as a useful analytic tool to sort of check our direction in a policy sense, but not a particularly useful standard for measuring specific inventions.” Pooley 10/30 at 55.

trend since the advent of the Federal Circuit toward reducing the size of the step required for patentability – that is, reducing the rigor of the nonobviousness standard.⁴⁵ Several participants voiced concern about too great an issuance of obvious patents.⁴⁶ Panelists

⁴⁵ See, e.g., R. Levin 2/6 at 102-03 (nonobviousness standard “diluted”); Kitch 2/20 at 68 (Federal Circuit has “seemed to soften the non-obviousness test”); Lunney 7/10 at 97-99 and Glynn S. Lunney, Jr., *Patents, the Federal Circuit, and the Simply Property Perspective* (7/10/02) (slides) at 13, at <http://www.ftc.gov/opp/intellect/020710glynnslunneyjr.pdf>; Duffy 7/10 at 185; Dreyfuss 7/10 at 196-97; Hunt (Nonobviousness stmt) 2, 8; Cecil D. Quillen, Jr., *The U.S. Patent System: Is It Broke? And Who Can Fix It If It Is* (Public Comment) 3-5, at <http://www.ftc.gov/os/comments/intelpropertycomments/quillenattachments/isitbrokewhocanfixit.pdf> (hereinafter Quillen (U.S. Patent System stmt)); see also Lunney, 7 MICH. TELECOMM. & TECH. L. REV. at 366-80; Gerald Sobel, *The Court of Appeals for the Federal Circuit: A Fifth Anniversary Look at its Impact on Patent Law and Litigation*, 37 AM. U. L. REV. 1087, 1089 (“a climate more favorable to upholding the validity, and particularly the non-obviousness of patents has emerged”); Charles Weller, *Patent Reform by Daubert Litigation*, 2 EXPERT EVIDENCE REPORT 232, 234-35 (2002) (Public Comment), at <http://www.ftc.gov/os/comments/intelpropertycomments/weller2.pdf>. But see Polk 2/20 at 71-72 (nonobviousness standard has become “more uniform” but has not been lessened). Some of the panelists found the trend toward a less rigorous nonobviousness standard particularly pronounced in biotechnology contexts. See Kunin 7/10 at 27-28 (in biotechnology Federal Circuit has made it “fairly easy to pass muster” under nonobviousness requirement); Burk 7/10 at 29; Arti Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999) (“In considering DNA-based inventions, the CAFC has employed nonobviousness in a manner that dramatically lowers the bar for patentability and, therefore, significantly impoverishes the public domain.”); cf. Dreyfuss 7/10 at 141-42 (“a lot of the watering down on nonobviousness has come in the chemical field”).

⁴⁶ See, e.g., Ziedonis 3/20 at 16 (consistent view expressed in semiconductor industry interviews was that “if we had to change one thing, let's just make it a little harder to get all of these very trivial inventions coming out from the patent office”); Scherer 7/10 at 53 (“the inventive content of the average U.S. patent is quite low”); Kohn 2/27 at 413; T.S. Ellis 7/11 at 109; John H. Barton, *Reforming the Patent System* (Public Comment) 1-2, at

spoke of serious clutter problems and issues involving market power maintenance and extension.⁴⁷

Participants viewed the Federal Circuit’s application of its “suggestion test” and its treatment of secondary factors such as “commercial success” as applications of nonobviousness doctrine that can result in “obvious” patents. As interpreted by the Supreme Court in *Graham*, nonobviousness requires a three-part inquiry:

the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.⁴⁸

Although the Court lists the key elements, it does not tell how to apply them.⁴⁹ The Federal Circuit has filled the gap in part through its “suggestion” test, which focuses on the extent to which “the prior art would have *suggested* to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of

<http://www.ftc.gov/os/comments/intelpropertycomments/bar-tonjohnh.htm>; Cecil D. Quillen, Jr., *Testimony of Cecil D. Quillen, Jr. Presented at the Public Hearing on the Standard of Nonobviousness* (Public Comment), at <http://www.ftc.gov/os/comments/intelpropertycomments/quillenattachments/nonobviousness.pdf>; Eric Buddington, *Comments Regarding Competition and Intellectual Property* (Public Comment) 1, at <http://www.ftc.gov/os/comments/intelpropertycomments/buddingtoneric.pdf>.

⁴⁷ See *supra* Ch. 4(II)(A)(1).

⁴⁸ *Graham*, 383 U.S. at 17.

⁴⁹ See Duffy 7/10 at 116 (“[T]hese primary factors . . . sort of leave you off at the very point you think the analysis should start.”).

success”⁵⁰

The Supreme Court’s *Graham* opinion also identified a number of “*secondary considerations*,” including “commercial success, long felt but unsolved needs, [and] failure of others,” that “may have relevancy” as “indicia of obviousness.”⁵¹ The Federal Circuit has required consideration of any evidence of these secondary characteristics and, at times, has given them considerable weight as means for overcoming what might otherwise be a *prima facie* case of obviousness under the primary *Graham* factors.⁵²

a. *Nonobviousness and the “Suggestion Test”*

Section 103 requires two basic inquiries to determine “nonobviousness.” First, what is the prior art for the claimed invention?⁵³ Prior art typically consists of documents – often patents and publications, although affidavits and testimony also may

⁵⁰ *Brown and Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000) (emphasis added).

⁵¹ *Graham*, 383 U.S. at 17-18 (emphasis added).

⁵² See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) (“Objective evidence [i.e., evidence of secondary considerations] . . . must be considered *before* a conclusion on obviousness is reached and is not merely ‘icing on the cake’”) (emphasis in original); *cert. denied*, 480 U.S. 947 (1987); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (“evidence rising out of the so-called ‘secondary considerations’ must always when present be considered”).

⁵³ See 35 U.S.C. § 103 (inquiry focuses on “differences between the subject matter sought to be patented and the prior art”); see, e.g., Kesan 4/10 at 88 (“That’s the first thing, knowing what the prior art is.”).

present prior art⁵⁴ – that reflect one or more of the features or elements of the claimed invention. Comparing the claimed invention to the prior art requires identifying the major features of the claimed invention and determining the extent to which those features already exist in the prior art.⁵⁵ Second, what “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[?]”⁵⁶ Patent practitioners sometimes shorten the term “person having ordinary skill in the art” to “PHOSITA.”⁵⁷

Sometimes all of the elements of a claimed invention exist not in any one document, but in a combination of different prior art references.⁵⁸ For example, in one case, the PTO rejected as obvious a patent application for a plastic orange garbage bag decorated with a face and lines that would look like a jack-o-lantern when filled with

trash or leaves. There were four prior art references – two about conventional trash or lawn bags, and two about children’s art projects to make jack-o-lanterns. When combined, these four prior art references held all of the major elements of the claimed invention. That fact alone was insufficient to meet the Federal Circuit’s suggestion test, however, and thus did not establish obviousness.⁵⁹

In discussing the decision of the Board of Patent Appeals and Interferences, which upheld the examiner’s rejection of the patent application as obvious, the Federal Circuit stated:

Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the children’s art references . . . with the conventional trash or lawn bag references, nor does the Board make specific – or even inferential – findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness

⁵⁴ See, e.g., *Sakraida v. Ag Pro Inc.*, 425 U.S. 273, 280 (1976) (“The scope of the prior art was shown by prior patents, prior art publications, affidavits of people having knowledge of flush systems analogous to respondent’s, and the testimony of a dairy operator with 22 years of experience who described flush systems he had seen on visits to dairy farms throughout the country.”).

⁵⁵ See, e.g., MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 44-48 (in drafting a patent around the prior art, “[i]t is often useful to construct a table listing the major features or elements of the invention and showing which of those features are shared by items in the prior art”).

⁵⁶ See 35 U.S.C. § 103; Kesan 4/10 at 88 (“secondly, what is a person in that field, what do they think of that prior art.”).

⁵⁷ See Kieff 4/10 at 77.

⁵⁸ If all of the elements already exist in a single prior art reference, “that’s anticipation and we’re done.” See Kieff 4/10 at 80.

⁵⁹ *In re Dembiczak*, 175 F.3d 994 (1999). Accord, *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) (“It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, *absent some teaching or suggestion, in the prior art, to combine the elements.*”) (emphasis added). See, e.g., Thomas 2/8 (Patent Session) at 56-57; Duffy 7/10 at 117. Similarly, the PTO must identify a suggestion, teaching, or motivation for modifications to a piece of prior art before declaring such modifications obvious. See John F. Duffy, *Nonobviousness: The Economics and Legal Process of the Doctrine* (7/10/02) (slides) at 14, at <http://www.ftc.gov/opp/intellect/020710johnfduffy.pdf> (hereinafter Duffy Presentation).

analysis.⁶⁰

This is one in a line of recent cases in which the Federal Circuit has rigorously imposed the suggestion test in overturning PTO findings of obviousness.⁶¹

(i). Hearings Record

Panelists identified the Federal Circuit's application of the "suggestion test" as a core issue in assessing nonobviousness and a focal point of current debate.⁶² As PTO Deputy Commissioner for Patent Examination Policy Stephen Kunin phrased it, the Federal Circuit is insisting that the PTO find "the glue expressly leading you all the way" and that it "connect the dots . . . very, very clearly"⁶³

⁶⁰ *In re Dembiczak*, 175 F.3d at 1000.

⁶¹ See *In re Sang-Su Lee*, 277 F.3d 1338 (Fed. Cir. 2002) (rejecting the PTO's finding that a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust those functions was obvious in light of separate prior art references describing (i) a television set with a display for adjusting audio and video functions and (ii) a video game display with a "demonstration mode" showing how to play the game); *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001); *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000); Wamsley 7/10 at 19-25; Kunin 4/10 at 47. Stephen Kunin cited the pre-Federal Circuit opinion *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981), which stated that "the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art," and concluded that "with [recent] cases like *Dembiczak* and *Kotzab*" it's like the approach based on the collective suggestion of the references "never existed in the law." Kunin 4/10 at 47; 7/10 at 137. See *infra* at Ch. 4(II)(A)(3)(a)(i).

⁶² See, e.g., Chambers 2/8 (Patent Session) at 98-99 ("from the standpoint of obviousness that's usually what the argument is about"); Duffy 7/10 at 117-18 ("suggestion test . . . has become extremely important"); Wamsley 7/10 at 19-25.

⁶³ Kunin 7/10 at 137.

Hearings participants generally agreed that the Federal Circuit's suggestion test asks a helpful question – *i.e.*, to what extent would the prior art "have *suggested* to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success"⁶⁴ Nonetheless, they disagreed with the Federal Circuit's recent applications of the test, which seem to require "specific and definitive [prior] art references with clear motivation of how to combine those references."⁶⁵ To illustrate problems with the "suggestion test," Professor Duffy pointed to the Selden patent on the automobile. Assuming that Selden was the first to mount the newly developed gasoline engine on a carriage, no specific prior art would have suggested the mounting, yet it is something that likely was obvious:

Everybody seemed to know that if you got a new engine of any kind, you would put it on a carriage. That's the first thing that people did with just about any kind of engine, put it on a carriage with some gears and see how it works.⁶⁶

Participants noted that Federal Circuit articulations of the suggestion test are not uniformly rigid. The court sometimes has stated that the suggestion need not be express, but can be "implicit from the prior art as a whole," or may come from "the knowledge of one of ordinary skill in the art" or from "the nature of the problem to be

⁶⁴ *Philip Morris*, 229 F.3d at 1124 (emphasis added).

⁶⁵ *Dickinson* 2/6 at 66.

⁶⁶ See Duffy 7/10 at 132-33.

solved.”⁶⁷ Nonetheless, commentators such as Professor Duffy noted that references to implicit suggestions and suggestions from the nature of the problem to be solved may be “a point in the case law,” but “not perhaps the feel of the case law.”⁶⁸ Criticisms of recent opinions focus on the rigorous manner in which the Federal Circuit has applied the suggestion test, rather than the totality of the court’s language.

Stephen Kunin contrasted some of the recent applications of the suggestion test with earlier interpretations that “would permit one . . . to look at the information from the perspective of one of ordinary skill in the art” and “glean the information . . . with some level of technical knowledge and skill.”⁶⁹ As another panelist, Kenneth Burchfiel, has written, “the court’s frequent emphasis on ‘motivation’ from the teachings of the prior art bypasses the knowledge of those of ordinary skill in the art, and restricts the obviousness inquiry to a literal reading of the disclosure of the prior art.”⁷⁰ Summing

up these developments, former PTO Director Q. Todd Dickinson stated:

[T]he courts have required the Office to apply only specific and definitive art references with clear motivation of how to combine those references, and only that will suffice for this obviousness determination. . . . [T]he examiner could not even rely on the general knowledge that the examiner had in the field or even common sense for an obviousness determination.⁷¹

Several panelists recommended that the test be moderated.⁷²

(ii). Analysis

Policy Issues. The Federal Circuit has repeatedly sought to protect inventors from findings of obviousness based purely on hindsight. “Good ideas may well appear ‘obvious’ after they have been disclosed, despite having been previously unrecognized.”⁷³ As Judge Newman of the

⁶⁷ *Kotzab*, 217 F.3d at 1370; see *In re Huston*, 308 F.3d 1267, 1280-81 (Fed. Cir. 2002) (quoting some of the same language from *Kotzab* reproduced in the text but finding adequate motivation in the prior art references themselves); *In re Thrift*, 298 F.3d 1357, 1363 (Fed. Cir. 2002) (same). See generally *In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003) (explaining that absent legal error or contrary factual evidence, the PTO’s determination of the meaning of prior art references and the motivation to make the claimed invention that those references provide can establish a *prima facie* case of obviousness).

⁶⁸ See Duffy 7/10 at 119.

⁶⁹ Kunin 7/10 at 137.

⁷⁰ KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 84 (1995) (footnote omitted). See generally Barr 10/30 at 53-54 (arguing that current obviousness standards fail to reflect the skill of his firm’s engineers, who “every day” independently invent things that have been deemed nonobvious); Quillen (U.S. Patent

System stmt) 4 (criticizing the Federal Circuit’s treatment of the person of ordinary skill in the art as “a literalist, without imagination or creativity . . . who is incapable of considering collectively the combined teaching of relevant prior art references unless ‘motivated’ to do so by explicit directions in the references themselves”).

⁷¹ Dickinson 2/6 at 66.

⁷² See, e.g., Duffy 7/10 at 120-21 and Duffy Presentation at 17; Wamsley 7/10 at 154-55; Banner 10/30 at 73-74; cf. Gambrell 10/25 at 19 (insistence on express references leads to patents that should not be issued); Merges 2/28 at 631 (implicit in the Supreme Court’s *Graham v. John Deere* analysis is a “rejection of some of the more extreme Federal Circuit cases on the so-called suggestion test”).

⁷³ *Arkie Lures, Inc.*, 119 F.3d at 956.

Federal Circuit noted at the Hearings, many patents are attacked on grounds of obviousness. “It’s fuzzy ground. It’s hard to decide, difficult to administer, even harder to set.”⁷⁴ Thus, Federal Circuit “case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”⁷⁵ Otherwise, the Federal Circuit has said, “[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.”⁷⁶ In addition, the Federal Circuit’s application of the suggestion test arguably has the virtue of certainty and predictability,⁷⁷ and it helps to ensure fulfillment of the PTO’s “obligation to develop an evidentiary basis for its findings.”⁷⁸ One can readily see the validity

of the Federal Circuit’s concerns.

Yet, there are competing, and competitive, concerns to weigh on the other side of the ledger. A demand for specific and definitive motivating prior art references effectively raises the bar for finding obviousness⁷⁹ – thus permitting more patents to issue – and does so in a way that raises competitive concerns to the extent that it violates “but for” principles. As noted earlier, “obvious” patents can convey market power or provide means for its extension and can contribute to a proliferation of patents that increase search and licensing costs unnecessarily, so a standard that fails to weed out patents on obvious inventions can cause competitive harm.⁸⁰ Whether the goal is protecting against judgments based on hindsight or ensuring reviewable administrative records, a standard that requires suggestions or motivations exceeding what inventors actually need, or that rigidly insists upon concrete documentation of facts that by their very nature are not concretely demonstrable, could impair competition.

Interpretation of Section 103. Some of the patents recently upheld as nonobvious under the suggestion test may be obvious under the statutory standards. As noted in Professor Duffy’s example of the Selden automobile patent, an invention may be obvious even if the combination of elements

⁷⁴ Newman 2/6 at 45.

⁷⁵ *In re Dembiczak*, 175 F.3d at 999 (citing cases).

⁷⁶ *Id.*; see also *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).

⁷⁷ One panelist praised the Federal Circuit’s interpretations as “relatively crisp and objective and relatively easy to apply.” Kieff 4/10 at 81. Another panelist, however, expressed doubt that application of the test would really be so clear-cut in practice. See Katsh 4/10 at 90-93.

⁷⁸ See *In re Sang-Su Lee*, 277 F.3d at 1344. Following the Supreme Court’s determination that review of PTO findings of fact ought to proceed under the “substantial evidence test” rather than the less deferential “clearly erroneous” test, see *Dickinson v. Zurko*, 527 U.S. 150 (1999), the Federal Circuit has stressed the need for the PTO to ensure that each administrative record is amenable to review. See *In re Sang-Su Lee*, 277 F.3d at 1342, 1344-45; *In re Zurko*, 258 F.3d at 1385-86 (requiring “concrete evidence in the record” rather than “general conclusions

about what is ‘basic knowledge’ or ‘common sense’” for interpreting the consequences of particular items of prior art).

⁷⁹ See Kunin 4/10 at 47 (“cases like *In re Kotzab*, *In re Sang Lee* . . . make[] it extremely difficult to satisfy a 103 [obviousness] standard”).

⁸⁰ See *supra* Ch. 4(II)(A)(1).

that it reflects was not specifically suggested or motivated in any prior art. The combination may nonetheless be “obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”⁸¹ Some applications of the suggestion test, however, appear almost to have read the PHOSITA out of the statute.⁸² Inventive processes typically involve judgment, experience, and common sense capable of connecting some dots. The suggestion test, rigidly applied, assumes away a PHOSITA’s typical levels of creativity and insight and supports findings of nonobviousness even when only a modicum of additional insight is needed.

Indeed, too rigorous an application of the “suggestion” test can operate as a one-way ratchet: it can help confirm obviousness, but it does not necessarily identify nonobviousness. The presence of “specific and definitive art references with clear motivation of how to combine those

references”⁸³ may confirm the obviousness of an invention. In contrast, the absence of such prior art references does not provide any evidence about whether a PHOSITA could have combined prior art references to achieve the invention, given the typical level of insight in that field. In sum, the suggestion test, as it has been applied in some cases, seemingly understates levels of ordinary skill, awards patents for inventions that inevitably would be forthcoming, and potentially confers market power when competition need not be sacrificed.

In one very recent case, the Federal Circuit appears to have moved away from rigid application of the suggestion test, stating:

As persons of scientific competence in the fields in which they work, examiners and administrative patent judges on the Board [of Patent Appeals] are responsible for making findings, informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art and the motivation those references would provide to such persons. Absent legal error or contrary factual evidence, those findings can establish a *prima facie* case of obviousness.⁸⁴

This more flexible articulation might signal an approach that would better enable

⁸¹ 35 U.S.C. § 103.

⁸² See, e.g., *In re Sang-Su Lee*, 277 F.3d at 1340-45 (in rejecting patent application as obvious, PTO did not provide a “specific hint or suggestion in a particular reference,” but instead relied on “the common knowledge and common sense of a person of ordinary skill in the art” and the fact that the claimed invention came from same field of endeavor as one prior art reference; the Federal Circuit vacated the conclusion of obviousness, stating that “[c]ommon knowledge and common sense,” even if assumed to derive from the agency’s expertise, do not substitute for authority when the law requires authority.”). The Federal Circuit has recognized that a suggestion may be express or implicit, see *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205 (Fed. Cir. 2003); *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999), and has at times found implicit suggestions sufficient to demonstrate obviousness. See, e.g., *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1357 (Fed. Cir. 2000). But, as noted by Professor Duffy, that is not the “feel” of the case law. See Duffy 7/10 at 119.

⁸³ Dickinson 2/6 at 66.

⁸⁴ *In re Berg*, 320 F.3d at 1315 (affirming determination of obviousness in absence of legal error or contrary factual evidence sufficient to question findings made by the PTO as to teachings of prior art and motivation that prior art references would give a skilled artisan to make the claimed invention).

application of the suggestion test in ways sensitive to competitive concerns.

Recommendation. The Commission urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. Requiring concrete suggestions or motivations beyond those actually needed by a person of ordinary skill in the art, and failing to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

b. Nonobviousness and the “Commercial Success Test”

In *Graham v. John Deere*, the Supreme Court noted that:

Such secondary considerations as *commercial success*, long felt but unsolved needs, failure of others, etc., *might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries *may* have relevancy.⁸⁵

The Federal Circuit has elevated the

⁸⁵ *Graham*, 383 U.S. at 17-18 (1966) (emphases added).

importance of these so-called “objective factors” as considerations that potentially override conclusions of obviousness based on consideration of prior art:

Objective evidence such as *commercial success*, failure of others, long-felt need, and unexpected results *must* be considered *before* a conclusion on obviousness is reached, and is not merely ‘icing on the cake,’ as the district court stated at trial.⁸⁶

Hearings participants generally did not question the Federal Circuit’s use of “secondary” or “objective” factors such as long-felt need,⁸⁷ but did question whether and, if so, under what circumstances, an invention’s commercial success evidences its nonobviousness, and whether, as applied by the courts in practice, the commercial success standard merits the weight given to it as an “objective” factor.

⁸⁶ *Hybritech*, 802 F.2d at 1380 (emphases added, but not for third emphasis). See MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 736 (stating that the objective factors have “grown in stature” since *Graham*). Although the Federal Circuit has stressed that “secondary [*i.e.*, objective] considerations are not secondary in importance to primary considerations,” it also has explained that secondary/objective considerations will not always “carry sufficient weight to override a determination of obviousness based on primary considerations.” See *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991).

⁸⁷ See Katsh 4/10 at 97-98; cf. Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 830 (1988) (finding a direct connection between failure of others and nonobviousness but arguing that long-felt need depends on an inference that others were contemporaneously trying to produce a similar invention).

(i). Hearings Record

Participants expressed concern that courts might unduly rely on “secondary” or “objective” factors, such as commercial success, to rebut a *prima facie* case of obviousness based on the prior art. Yale University President Richard Levin and U.S. District Judge T.S. Ellis III, for example, voiced concern that the commercial success test has “diluted”⁸⁸ or “trivialized”⁸⁹ the obviousness inquiry.⁹⁰

Legal scholars long have debated whether courts should consider an invention’s commercial success as evidence of nonobviousness. Some conclude that any relevance of commercial success to nonobviousness rests on a chain of inferences, with weaknesses evident at each link.⁹¹ In contrast, others see a measure of an

invention’s contribution to the field in the willingness of customers to buy it.⁹² From a practical perspective, supporters stressed that secondary factors such as commercial success have value as objective guideposts for the obviousness inquiry.⁹³ Critics, in contrast, saw a vice in that virtue: several panelists expressed concern that juries find it too easy to avoid difficult questions about prior art and instead to focus on readily perceived facts about a product’s success.⁹⁴

Several panelists criticized how the Federal Circuit has *interpreted* the commercial success standard. Although the court requires a nexus between the invention

⁸⁸ R. Levin 2/6 at 103.

⁸⁹ T.S. Ellis 7/11 at 109.

⁹⁰ President Levin noted that “[a] recent study documents how decisions by the Court of Appeals for the Federal Circuit have tended to substitute “secondary” for “primary” tests of obviousness, resulting in a standard that comes perilously close to ‘if someone invested money in developing this invention, it must not be obvious.’” Richard C. Levin, *Testimony of Richard C. Levin, President, Yale University* (2/6/02) 2, at <http://www.ftc.gov/os/comments/intelpropertycomments/levinrichardc.htm> (hereinafter R. Levin (stmt)), citing Glynn S. Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363 (2001).

⁹¹ As Professor Kitch has explained:

The argument involves four inferences. First, that the commercial success is due to the innovation. Second, that if an improvement has in fact become commercially successful, it is likely that this potential commercial success was perceived before its development. Third, the potential commercial success having been perceived, it is likely that

efforts were made to develop the improvement. Fourth, the efforts having been made by men of skill in the art, they failed because the patentee was the first to reduce his development to practice. Since men of skill in the art tried but failed, the improvement is clearly non-obvious.

Kitch, 1966 SUP. CT. REV. at 332 (concluding that “[e]ach inference is weak”); see also Merges, 76 CAL. L. REV. at 838 (terming commercial success “a poor indicator of patentability” because “it depends on a long chain of inferences, and the links in the chain are often subject to doubt”).

⁹² See Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 9 (1989). See generally ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(b) at 170 (5th ed. 2001) (asserting, without explanation, that commercial success is persuasive evidence of nonobviousness).

⁹³ See Frankel 4/10 at 98-99; Dreyfuss 7/10 at 142-43; see also Dreyfuss, 64 N.Y.U. L. REV. at 8-10.

⁹⁴ See Pooley 10/30 at 56-57; Banner 10/30 at 72; Katsh 4/10 at 97-98 (referring to secondary factors in general); cf. Mossinghoff 10/30 at 70 (acknowledging attractiveness to juries). Nor are judges necessarily immune. Professor Kitch suggests, “Perhaps commercial success is a familiar distraction for judges confused by the facts.” Kitch, 1966 SUP. CT. REV. at 332.

and the success,⁹⁵ it typically demands only that the invention *be* a success.⁹⁶ It does not require the patentee to demonstrate that the invention *caused* that success. Thus, if the patentee shows that the claimed features of the patent are coextensive with those of a successful product, such as when a patented paving stone has succeeded in the marketplace,⁹⁷ then the burden shifts to the challenger to present evidence to rebut the inference that the invention – rather than factors such as marketing, advertising, an incumbent’s advantages, etc. – caused the commercial success.⁹⁸

Some argued in favor of changing the test to require patentees to show that the

invention *caused* the commercial success.⁹⁹ According to a panelist, such a standard prevailed in the pre-Federal Circuit era,¹⁰⁰ and the PTO continues to require that commercial success be “directly derived from the invention claimed” and not the result of “business events extraneous to the merits of the claimed invention.”¹⁰¹ One panelist objected, cautioning against requiring patentees to prove a negative – *i.e.*, that no other factor caused the invention’s success.¹⁰² Another panelist countered, however, that a patentee might reliably show causation from proof of positives: that “the problem existed for a long time and . . . the materials to solve that problem were in existence, but for the intellectual component.”¹⁰³

A number of panelists voiced concern

⁹⁵ See, e.g., Parkhurst 4/10 at 96-97; Duffy 7/10 at 120.

⁹⁶ See *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991) (“prima facie evidence of nexus is established if there was commercial success and if the invention disclosed in the patent was that which was commercially successful”); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1394 (Fed. Cir.) (“It is sufficient to show that the commercial success was of the patented invention itself”), *cert. denied*, 488 U.S. 956 (1988).

⁹⁷ See *Demaco*, 851 F.2d at 1391-94.

⁹⁸ See HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(a) at 169-70. One recent opinion explains:

A nexus between commercial success and the claimed features is required. However, if the marketed product embodies the claimed features and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to rebut the presumed nexus. The presumed nexus cannot be rebutted with mere argument; evidence must be put forth.

Brown & Williamson Tobacco Corp., v. Philip Morris Inc., 229 F.3d 1120 (Fed. Cir. 2000) (concluding that sufficient evidence had been put forward to rebut the presumed nexus).

⁹⁹ See, e.g., Kesan 4/10 at 200-01 (urging that the test be restructured to require that “but for” the inventive activity the commercial success would not have occurred); Duffy 7/10 at 121 and Duffy Presentation at 17 (“[I]mit to situations where patentee can prove that no exogenous changes account for success”).

¹⁰⁰ See Lunney 7/10 at 148; see also Merges, 76 CAL. L. REV. at 824-25 (collecting case authority comparing some pre-Federal Circuit opinions that had required that commercial success be the “direct result” of the claimed invention with Federal Circuit interpretations, viewed as merely requiring “some connection” between the invention and the success).

¹⁰¹ United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 716.03(b) (8th ed. 2001), available at <http://www.uspto.gov/web/offices/pac/mpep/mpep.htm> (hereinafter MPEP). See also *In re Huang*, 100 F.3d 135, 139-46 (Fed. Cir. 1996); *Ex parte Remark*, 15 U.S.P.Q. 2d 1998 (Bd. Pat. App. & Interf. 1990).

¹⁰² See Dreyfuss 7/10 at 143-44; see also HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(a) at 170.

¹⁰³ Duffy 7/10 at 144-46.

that courts and juries do not always apply the current nexus requirement properly.¹⁰⁴ For example, panelists indicated that judges and juries have sometimes erroneously given weight to the success of a product as a whole, rather than focusing on the invention embedded in the product.¹⁰⁵ Others voiced concern that the Federal Circuit has sometimes given insufficient weight to challengers' identification of reasons other than the invention itself that explain an invention's commercial success.¹⁰⁶

(ii). Analysis

As noted by some during the Hearings, application of the "secondary" or "objective" factors can give greater certainty in answering whether an invention is nonobvious. That certainty is problematic, however, when a factor – such as commercial success – is arguably an unreliable indicator of nonobviousness. Legal tests should achieve a proper balance

between the costs they entail (including those of uncertainty) and their accuracy in result.¹⁰⁷ The commercial success test does not appear to achieve that balance.

To begin with, the commercial success test has no direct connection to the "technical advance" at issue in the nonobviousness inquiry.¹⁰⁸ Even if commercial success reflects a claimed invention's economic significance, economic significance does not necessarily reflect technical significance – as illustrated by the Selden patent on the automobile¹⁰⁹ – so a commercial success standard will not necessarily yield accurate nonobviousness results. The single source relied upon by the Supreme Court's *Graham* opinion justifies the commercial success test only through the inference that others had tried and failed,¹¹⁰ and the separate objective factor that focuses directly on failure by others seems to take account of the same consideration with

¹⁰⁴ See, e.g., Kesan 4/10 at 201; Banner 10/30 at 72-73. But cf. Parkhurst 4/10 at 97 (effectiveness of nexus requirement can only be assessed on case-by-case basis).

¹⁰⁵ See Pooley 2/27 at 382-83 (juries fail to isolate the relevant success of an invention buried within a successful product); Banner 10/30 at 72. See generally Merges, 76 CAL. L. REV. at 826 (citing *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490 (Fed. Cir. 1985), as upholding a patent primarily on commercial success evidence even though the patented invention "played only a small part" in an overall generator testing service). In other instances, the court has been more careful to insist on a nexus between the commercial success and the specific invention claimed. See, e.g., *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

¹⁰⁶ See Lunney 7/10 at 148-49 (Federal Circuit not giving much weight to showings of extraneous factors such as heavy advertising and distribution advantages); Merges, 76 CAL. L. REV. at 826-27 (Federal Circuit has given reduced weight to advertising and marketing advantages, citing, *inter alia*, *Hybritech*, 802 F.2d at 1382).

¹⁰⁷ See generally Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEXAS L. REV. 1, 16 (1984); Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974); Richard A. Posner, *An Economic Approach to Legal Procedure & Judicial Administration*, 2 J. LEGAL STUD. 399, 401 (1973).

¹⁰⁸ See *supra* Ch. 4(I).

¹⁰⁹ See Duffy 7/10 at 110-13.

¹¹⁰ See *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169 (1964) (citing *S. H. Kress Co. v. Aghnides*, 246 F.2d 718 (4th Cir. 1957), *cert. denied*, 355 U.S. 889 (1958), for the explanation that a substantial latent demand would likely already have induced others to produce the invention if it had been obvious). Indeed, some of the Supreme Court's pre-*Graham* cases that gave weight to considerations of commercial success clearly arose in contexts of long-felt need and failure of others. See *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 379-81 (1909); *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 445-46 (1902).

greater accuracy.¹¹¹

Moreover, experience with competition analysis teaches that a product's commercial success may result from many factors other than the nonobviousness of a particular invention. Incumbents may have advantages over entrants. Vertical integration sometimes yields other advantages. Economies of scope may be present from simultaneously producing, distributing, or marketing other products. Inventions compatible to *de facto* or *de jure* standards in contexts that exhibit strong network effects may have commercial advantages over incompatible, but less obvious inventions.¹¹² Of course, these advantages will not always accrue, but the fact that they may arise suggests that a mere correlation between invention and success is not enough. Case-by-case inquiry into the *cause* of the product's success is necessary in court litigation, just as it is in PTO examination. In addition, the number of different reasons that may explain a product's commercial success and the fact that the patentee is likely to have the greatest access to relevant information counsel against a default rule that establishes a presumption that the invention caused the commercial success.

All of this is cause for concern, because the commercial success test raises significant issues from a competition perspective. For any given level of

appropriability, commercially successful inventions are more likely than others to emerge even without the prospect of patent protection.¹¹³ In addition, commercially successful patents are the ones most likely to confer market power.¹¹⁴ Thus, the commercial success test could tend to allow grants of unnecessary patents that confer market power and could thereby work at cross purposes to the “but for” principles discussed *supra* in Ch. 4(II)(A)(2). Moreover, a nexus test that requires only that an invention be successful could cause competitive harm by systematically tilting the patent rules toward those whose preexisting prominence may make commercial success more likely.¹¹⁵

Recommendations. First, the Commission recommends that courts evaluate on a case-by-case basis whether commercial success is a valid indicator of the nonobviousness of the claimed invention. Second, the Commission recommends that patentees bear the ultimate burden of demonstrating that the claimed invention caused the commercial success. In the absence of these inquiries, application of the commercial success test errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

¹¹¹ See Merges, 76 CAL. L. REV. at 874 (suggesting that courts link consideration of commercial success with that of failure by others).

¹¹² See Kesan 4/10 at 201; see generally Guerin-Calvert 2/20 at 214-221 (discussing network effects and competition).

¹¹³ See Scherer 7/10 at 54 (“When it has commercial value, that’s a stimulus to inventors, and sooner or later they’re going to invent with or without the patent.”).

¹¹⁴ See Kitch, 1966 SUP. CT. REV. at 333-34.

¹¹⁵ See *supra* note 112 and accompanying text.

B. Enablement, Written Description, and Best Mode

Section 112 of the Patent Act states a second set of doctrines crucial to patentability:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.¹¹⁶

Section 112 gives rise to three distinct disclosure doctrines: written description, enablement, and best mode.¹¹⁷ See Box 4-3 for further details.

1. Relationship to Patent Breadth

The disclosure doctrines play major roles in defining patent breadth – that is, how broad the claims are that an inventor may make. Patent breadth determines the extent of protection from competition that a patented invention receives. Products or processes within the patent’s breadth infringe; those outside that breadth do not.

Frequently, much will be learned and developed after an initial invention is made:

follow-on innovations will occur, and new uses will be found. The question then becomes, how many of these subsequent developments ought to be ascribed to the initial inventor and made subject to his or her patent? For example, in determining that an inventor who had obtained rat insulin cDNA could not validly assert a claim covering human insulin cDNA, the Federal Circuit applied an analysis based on one of the disclosure doctrines.¹¹⁸

The *enablement* inquiry asks how many of the future embodiments of a claimed invention the initial patent has made viable. A patent’s claims may extend until they reach the boundary of what the patent enables – that is, the point at which a follow-on innovator must engage in undue experimentation to move beyond the original invention.¹¹⁹ If a patent applicant claims more than he or she has enabled, the patent claim must be narrowed or rejected.¹²⁰ Nonetheless, because the examination determines enablement as of the time of the patent application, a patent claim can cover then-unknown, subsequent developments

¹¹⁸ See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

¹¹⁹ See *Merges* 2/28 at 639-41 and 2/26 at 154-55. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (“Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”).

¹²⁰ See *Chambers* 2/8 (Patent Session) at 64-65; *HARMON, PATENTS AND THE FEDERAL CIRCUIT* § 5.2(b) at 200-01.

¹¹⁶ 35 U.S.C. § 112.

¹¹⁷ See SCHECHTER & THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK* § 18.1 at 394-404.

and uses.¹²¹

The courts and the PTO traditionally have used the *written description* requirement to police amendments to claims.¹²² An applicant must show that the original written description of the claimed invention supports the matter introduced in any claim amendments. If the applicant does not thereby demonstrate possession of that matter when he or she first filed the application, the claim amendment cannot rely on the original filing date.¹²³ Recently, the Federal Circuit has extended its use of the written description requirement to invalidate some *initially* filed claims, particularly in biotech contexts, finding that without having undertaken the additional work necessary for a more detailed description, the applicant had not shown that he or she was truly in possession of the claimed invention.¹²⁴

2. Significance for Competition: General Application of Disclosure Doctrines

a. Hearings Record

From a competition perspective, patent breadth raises a variety of potential

concerns. If breadth is defined too broadly – that is, more broadly than is truly enabled – products that should be free to compete instead will infringe, and unwarranted market power may result.¹²⁵ Numerous business panelists voiced concerns about patents with undue breadth.¹²⁶

In contrast, defining breadth too narrowly may unnecessarily subdivide patent rights, potentially adding to the number of patents and contributing to the growth of patent thickets. Breadth in some instances can affect the number of patents needed to produce a product (or a commercially viable line of products). It can affect whether an industry evolves along a discrete product model (with relatively few patents necessary per commercializable product) or along the complex product model (with many patents necessary per product) that is characteristic

¹²¹ See Duffy 10/30 at 107-09; Rai 4/10 at 127-28; Kunin 4/10 at 123-24; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 299-301; *In re Hogan*, 559 F.2d 595, 606-07 (C.C.P.A. 1977).

¹²² See, e.g., Chambers 2/8 (Patent Session) at 72-73; Rai 4/10 at 135-36; Merges 2/26 at 156-58; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998).

¹²³ See 35 U.S.C. § 120.

¹²⁴ See, e.g., Chambers 2/8 (Patent Session) at 73-74; Rai 4/10 at 136; *Eli Lilly*, 119 F.3d at 1566-69.

¹²⁵ See *Scotchmer* 2/26 at 171 (“the thing that determines who gets to compete in the market is the distance between them that’s required not to infringe”). See *Scotchmer* 4/10 at 71 (overly broad patents may enable excessive market power consolidation). Similarly, an unduly broad patent can obscure the competition that should exist and prevent antitrust enforcement to protect that competition. Cf. *Scotchmer* 2/26 at 130-31, 136 (IP Guidelines analysis depends on whether, absent a license, one firm would have infringed the other’s patent); U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property § 3.3 (Apr. 6, 1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132 (horizontal relationship between licensor and licensee depends on whether they would have been actual or potential competitors in a relevant market absent a license), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>.

¹²⁶ See, e.g., Kirschner 2/26 at 242; Friedman 2/27 at 411-12; Kohn 2/27 at 413; Fox 2/28 at 696; Thurston 3/20 at 34; Richard Stallman, *The Danger of Software Patents*, Speech by Richard Stallman at Cambridge University, March, 25 2002 (Public Comment) 4, at <http://www.ftc.gov/os/comments/intelpropertycomments/stallmanrichard.pdf>.

of thickets.¹²⁷

Finally, patent breadth can have major consequences for follow-on innovation. Here the testimony split into diverging strands. One strand emphasized that broad initial patents may raise significant problems for follow-on innovation.¹²⁸ From this perspective, vesting the initial innovator with broad patent rights reduces the incentives of follow-on innovators and potentially impedes their access to upstream innovation inputs. Follow-on innovators, some argued, would receive high royalty demands or endure unwarranted design-around expense.¹²⁹ The opposing viewpoint stressed that broad initial patents may be beneficial, providing adequate rewards for initial innovators and furthering prospect theory goals of efficient future development.¹³⁰ They stressed that the holder of a broad initial patent generally will

¹²⁷ See Cohen 2/20 at 37-38 (numerous patents per commercializable product implies “mutual dependence across firms’ patent holdings”) and 10/30 at 92-93 (explaining that in Japan, where patents tend to be narrow “everything is a complex product industry”).

¹²⁸ See, e.g., Scherer 7/10 at 54-55 (“early basic patents can retard or bar innovation by a downstream inventor or developer, slowing down the pace of technological advance”); Cohen 2/20 at 22 (broad patents problematic when innovation cumulative), 71 and 10/30 at 93-95 (citing research indicating “significant potential for problems” with access to upstream biomedical inventions); Langenfeld 2/20 at 10, 12, and James Langenfeld, *Innovation, Competition, and Intellectual Property: Providing an Economic Framework* (2/20/02) (slides) at 4, at <http://www.ftc.gov/opp/intellect/langenfeld.pdf>; Lemley 2/25 at 37-38; Rai 4/10 at 21-22 and 51-52.

¹²⁹ See, e.g., Rai 4/10 at 19; Kesan 10/25 at 25-26.

¹³⁰ See, e.g., Scotchmer 2/26 at 130-34, 171-72 and 4/10 at 68-69 (emphasizing the importance of “leading breadth” – an economic stake in things beyond what the initial innovator has actually invented); Kitch 2/20 at 81-84.

Box 4-3. Enablement, Written Description, and Best Mode

Written description ensures that the inventor actually has invented what the patent application claims; the inventor must describe the invention sufficiently to show that he or she is in possession of the invention. See, e.g., Chambers 2/8 (Patent Session) at 64; Kushan 4/11 at 102.

Enablement ensures that the *public* is put in possession of the invention, *i.e.*, enablement implements the patent system’s disclosure requirement. An inventor must disclose the claimed invention sufficiently that a person skilled in the art can make and use it without undue experimentation. See, e.g., Chambers 2/8 (Patent Session) at 63-68; Kushan 4/11 at 102; Kunin 4/10 at 122.

The **best mode** requirement adds a subjective test: if the inventor has developed techniques that he or she recognizes at the time of filing as the best way of carrying out the invention, those techniques must be disclosed. See Chambers 2/8 (Patent Session) at 64, 78-79.

have incentives to find ways to foster follow-on activities.¹³¹

Economic analysis substantially informed the follow-on innovation discussion. As discussed *supra* in Chapter 2(III)(B)(2), Professor Scotchmer focused attention on the division of profit between successive generations of innovation.¹³² When the first generation lays the foundation for the second, the first innovator should receive some portion of the second

¹³¹ See, e.g., Kieff 4/10 at 163; Blackburn 2/26 at 264-65.

¹³² See Scotchmer 2/26 at 128-30, 135-36 and 4/10 at 71. “The challenge is to reward early innovators fully for the technological foundation they provide to later innovators, but to reward later innovators adequately for their improvements and new products as well.” Scotchmer, 5 J. ECON. PERSP. at 30.

generation profits.¹³³ According to Professor Scotchmer, an unduly narrow initial patent may allow competition from follow-on products to undermine the incentive for the initial innovation on which both generations rest;¹³⁴ at the same time, an unduly broad initial patent may stifle follow-ons.¹³⁵

Different assessments of the likelihood of licensing distinguish the opposing views. Broad initial patents are most likely to support efficient follow-on activity if *ex ante* licensing occurs – that is licensing before the follow-on innovator makes investments. Once the follow-on innovator makes sunk investments, however, the follow-on innovator faces heightened exposure to opportunistic royalty demands.¹³⁶

Several panelists questioned whether *ex ante* licensing would likely occur. They noted that it would likely be difficult to protect a follow-on innovator’s not-yet-patented ideas during *ex ante* licensing negotiations; that negotiations focused on uncertain research results and inchoate patent rights typically have high transactions costs; that, especially given the early stage of the follow-on research, the initial and follow-on

inventors may place significantly different relative values on their contributions; and that some initial innovators may refuse to license, wishing to maintain market power by developing follow-on products in-house rather than licensing to potential future competitors.¹³⁷ Others responded that transaction costs and the effects of uncertainty usually can be overcome.¹³⁸ Anecdotal information and case studies point both ways.¹³⁹

b. Analysis

A synthesis of the follow-on innovation discussion suggests that if initial innovation is costly and follow-on innovation is relatively predictable, quick, and inexpensive, then in theory initial innovators should receive patents of greater breadth. In contrast, if initial innovation is inexpensive and follow-on innovation is relatively risky, time-consuming, and costly, then in theory initial innovators should receive narrower patents, leaving follow-on innovators greater opportunity for reward. Such an arrangement, in general terms, would serve efficiency goals by allocating

¹³³ Scotchmer, 5 J. ECON. PERSP. at 31.

¹³⁴ Scotchmer 2/26 at 130.

¹³⁵ *Id.* at 135; Scotchmer, 5 J. ECON. PERSP. at 31 (“enough profit must be left for the second innovators so that they will invest if investing is efficient”); *see also* Stoner 2/26 at 118-19.

¹³⁶ *See, e.g.,* Scotchmer 2/26 at 135; Rai 4/10 at 19; *see also supra* Ch. 2(III)(B)(3). In contrast, some panelists argued that when improvements are significant and adequate information is available, awarding a blocking position to the follow-on innovator may sufficiently protect that innovator even if licensing negotiations are conducted *ex post*. *See* Parkhurst 4/10 at 93-94; Kieff 4/10 at 163-64.

¹³⁷ For more detailed discussion of possible licensing impediments, *see supra* Ch. 2(III)(B)(3); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1048-61 (1997); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1073-74 (1989). Professor Scherer highlights the potential for bargaining stalemates when the initial innovation involves basic research with little commercial value itself and the follow-on innovations require substantial investment. Frederick M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348, 1362 (2002).

¹³⁸ *See, e.g.,* Teece 2/26 at 210-11; Arora 2/25 at 88; Kieff 4/10 at 159-60, 199-200.

¹³⁹ *See supra* Ch. 2(III)(B)(3).

patent protection to the stage “where appropriability can make the greatest contribution to innovation.”¹⁴⁰

Current disclosure doctrines accord reasonably well with these goals. For example, enablement of a given embodiment depends in part on the amount of experimentation required and on the predictability of the art. When considerable experimentation is necessary, follow-on innovation is likely to be costly; the more stringent enablement requirements that follow from greater need to experiment reduce the breadth of the initial innovator’s patent,¹⁴¹ and expand the rewards potentially available to follow-on innovators. Similarly, less predictability makes follow-on innovation more costly; again the more stringent enablement requirements that follow reduce the breadth of the initial patent and provide opportunities for expanded follow-on rewards. These results are in line with the economic reasoning for settings in which initial innovation is inexpensive and follow-on innovation is costly¹⁴² and accord with advice of antitrust innovation

theorists.¹⁴³

3. Significance for Competition: Disclosure Doctrines in Practice

a. *Hearings Record*

Variations in the predictability of the art and differences in the nature of the person having ordinary skill in the art (the “PHOSITA”) necessarily require different levels of disclosure in different fields of endeavor. The distinctions do not arise because of special industry treatment under the statute; a single standard applies across industries and technologies. Rather, as already noted, an industry or technology where the art is more unpredictable requires greater disclosure.¹⁴⁴ Similarly, an industry or technology in which the PHOSITA is relatively unskilled requires greater disclosure than when the PHOSITA possesses greater ability.¹⁴⁵

Panelists found differences in the disclosure requirements in different industries or technologies. Most typically, they contrasted software disclosures with those required for biotechnology.¹⁴⁶ Many

¹⁴⁰ See Stoner 10/30 at 99-100.

¹⁴¹ When more experimentation is needed, a given level of disclosure enables fewer future embodiments.

¹⁴² See Merges 2/28 at 641-43 (suggesting that “where it is more costly to build on old inventions” enablement principles appropriately restrict the initial patent right). The correspondence, however, may not always be perfect. For example, if the initial innovator had to overcome the same unpredictable art or engage in the same type of experimentation as the follow-on innovator, the initial innovation may not have been inexpensive, as assumed, and there would be no basis for preferring one generation over the other.

¹⁴³ See Rubinfeld 2/25 at 19, 23 (when the strategy of innovation is unpredictable or random, a reasonably large number of innovation efforts is desirable – more innovation is likely with more diversity).

¹⁴⁴ See, e.g., Kunin 4/10 at 122; Mossinghoff 10/30 at 113-14; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 290.

¹⁴⁵ See, e.g., Burk 3/20 at 132-34 and 7/10 at 155-56.

¹⁴⁶ See, e.g., Burk 3/20 at 107-10 and 7/10 at 155-56 (finding a much less rigorous disclosure requirement for software than for biotechnology inventions); Kesan 4/10 at 55, 121 (same); Rai 4/10 at 105-06 (same); Kunin 7/10 at 28, 191-92.

viewed the software disclosure requirements as relatively lax. Several cases have concluded that patent applicants need not reveal source code;¹⁴⁷ some panelists indicated that mere recitation of a program's function will be adequate.¹⁴⁸ Several panelists urged the requirement of greater software disclosures.¹⁴⁹ In comparison, panelists indicated that biotech disclosures have been rigidly policed, with genetic sequence codes often required to satisfy

written description requirements.¹⁵⁰ Indeed, some found the disclosure requirements in biotech excessive, forcing inventors to take time tying down details that readily could be elucidated by others, and thereby delaying the raising of venture capital.¹⁵¹

¹⁴⁷ See, e.g., *Robotic Vision Systems, Inc.*, 112 F.3d 1163, 1166-67 (Fed. Cir. 1997); *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1548-49 (Fed. Cir.), cert. denied, 522 U.S. 909 (1997); *Hayes Microcomputer Products, Inc. v. Ven-Tel, Inc.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941-43 (Fed. Cir.) (stating that "[t]he possible design of superior software . . . is not relevant in determining whether the inventor has complied with the enablement requirement"), cert. denied, 498 U.S. 920 (1990).

¹⁴⁸ See, e.g., Burk 3/20 at 108 ("essentially . . . no disclosure requirement for software;" neither code nor flowcharts are necessary) and 7/10 at 155 ("you don't need to give us the code . . . [y]ou don't need to give us a flow chart . . . just give us a functional disclosure, tell us what it does"); Kesan 4/10 at 56 (no policing of enablement in software; "functional descriptions" suffice, and system is "essentially giving patents to ideas"); Rai 4/10 at 106 ("incredibly broad claims without any disclosure whatsoever"); Kunin 7/10 at 191-92 ("mere functional description" adequate).

¹⁴⁹ See, e.g. Janis 4/10 at 118-19 (enablement standard for software could be made "much more rigorous with good effect"); Kesan 4/10 at 55-57, 120-21 (disclosure fails to show "how the algorithm is being tailored for use in this application"), 130 ("disclosures are so scant that you're really talking about basically taking another invention to actually enable what is disclosed"); Kieff 4/10 at 113 (suggesting that inventors submit source code); Burk 3/20 at 110-11. See generally Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific*, 17 BERKELEY TECH. L. J. 1155, 1196 (2002) (suggesting that narrower patents resulting from more stringent disclosure requirements might better promote innovation in a software industry characterized by incremental improvements).

¹⁵⁰ See, e.g., Burk 3/20 at 110, 134 ("You must have actually found the sequence even if one of ordinary skill would know how to find the sequence.") and 7/10 at 156, 160-61; Rai 4/10 at 105; Kunin 7/10 at 28; Boulware 10/30 at 158 ("the Federal Circuit is looking at written description and enablement very closely in the biotech area"). For the PTO's interpretation and implementation of written description requirements, see United States Patent and Trademark Office, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1*, "Written Description" Requirement, 66 Fed. Reg. 1099 (2001).

¹⁵¹ See, e.g. Burk 3/20 at 110-11, 134-35; Burk & Lemley, 17 BERKELEY TECH. L. J. at 1195-96 (suggesting that the narrow patents that follow from rigorous disclosure requirements may increase the potential for anticommons problems in biotechnology); cf. Merges 2/28 at 642 (discussing, as a general matter, the potential waste inherent in an unduly rigorous enablement standard); Rai 4/10 at 106 (arguing that although the written description demands for biotech are excessive, they will yield an economically desirable result if confined to upstream research).

Similar, though not identical, patterns emerged from testimony regarding the usefulness of patent disclosures in different industry contexts. The strongest criticism involved software, for which the predominance of industry panelists found patent disclosures of little value. See, e.g., Webbink 3/20 at 145; Casey 4/9 at 32; Young 4/11 at 99-100 ("Software is not software without source code."); Barr 10/30 at 142; cf. Kahin 3/19 at 56 (software patents not read). But see Myrick 10/30 at 59-60 ("Software patents disclose an enormous amount"); Alderucci 4/9 at 40 (disclosures useful). In contrast, as noted *supra* in Chapter 3(II)(C), testimony from the pharmaceuticals industry almost uniformly indicated value in the patent disclosures. See, e.g., Blackburn 2/26 at 319; Glover 3/19 at 174, 224-25; Coffin-Beach 3/19 at 212. Biotech industry testimony on this point was mixed. Compare Boulware 10/30 at 159 (patent literature looked at regularly) with Kirschner 2/26 at 318 (patents not a significant source of ideas) and Blackburn 2/26 at 319-20 (suggesting that patent literature may be more significant in pharmaceuticals than in biotech, but adding that patents enable information transfer through scientific literature). Semiconductor and high-tech hardware industry participants expressed diverse views. See, e.g., Telecky 2/28 at 754 (disclosures useful); McCurdy 3/20 at 53 (patents seldom

b. Analysis

Critics of current disclosure requirements in particular industries typically argued that the Federal Circuit has an erroneous view of the predictability of the art or the skill of the PHOSITA.¹⁵² They observed that these variables change over time as industries develop and mature, and they suggested that the patent system has not always kept current in its assessments.¹⁵³ They directed their criticisms toward the *application* of the disclosure requirements, not toward any fundamental problem inherent in the basic standards.

The role of disclosure requirements in shaping patent breadth and the consequences of that breadth for potential market power and cumulative innovation make the nature and effective application of the disclosure requirements a matter of significant competitive concern. Accurate, up-to-date assessments of the predictability of the art and of the abilities of the PHOSITA in evolving industries are

disclose enough to allow practice of the invention without some work); Barr 2/28 at 756 (“I’ve actually never met an engineer that learned anything from a patent.”).

¹⁵² See, e.g., Burk 3/30 at 133 (seeing an underestimate of the difficulty of writing software) and 7/10 at 155 (same); Rai 4/10 at 106 (Federal Circuit thinks everything in biotech is “incredibly unpredictable”).

¹⁵³ See, e.g., Burk 3/20 at 111-12 (“courts developing standards that might have applied 5, 10, 15 or even 20 years ago”) and 7/10 at 198-99 (courts have not kept up with growing predictability of some biotech techniques); Kesan 4/10 at 120 (software has become more complex since the early cases governing enablement); see also Kunin 7/10 at 192-93 (increasing complexity of software inventions may have reduced the predictability); Burk & Lemley, 17 BERKELEY TECH. L. J. at 1199-1201 (explaining how reliance on precedent rather than the particulars of each case may lead to outdated conceptions of the PHOSITA’s level of skill).

important elements for achieving efficiency goals and harmonizing the patent and antitrust regimes.

C. Other Doctrines that Affect Patent Breadth

Other doctrines, beyond the disclosure requirements, also set and interpret the scope of a patent’s claims and thus affect patent breadth. This section highlights two of these doctrines. The first is the use of “continuing applications” – that is, “continuations” – to redefine the scope of a patent’s claims. The second is the application of the doctrine of equivalents in interpreting claims. Both can significantly affect competition.

1. Continuations and the Formulation of Claims

a. Hearings Record

The patent system has long struggled with problems that flow from delay and secrecy in handling patent applications. Until recently, patent applications were not public information. Years might pass between the filing of an application and the issuance of a patent. An applicant’s competitors may have invested substantially in the interim in designing and developing a product and bringing it to market, only to learn, after the patent finally issues, that they are infringing someone else’s claims. At that point, redesign might be prohibitively expensive, and the newly announced patentee might be in position to extract large

royalties.¹⁵⁴ Such a scenario raises the potential for what some panelists have termed “a hold-up.”¹⁵⁵

A statutory change that now requires all patent applications (other than those filed only in the United States) to be published 18 months after filing¹⁵⁶ may have considerably eased this problem with unanticipated “submarine” patents.¹⁵⁷ A PTO panelist indicated that 90% of current applications are so published.¹⁵⁸ Several panelists anticipated that the new publication rule would help substantially with submarine concerns,¹⁵⁹ although some indicated dissatisfaction with the remaining 18-month delay¹⁶⁰ and with excepting from publication patents filed only domestically.¹⁶¹

Another potential hold-up problem remains, however. Through the use of claim amendments during the prosecution process, a patent that states broader claims than those

published at 18 months can still emerge.¹⁶² To maintain the filing date of the original application, the original specification must contain support for the new claims.¹⁶³ If that is the case, the applicant may enlarge or otherwise modify the scope of its claims during the examination process.¹⁶⁴ The potential for anticompetitive hold-up increases the longer it takes for the broader claims to emerge. By filing one or more continuing applications¹⁶⁵ the applicant may extend the prosecution period – and the potential for working mischief by broadening claims – for years.

Panelists explained that continuations can serve legitimate functions when the applicant, or the applicant’s attorney, has in

¹⁵⁴ See, e.g., Stallman 4/9 at 18-19 (describing unknowing infringement of patents kept secret during the application period as “stepping on . . . a land mine”); Barr 2/28 at 675-76.

¹⁵⁵ See, e.g., Shapiro 11/6 at 15-16, 176.

¹⁵⁶ 35 U.S.C. § 122(b)(1). Applications that are filed only domestically, however, need not be made public. 35 U.S.C. § 122(b)(2)(B).

¹⁵⁷ See also *supra* Ch. 1(III)(A)(2)(a).

¹⁵⁸ John Love 2/28 at 647.

¹⁵⁹ See, e.g., *id.*; Kohn 2/27 at 429; Gable 3/20 at 118-19; Casey 4/9 at 32.

¹⁶⁰ See Oehler 2/26 at 254 (“18 months can seem like an eternity when you’re caught in the middle of it trying to answer ‘am I free to operate’”).

¹⁶¹ See *infra* at Ch. 5(II)(C)(4).

¹⁶² See, e.g., Katsh 4/10 at 193; Barr 2/28 at 676.

¹⁶³ 35 U.S.C. § 120. Similarly, novelty requirements prevent issuance of a patent on inventions “known or used by others in this country . . . before the invention thereof by the applicant for a patent,” and the prohibition on derivation in theory bars issuance of a patent to one who “did not himself invent the subject matter sought to be patented . . .” 35 U.S.C. §§ 102(a) and (f). See MERGES & DUFFY, PATENT LAW & POLICY: CASES AND MATERIALS at 398-403, 437-39.

¹⁶⁴ See, e.g., Merges 2/26 at 156-58; Chen 2/28 at 718; Rai 4/10 at 135-36.

¹⁶⁵ The filing may take various forms. It may involve a new application, which might take the form of a “continuation application,” retaining the original written disclosures and the original filing date; a “continuation-in-part,” which adds some new matter to the disclosures and loses the original filing date insofar as its claims rely on the new matter; or a “divisional,” which carves out what had been a separate invention within the original application while retaining the original filing date. See 35 U.S.C. §§ 120-21; 37 C.F.R. § 1.53(b); Chambers 2/8 (Patent Session) at 101-02. Alternatively, the filing may involve a request for continued examination, which works to extend the examination of the original application. 37 C.F.R. § 1.114. For ease of exposition, this discussion will refer to all of these variants, including those portions of continuations-in-part that maintain the original filing date, as “continuing applications” or “continuations.”

essence missed its own product in the initial application¹⁶⁶ or when the applicant and examiner need to maintain an extended dialogue.¹⁶⁷ Several panelists expressed concern, however, regarding the use of continuation practice in ways harmful to competitors. They explained that some applicants keep continuations pending for extended periods, monitor development of the market, and modify their claims to ensnare competitors' products after sunk costs have been incurred.¹⁶⁸ One panelist voiced the further worry that continuations could be used to undercut standard setting organizations' disclosure rules.¹⁶⁹ None of the testimony offered justification for the use of continuation practice to broaden claims to cover competitors' subsequent products and to exploit the consequences of their subsequent sunk investments. As American Intellectual Property Law Association

¹⁶⁶ See Barr 10/30 at 146; Chambers 2/8 (Patent Session) at 103; Telecky 2/28 at 720-21 (finding nothing wrong with "chang[ing] your mind as you see the art, and as you think about it, as to what your invention is," as long as the claims are supported by the disclosure). But see Poppen 2/28 at 692 ("an inventor ought to know what his invention is and shouldn't have to wait to see what everybody else is doing").

¹⁶⁷ See Armbrrecht 3/19 at 68-69; cf. Myrick 10/30 at 179-80 (explaining possible use of continuations to correct the prosecution history).

¹⁶⁸ See, e.g., Poppen 2/28 at 687-88; Mar-Spinola 2/28 at 715-16; Quillen 3/19 at 70-71; McCurdy 3/20 at 37; Rai 4/10 at 136; Barr 10/30 at 79, 146; Myrick 10/30 at 178 (warning that divisionals may be similarly used to "game the system"), 180; Cecil D. Quillen Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. BAR J. 1, 6 (2001). See generally Banner 10/30 at 181-82 (continuations a problem).

¹⁶⁹ See Stoner 10/30 at 145-46 (noting that continuations might be used "to spring a new patent claim on firms that are producing pursuant to a standard" absent a controlling disclosure requirement).

President Ronald Myrick summarized, "[T]he continuation practice we have today is not good. It's out of control."¹⁷⁰

b. Analysis

Implications for Competition and Innovation Continuation practice can allow opportunistic behavior, such as post-filing modification of patent claims to capture competitors' products or processes that would not have infringed the original claims. Such opportunistic behavior can disrupt competitive activity. It wastes inventive resources that a competitor could have redirected, had it fully known the scope of an applicant/patentee's claims. It imposes redesign costs that might have been avoided if the competitor had had greater lead time. It fosters high royalties, inflated by a competitor's exposure to operational disruption from injunctive relief after sunk investments have been made. It magnifies potential competitors' risks and reduces their incentive to develop substitutes for the patentee's invention. Moreover, competitors' uncertain ability to predict from the written description at 18 months what the patentee ultimately will claim limits any opportunity to anticipate and avoid this exposure. Such behavior wastes resources, raises costs and risks, and potentially deprives consumers of the benefits of

¹⁷⁰ Myrick 10/30 at 177; see also Myrick 10/30 at 180 (use of continuation practice as marketplace develops to capture what was never in the applicant's mind "an exceedingly troublesome thing"). Such conduct, however, may not give rise to an offense under patent law. See, e.g., *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (holding that amending a claim to cover a competitor's product learned about in the course of the prosecution process was not in itself evidence of deceitful intent relevant to charges of inequitable conduct and stating, in *dictum*, that it was not "in any manner improper"), *cert. denied*, 490 U.S. 1067 (1989).

innovation and competition.¹⁷¹

Suggestions for Reform of Continuation Practice Patent reform efforts have long focused on how to remedy the opportunistic broadening of patent claims to capture competitors' products. The 1967 President's Commission on the Patent System determined that "it is desirable that claims never be broadened after publication," but concluded that it might be impossible to enforce an all-inclusive prohibition.¹⁷² The Hearings suggest that the same types of concerns persist and will likely remain a problem in the future unless changes are implemented.¹⁷³ Suggestions for dealing with the problems identified in continuation

¹⁷¹ For a general discussion of hold-up problems raised by unanticipated patents see Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam Jaffe et al. eds., 2001). Indeed, the Commission's complaint in a pending administrative proceeding cites continuations as an element contributing to broader, alleged anticompetitive conduct involving claim modifications during a patent applicant's participation in standard-setting activities. *Rambus Inc.*, No. 9302 at ¶¶ 37-38, 47-69 (Complaint June 18 2002), available at <http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf>.

¹⁷² REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, *reprinted in* TO PROMOTE THE PROGRESS OF THE USEFUL ARTS, SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 90TH CONG., 1ST SESS. 39 (1967). The President's Commission recommended imposing time limits on continuing applications. *Id.* at 26.

¹⁷³ Although some panelists suggested that a 1995 change in patent term – from 17 years after issuance to 20 years after filing – limits the ability to prolong examinations, see, e.g., Telecky 2/28 at 721 and Detkin 2/28 at 729, other testimony indicated that 20 years was more than enough time to abuse continuation practices. See Poppen 2/28 at 693. Moreover, some predicted that the use of continuations to broaden or otherwise add to literal claims will increase, given current trends toward narrowing the doctrine of equivalents (discussed *infra* in Ch. 4(II)(C)(2)). See, e.g., Mossinghoff 10/30 at 144-45; Myrick 3/19 at 48; Thomas 10/30 at 105-06.

practice include extending and making greater use of the doctrine of prosecution laches,¹⁷⁴ imposing time limits on broadening claims,¹⁷⁵ and creating intervening rights to protect competitors who become exposed to infringement claims by virtue of continuations.¹⁷⁶

Analysis Any of the remedies listed above could address competitive concerns. A remedy, however, should protect legitimate uses of continuing applications, as well as deter anticompetitive uses of continuations. Creating intervening or prior user rights¹⁷⁷ would most directly cure

¹⁷⁴ The Federal Circuit has approved a PTO rejection of patent claims on grounds that the applicant had forfeited his right to a patent under the doctrine of prosecution laches by filing twelve continuations over a period of eight years without advancing the prosecution of his application. See *In re Bogese II*, 303 F.3d 1362 (2002); see also Chen 2/28 at 718-19 (PTO exploring possibilities for rejecting applications based on prosecution laches). The doctrine of prosecution laches also potentially provides a defense to an infringement action when the patentee has engaged in unreasonable and prejudicial delay in securing the patent's issuance. See *Symbol Technologies, Inc. v. Lemelson Med., Educ., & Research Found.*, 277 F.3d 1361 (Fed. Cir.), *cert. denied*, 123 S. Ct. 113 (2002).

¹⁷⁵ See Poppen 2/28 at 692-94 (suggesting barring broadening of claims 18 months after filing); Chen 2/28 at 718 (18-month limit on broadening claims "an interesting idea . . . one way to promote some level of certainty"); cf. Katsh 4/10 at 139 (suggesting a time limit on continuations).

¹⁷⁶ See Myrick 10/30 at 180-81 (suggesting "intervening rights or some such thing that would protect the later entrant in the marketplace against these patents that show up so tardily").

¹⁷⁷ Analysts have not always distinguished these terms with consistency. For present purposes, we use "prior user rights" to refer to absolute defenses against infringement actions and "intervening rights" to refer to protections that, in whole or in part, depend on a court's weighing of the equities, as exemplified, respectively, by provisions in 35 U.S.C. § 273(b) and 35 U.S.C. § 252, discussed below.

potential competitive problems without interfering with legitimate needs for continuations, reducing business uncertainty without increasing costs of error. Such rights should shelter inventors and users that infringe a patent only because of claim amendments following a continuation, provided that the sheltered products or processes are developed or used (or the subject of substantial preparation for use) before the amended claims are published.¹⁷⁸ This would protect third parties from hold-ups derived from any extended period of secrecy made possible by continuations, while allowing the patent to be enforced against those who would have infringed a properly described pre-continuation claim¹⁷⁹ or who had timely opportunity to gain knowledge of the amendments.

Protections sheltering the legitimate expectations and investments of third parties affected by late-date claim amendments have substantial precedent. Limited intervening rights already are available under 35 U.S.C. § 252 to third parties who infringe a patent because of a broadening of claims through post-grant reissue, a procedure that, in cases of “error without any deceptive intention,” allows certain claim amendments *after* a

patent has issued.¹⁸⁰ The intervening rights proposed herein would provide protection to third parties similarly confronted with late-date claim amendments *during* the course of the prosecution process. The courts, however, have applied existing intervening rights narrowly¹⁸¹ and likely would need to broaden them to confer meaningful protection in light of investments made or business commenced by the third party and the likely costs and full economic consequences of any redesign to avoid infringement. Regarding prior user rights, Congress in 1999 enacted such protections to shelter some third parties from infringement claims based on business method patents.¹⁸² More broadly, the 1992 Advisory Commission on Patent Law Reform, in conjunction with a separate recommendation to determine patent priority on a first-to-file basis, proposed conferring prior user rights on those who “in good faith” use, or make

¹⁸⁰ See 35 U.S.C. § 251.

¹⁸¹ See, e.g., *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1361 (Fed. Cir. 2001) (refusing to consider intervening rights in view of defendant’s unclean hands from willful infringement); *Seattle Box Co. v. Industrial Crating and Packing, Inc.*, 756 F.2d 1574 (Fed. Cir. 1985) (leaving unanswered whether intervening rights would have been available for anything more than bundles made from pre-reissue inventory); J. Christopher Carraway, *The Uncertain Future of Enforcing Patents that Have Been Broadened through Reissue*, 8 FED. CIRCUIT B.J. 63, 68, 74 (1998) (“The grant of equitable intervening rights is extremely rare, however, most likely out of discomfort with allowing a party to continue to infringe a patent. . . . Although one who has designed around the original claims may be protected from paying damages on any pre-reissue activity, . . . equitable intervening rights to continue production of the originally noninfringing product are almost universally denied, thereby destroying investments made in creating and building the market for the product.”).

¹⁷⁸ Whether amended claims are published upon the filing of continuations depends upon the specific continuation format used and the way that amendments are presented, and often is “[a]t applicant’s option.” See 37 C.F.R. § 1.215; American Inventor’s Protection Act of 1999 Questions and Answers § C (Eighteen-Month Publication), available at <http://www.uspto.gov/web/offices/dcom/olia/aipa/infoexch.htm>.

¹⁷⁹ The phrase “properly described claim” refers to claims that satisfy the written description requirement of 35 U.S.C. § 112. The intervening or prior user right would not be defeated by a pre-continuation claim that exceeds the applicant’s written description.

¹⁸² See 35 U.S.C. § 273(b) (sheltering those who reduced a business method to practice at least a year before the patent application and used the method before the effective filing date).

substantial preparation for using, an invention before the filing date of a subsequently issued patent.¹⁸³

Recommendation. Accordingly, the Commission recommends the enactment of legislation to protect from infringement claims a third party who reduces to practice, uses, or makes substantial preparation for using a process, machine, manufacture, or composition of matter (“product or process”) prior to first publication of a claim covering that product or process in a continuing application, provided that no parent application¹⁸⁴ contained a properly described claim covering the product or process prior to the third party’s reduction to practice, use, or substantial preparation for use.¹⁸⁵

¹⁸³ ADVISORY COMMISSION ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE 11, 21 (1992) (Recommendation I-A), *available at* <http://world.std.com/obi/USG/Patents/overview>.

¹⁸⁴ “Parent application” is used broadly here to encompass all predecessors in a string of continuing applications.

¹⁸⁵ The Hearing record does not permit assessment of the extent to which reissue proceedings have been used to broaden patents to cover competitors’ products after the competitors have made their sunk investments, nor does it explore the justifications for broadening reissue. It nonetheless appears that reissue in some instances may be used like continuations “to encompass activity by a competitor.” See United States Patent and Trademark Office 21st Century Strategic Plan, *Permit Assignees to File Broadening Reissue* 1 (April 2, 2003), at <http://www.uspto.gov/web/offices/com/strat21/action/lr1fp55.htm>. To the extent that reissue poses, or develops in a way that poses, comparable competitive problems to those raised by continuations, corresponding protections, including a possible broadening of existing intervening rights, ought to be considered.

2. Doctrine of Equivalents

a. Hearings Record

Several panelists addressed claim interpretation issues under the doctrine of equivalents.¹⁸⁶ The doctrine of equivalents “protects [a patent holder] against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention.”¹⁸⁷ It does so by allowing a claim to be construed to cover more than its literal language, thereby extending patent breadth.¹⁸⁸ The answer to the question of when changes are “only insubstantial” thus can become an important determinant of patent breadth.

Some panelists favored the doctrine of equivalents as a means to protect patentees from imitators who might otherwise escape infringement by tinkering in trivial ways with patented products or

¹⁸⁶ Other discussion dealt with literal claim interpretation, in particular the effects of the ruling in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), that claim interpretation is a matter of law, not fact. Although panelists noted that the ruling had been expected to increase certainty by vesting interpretation issues in judges rather than juries, *see e.g.*, T.S. Ellis 7/11 at 113 (finding that certainty has increased) and Barr 10/30 at 185, some observed that achieving certainty has now been delayed until appeal of the trial judge’s conclusions. *See, e.g.*, Weinstein 2/27 at 451; Katsh 4/10 at 103-04; Kunin 7/10 at 37; Banner 10/30 at 182-83; *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 12 FED. CIRCUIT B.J. 1, 32 (2002) (advocating statutory reform that would permit “[e]xpedited appeals of a limited number of claim construction issues”). Neither the Hearing record nor the academic literature permits a sorting of competitive consequences.

¹⁸⁷ *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 727 (2002).

¹⁸⁸ *See, e.g.*, Sung 2/8 (Patent Session) at 128; Wamsley 7/10 at 14; *Festo*, 535 U.S. at 731-32; HARMON, PATENTS AND THE FEDERAL CIRCUIT § 6.3(a)(ii) at 343.

processes.¹⁸⁹ It may be unrealistic, some thought, to expect patentees to foresee and provide against all such tinkering; the inherent limits of language may ensure that whatever words are chosen will prove insufficient to cover every eventuality.¹⁹⁰ Others, however, stressed that leaving claim boundaries obscure increases uncertainty and makes negotiation and business planning more difficult.¹⁹¹ One panelist noted a further effect of the doctrine: it forces competitors to steer away from designs that would come close to literal infringement and instead direct their efforts toward beneficial, leapfrog innovation.¹⁹² The same effect, however, could also be viewed as permitting uncertainty to enhance the patentee's right to exclude,¹⁹³ suggesting that an unduly broad doctrine of equivalents can have a competitive downside.

b. Analysis

Recent trends show a narrowing of the doctrine of equivalents.¹⁹⁴ The Supreme Court's earlier decision in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*¹⁹⁵ and its more recent decision in *Festo*¹⁹⁶ narrow the

doctrine through application of prosecution history estoppel.¹⁹⁷ Other recent cases have kept tight rein by insisting on element-by-element comparisons with literal claims¹⁹⁸ and by deeming matter disclosed in the specification but not included in the literal claims to be excluded from the doctrine's operation.¹⁹⁹

In deciding how to interpret and apply the doctrine of equivalents, both the Supreme Court and the Federal Circuit have explicitly noted and discussed the tradeoffs involved.²⁰⁰ The Supreme Court stated:

It is true that the doctrine of equivalents renders the scope of patents less certain. . . . If competitors

¹⁹⁷ As explained by *Festo*, "When . . . the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo*, 535 U.S. at 733-34. The Court in *Festo* resolved questions regarding the nature of amendments that give rise to this estoppel and the circumstances under which some equivalents may still infringe. *Id.* at 735-41. The Federal Circuit has recently remanded the case for trial court determination whether one of those circumstances – the possibility that the equivalent was unforeseeable at the time of the claim amendment – was present. *Festo Corp. v. Soketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003).

¹⁹⁸ See, e.g., *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317 (Fed. Cir. 2002); see also Sung 2/8 (Patent Session) at 128-29 ("Ninety-nine of the elements or limitations may be identical in nature but the court is still going to only focus on that one particular element to decide is that change in that element substantial or insubstantial.").

¹⁹⁹ See *Johnson and Johnston Assoc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (*en banc*).

²⁰⁰ See *supra* Ch. 1(III)(A)(2)(b) and *infra* Ch. 6(I)(B)(1)(C).

¹⁸⁹ See Sobel 7/10 at 173-178.

¹⁹⁰ See Dreyfuss 7/10 at 83; Sobel 7/10 at 172.

¹⁹¹ See, e.g., Kieff 4/10 at 38-39; Kesan 4/10 at 196-97.

¹⁹² See Sobel 7/10 at 175.

¹⁹³ See *id.* at 80.

¹⁹⁴ See Wamsley 7/10 at 13-15.

¹⁹⁵ *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997).

¹⁹⁶ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002).

cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. . . . Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.²⁰¹

The Supreme Court concluded that, if the doctrine of equivalents were to be discarded, Congress should do so and not the Court.²⁰² These cases reflect decisions made with an awareness of the importance of public notice as well as a concern for the patentee's ability to secure the benefits of its patent.

D. Utility and Research Issues

One question is how to determine when an invention has evolved to the point that it should receive a patent. If patents covered very basic research, for example, then patent law could deter much follow-on innovation by independent inventors. If, in contrast, an inventor could not receive a patent on an invention ready for commercialization, that would substantially undermine the incentives of the patent system. Two means exist to address these issues. First, the statutory standard of utility requires that an invention be "useful" to receive a patent.²⁰³ Second, a common-law

"experimental use" exemption has developed, upon which researchers sometimes rely to exempt their activities from infringement claims.

1. The Utility Standard

Inventions must be "useful" to support issuance of a patent. As it has evolved, the utility standard is relatively lenient and typically is not a significant barrier to patentability.²⁰⁴ It has had some application, however, in biotechnology and chemistry, in which inventions may be forthcoming before their precise use is known.²⁰⁵

The utility doctrine may be important in protecting basic research from premature patenting. Analysts have characterized the utility requirement as "a timing device, helping to identify when an invention is ripe for patent protection."²⁰⁶ Its use relates to concerns that patents on basic research, very far upstream, may impede follow-on innovation by virtue of effects on incentives

²⁰¹ *Festo*, 535 U.S. at 732.

²⁰² *Id.* at 739.

²⁰³ 35 U.S.C. §§ 101 and 112.

²⁰⁴ See, e.g., Thomas 2/8 (Patent Session) at 39-40 ("generally that's a very lenient standard"); Caulfield 3/19 at 183 (utility test "a very big screen through which a lot of material goes"); Rai 4/10 at 106 (utility standard "low"); Kunin 4/10 at 123-24 (a single utility provides protection against all uses); Kieff 4/10 at 126 (questioning need for separate utility requirement); *but cf.* Kushan 4/11 at 85-86 (outlining how applicant's utility characterizations might be used to greater effect in applying other criteria of patentability).

²⁰⁵ See, e.g., *Brenner v. Manson*, 383 U.S. 519 (1966); *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); Thomas 2/8 (Patent Session) at 40-42.

²⁰⁶ See Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2087 (2000).

and on access to upstream technology.²⁰⁷ Commentary from the last few years has focused in particular on how inventors may have to combine a high number of basic patents to yield a downstream product. Some worry that too early patenting will create an “anticommons,” a setting in which follow-on technology is inadequately developed because too many upstream owners each hold separate patent rights.²⁰⁸ Analysts concerned with patenting “too close to the laboratory bench”²⁰⁹ have urged application of a somewhat more rigorous utility standard as a means to avoid such consequences.²¹⁰

The PTO has responded to concerns such as these by issuing (and revising) a set of Utility Examination Guidelines.²¹¹ These Guidelines require that before a patent can issue, there must be a utility well-established in the art (a utility that would be immediately appreciated by a person of ordinary skill in the art), or the applicant must have asserted a

specific, credible, and substantial utility.²¹² The Guidelines, as revised in 2001, have largely been well received,²¹³ and the Hearing record does not highlight substantial competitive issues regarding utility examination.

2. Experimental Use and Research Tools

The experimental use defense for research activities has been described as “a very nascent, ill-developed principle from a few early cases in the 19th century.”²¹⁴ Case law traditionally has exempted research activities that are noncommercial and “for amusement, to satisfy idle curiosity, or for

²⁰⁷ See, e.g., Caulfield 3/19 at 158-62; Rai 4/10 at 23-24, 51-52. See generally *supra* Ch. 4(II)(B)(2).

²⁰⁸ See, e.g., Thomas 2/8 (Patent Session) at 43-44; Scherer 7/10 at 56-57; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

²⁰⁹ Thomas 2/8 (Patent Session) at 42.

²¹⁰ See, e.g., Barton 2/26 at 222; Rai 4/10 at 23-24 (suggesting cautious use of the utility standard to limit patenting in “certain narrow [upstream] areas,” but warning that the utility standard ought not to be set too high as a general matter).

²¹¹ United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (2001) (current guidelines).

²¹² See *Id.* at 1098-99; Thomas 2/8 (Patent Session) at 45; Chambers 2/8 (Patent Session) at 46-47.

²¹³ See, e.g., Beier 2/26 at 297 (“the stakeholders are largely pleased”); Rai 4/10 at 23-24 (“applaud[ing]” the PTO for taking an “appropriately cautious approach”); Biotechnology Industry Organization, *Testimony* (2/26/02) 6, 8, at <http://www.ftc.gov/opp/intellect/020226davidwbeier.pdf>; see also John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 299 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) available at <http://books.nap.edu/books/0309086361/html/285.html#pagetop> (hereinafter *Research Tool*). But cf. Bendekgey 2/26 at 304 (Utility Guidelines not a “huge improvement”).

²¹⁴ Thomas 2/8 (Patent Session) at 30. The doctrine often is traced to an 1813 opinion by Supreme Court Justice Story on circuit. See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (“It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects”). There is no general statutory exemption covering experimental use of patented inventions. 35 U.S.C. § 271(e)(1) provides a limited exemption from infringement for uses reasonably related to the development and submission of information in order to secure Food and Drug Administration approval of pharmaceutical drugs.

strictly philosophical inquiry.”²¹⁵ The strength and contours of the defense have not been fully tested; as several panelists testified, corporations typically have not sued universities.²¹⁶ Some, however, have questioned whether the truce will endure,²¹⁷ and, if it does not, whether the existing experimental use doctrine will afford much protection.²¹⁸

The situation grew more complicated in October 2002 with issuance of a Federal Circuit opinion rejecting application of the experimental use defense.²¹⁹ The court ruled the defense inapplicable “regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”²²⁰ Moreover, the court determined that research projects with no

commercial applications “unmistakably further” a research university’s “legitimate business objectives, including educating and enlightening students and faculty participating in these projects.”²²¹ Although the panelists differed regarding how much precedential power to attach to the opinion’s holding,²²² the discussion indicated that the opinion could unsettle expectations regarding the availability of an experimental use defense and could have a chilling effect on university research.²²³

Panel discussion of the research exemption highlighted three distinct

²²¹ *Id.*

²²² Compare Cohen 10/30 at 161 (arguing that the case essentially deprives universities of the experimental use defense because research is the business of a university) with Kitch 10/30 at 165-66 (arguing that Duke asserted a very broad position – that anything used by a university in research cannot infringe – and suggesting that a more targeted research defense might be better received) and Mossinghoff 10/30 at 168 (case presents a unique set of facts and consequently is not of much guidance). The case involved Duke’s use of laser equipment that incorporated components covered by a former employee’s patents.

²²³ See Cohen 10/30 at 149-52, 162-63 (noting potentially significant chilling effect on those who previously assumed that they were protected by experimental use defense). The precise meaning of the Federal Circuit’s opinion remains in debate. In seeking *certiorari*, Duke University argued that, by its rulings regarding the legitimate business of universities, the opinion necessarily bars application of the experimental use defense to private universities. Petition for a Writ of *Certiorari*, at 14, *Duke University v. Madey* (No. 02-1007) (2002). In contrast, the United States opposed *certiorari* on grounds that by remanding for consideration of both “the legitimate business that Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,” 307 F.3d 1351, 1363 (emphasis added), the court preserved the traditional, narrow experimental use defense. See Brief of Amicus Curiae for the United States, *Duke University v. Madey* (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invt/2002-1007.pet.ami.inv.html>.

²¹⁵ See *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

²¹⁶ See, e.g., Blackburn 2/26 at 325; Dickinson 10/25 at 187; Mossinghoff 10/30 at 168.

²¹⁷ See Merrill 10/30 at 169; *cf.* Caulfield 3/19 at 183 (patentees increasingly demanding royalties from universities).

²¹⁸ See, e.g., Sung 2/8 (Patent Session) at 136-38 (seeing no experimental use exception, “broadly” speaking and describing it as “potentially anachronistic” and “extremely difficult” to establish); Cohen 10/30 at 152 (seeing an “extraordinarily narrow” exemption); Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17-24 (2001).

²¹⁹ See *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003).

²²⁰ *Id.*, 307 F.3d at 1362.

scenarios.²²⁴ One involves research on a patented invention to see how or if it works. Panelists generally supported a research exemption for this purpose.²²⁵ A second scenario involves research to improve a patented invention, either creating a blocking situation (in which both the initial and the follow-on innovator need licenses to use the other's invention) or designing around the initial patent. This case was cast as a middle ground, invoking potentially conflicting goals of fostering competition for improvements and protecting incentives of, or coordination by, the initial innovator.²²⁶ Panelists expressed a range of views – from support through uncertainty and doubt – whether this research should be exempted.²²⁷ Third, there is the possibility of using a patented item as a research tool to create an unrelated product. Panelists generally voiced objections to exempting patented items produced for use by researchers.²²⁸

²²⁴ See Duffy 10/30 at 170-74; *see also* Eisenberg, 56 U. CHI. L. REV. at 1074-76.

²²⁵ See, e.g., Kitch 10/30 at 167; Duffy 10/30 at 171.

²²⁶ See Duffy 10/30 at 160, 172-74.

²²⁷ See, e.g., Barton 2/26 at 172 (supporting compulsory licensing, with or without royalty, for research in this context); Duffy 10/30 at 172 (noting Professor Kitch's nodded assent to statement of reservations), 173-74 ("a hard question"); Kitch 10/30 at 167.

²²⁸ See, e.g., Barton 2/26 at 221; Bendekgey 2/26 at 258-59, 267-68; Kitch 10/30 at 163-64, 166 (emphasizing adverse effect on incentive to produce equipment for researchers). Some panelists identified a separate variant of the third research category. They focused on a subset of patented research tools that are not sold as products in the marketplace, but rather are used only to develop products that are sold. An example might be a patent on a target or receptor used in biotechnology. See McGarey 11/6 at 159; Blackburn 2/26 at 260-61. The Hearing record, however, did not resolve whether this subset warranted separate analysis for purposes of an

a. *Analysis*

Both scholarly analysis and Hearing participants favor an experimental use defense in the first setting.²²⁹ Research to determine if or how a patented invention works essentially makes effective the required enablement disclosure. Indeed, some of the panelists suggested that such activity is already covered by the experimental use defense.²³⁰ The primary issue, then, appears to be whether a more explicit affirmation would be useful.

Extending an experimental use defense to infringement arising through use of tools to develop unrelated products appears problematic. Inventors of tools used by researchers need an income stream from those who use their inventions. The Hearing record provides no basis for exempting such tools from patent protection, and leading scholarly commentary agrees.²³¹

experimental use defense. Compare McGarey 11/6 at 159 (distinguishing, in a context of discussing reach-through royalties, "broad enabling tools that are not destined to be products themselves one day" from tools that are "produce[d] as a product") and Caulfield 3/19 at 158-59, 161-63 (recommending a research exemption to encourage genomic research) with Blackburn 2/26 at 262-63 (viewing patent protection as essential for maintaining proper incentives and raising venture capital for future research tool development).

²²⁹ See Eisenberg, 56 U. CHI. L. REV. at 1074-75.

²³⁰ See Armitage 3/19 at 186. In fact, this first scenario was expressly referenced by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. at 1121. See *supra* note 214. A defense of this nature is typically available abroad. See Duffy 10/30 at 171.

²³¹ See Eisenberg, 56 U. CHI. L. REV. at 1074. Citing concerns over increasing royalty stacking problems in biotechnology, one author advocates compulsory licensing, under reasonable, reach-through royalty arrangements, of research tools used in developing other products. See Mueller, 76 WASH. L. REV. at 58. A recent

Use of a patented invention in research directed toward its own improvement poses the most difficult problem, because it affects the division of profits between initial and competing follow-on innovators, both of which need adequate incentives if their independent contributions are to be sustained.²³² Arguably, such use could be justified as essentially an extension of disclosure requirements.²³³ Some have argued that a research exemption for improvers might be “consistent with the overall thrust of our patent system”²³⁴ and is

survey, however, indicates that, at least thus far, the negotiation breakdowns and royalty stacking problems suggested by anticommons theories have not significantly blocked biomedical research. *See* Cohen 10/30 at 149; Walsh, et al., *Research Tool* at 297-300. Moreover, a panelist explained that many significant research tools are now covered by National Institutes of Health requirements ensuring nonexclusive licensing, *see* Boulware 10/30 at 155-57, and this may mitigate some of the concerns regarding research tools in biotechnology.

²³² Of course follow-on innovation may also come from other routes: an initial innovator with a broad patent covering future development might pursue, or license others to pursue, the follow-on innovations. *See, e.g.,* Kitch 2/20 at 83-84; Scotchmer 2/26 at 129-30.

²³³ *See Integra Lifesciences I, Ltd. v. Merck KgaA*, 331 F.3d 860, 875, 878 (Fed. Cir. 2003) (Newman, dissenting) (arguing that the prohibition of improvement research cannot be squared with the framework of patent law and distinguishing between research into the technology used in patents and the use in research of patented products or methods). In some settings, such as with some methods and processes, follow-on innovators may develop improvements simply from knowledge of the nature of the patented invention; in other settings, such as in software contexts in which the program must be run in order to support any improvement efforts, the patented invention must be used. Plainly, the need to secure a license in order to develop an improvement is more a matter of the nature of the invention than of any general patent law principle.

²³⁴ *See* Duffy 10/30 at 173-74; *see also* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1008 (“Traditionally, patent law has operated on the assumption that other inventors remain free to seek improvement patents within the claims of an earlier

widely accepted abroad.”²³⁵ Others note that so long as follow-on research yields a product or process that infringes the initial patent, the initial patentee will share in any follow-on benefits even if the research is deemed non-infringing. Nonetheless, they concede, the patentee would be harmed if the research designs around the patent.²³⁶ With such offsetting incentive effects, the ideal balance is unclear.

The Federal Circuit’s ruling in *Madey v. Duke University* has a potential to upset the equilibrium regarding research uses of patented inventions and may heighten any problems raised by uncertainty over the reach of the experimental use defense. This warrants continued attention as the implications of these recent developments in the law become better understood.

E. Business Method Patents: An Illustration of Transition Issues

Section 101 of the Patent Act states, “Whoever invents or discovers *any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof*, may obtain a patent”²³⁷ Despite this broad mandate, courts have long interpreted certain types of inventions as unpatentable. Traditional common law

patent.”).

²³⁵ *See* Duffy 10/30 at 172-74 (“de facto, there is a research exemption like that in U.S. law. It’s called Europe.”); MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1015-16; Mueller, 76 WASH. L. REV. at 37-39.

²³⁶ *See* Eisenberg, 56 U. CHI. L. REV. at 1076.

²³⁷ 35 U.S.C. § 101 (emphasis added).

exceptions include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter and, for many years, business methods.²³⁸ Over time, however, these common law exceptions to patentability have eroded.²³⁹

The applicability of § 101, and its common law exceptions, to business methods received particular attention during the Hearings.²⁴⁰ According to the PTO, business methods follow software controlled microprocessors as the next step in the “unbroken evolutionary path” in business data processing.²⁴¹ As one panelist stated, “99 percent of . . . business method inventions are automated techniques for doing something that people used to do in a nonautomated way.”²⁴²

Some Hearing participants observed

²³⁸ See, e.g., Thomas 2/8 (Patent Session) at 25-27, 32, and John Thomas, *Patent Law & Policy: An Introduction* (2/8/02) (slides) at 17, at <http://www.ftc.gov/opp/intellect/jayth1.pdf> and 4/11 at 73; Sung 2/8 (Patent Session) at 139.

²³⁹ See, e.g., Nydegger 4/11 at 106-07; Thomas 4/11 at 70. In two landmark decisions, *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980), and *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), the Supreme Court held, respectively, that man-made, living organisms and computer software constitute patentable subject matter under Section 101.

²⁴⁰ Though business method patents were discussed intermittently throughout the Hearings, the following sessions provided sustained treatment: 2/27 (pm); 3/19 (am); 3/20 (pm); and 4/11 (am).

²⁴¹ See generally AUTOMATED FINANCIAL OR MANAGEMENT DATA PROCESSING METHODS (BUSINESS METHODS), USPTO WHITE PAPER (March 2000) (emphasis added), at <http://www.uspto.gov/web/menu/busmethp/> (hereinafter PTO BUSINESS METHOD WHITE PAPER).

²⁴² Kushan 4/11 at 113-14.

that whenever common law exceptions to patentability erode, a transition period ensues during which the patent system struggles to adapt its standards and procedures to apply to the new technology.²⁴³ Presumably, patent quality may suffer during this period.²⁴⁴ Society’s experience with patents on “automated financial or management data processing methods (*Business Methods*)” exemplifies both such a transition period and the initiatives that may be required to minimize the problems posed during the transition.²⁴⁵ At the Hearing, discussion suggested that the challenge these transition periods pose lies not only in resolution of whatever specific problems arise when examining these newer subject matters, but – perhaps of greater importance – in the anticipation of and proactive treatment of those problems before they fully

²⁴³ See, e.g., Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 589 (1999).

²⁴⁴ John Love 2/27 at 467 (The PTO undertook the Business Method Initiative “partially in response to a public concern about the quality of patents that were being issued in the business method area . . .”). See also Merges, 14 BERKELEY TECH. L.J. at 589 (noting that the scope of the transition problem may be worse for business methods than in the early years of software and biotech patents owing to the “simple matter of overall volume” – the rapid increase in the number of business method applications filed).

²⁴⁵ See PTO BUSINESS METHOD WHITE PAPER at iv (The PTO Business Method Initiative culminated in a white paper that “discusses the patent history of business data processing, the transition this technology is beginning, and the initiatives the USPTO is engaged in to keep pace with this transition and to improve quality in the examination of this technology.”). In 1999, Congress took steps to ease the transition to an era of business method patenting by creating a defense to infringement allegations in the form of prior user rights covering third parties who (i) reduce a business method to practice at least a year before the filing of a patent application and (ii) use that business method before the application’s effective filing date. 35 U.S.C. § 273(b). See *supra* Ch. 4(II)(C)(1).

materialize.²⁴⁶

More fundamentally, the continuing debate regarding business method patents raises the issue of the proper boundaries of patentable subject matter and provides an opportunity to consider some of the ongoing controversies (including the relationship between innovation and patents) underlying the patent system more generally. As these issues arise in fresh contexts, policy makers should use the opportunities to ensure that the patent law reflects an integration of competition values.

1. Legal Status of Business Method Patents

In *State Street Bank & Trust v. Signature Financial Group*, the Federal Circuit ruled that business methods can be patented.²⁴⁷ The court held, “[s]ince the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.”²⁴⁸ Whatever the status of business method patents prior to 1998,²⁴⁹ *State Street* clearly sanctioned their use prospectively. The

²⁴⁶ Aharonian 2/27 at 551.

²⁴⁷ *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999).

²⁴⁸ *State Street*, 149 F.3d at 1375.

²⁴⁹ Panelists expressed a wide range of opinions about whether *State Street* accurately captured the prior treatment of business methods under patent law. Compare Thomas 4/11 at 71 (“[P]atent law has been concerned about business methods from the very beginning. The earliest common law antecedent . . . said business methods are out.”) with Dickinson 2/6 at 67 (stating that business method patents have been issuing “since the mid-1860’s on”).

Federal Circuit’s ruling launched a surge in the number of business method patent filings, though, in absolute terms their numbers remain relatively small.²⁵⁰ In its 2000 White Paper on business methods, the PTO noted that *State Street* “triggered an awareness of the ‘business method claim’ as a viable form of patent protection. We are at the beginning of a change in the approach to how inventors choose to describe their inventions.”²⁵¹

2. Application of Patentability Criteria to Business Methods

Panelists had decidedly mixed assessments regarding both the quality of business method patents issued to date and the prospects for improving quality in the future. In general terms, some worried that the level of abstraction and the multi-disciplinary nature of many business methods prevent efficient application of traditional patent standards.²⁵² Others, however, found little cause for concern; like other areas of patent growth, they reasoned, business method patenting will undergo a maturation process that will eliminate initial

²⁵⁰ Dickinson 2/6 at 68. The PTO assigns most computer-implemented business method patent applications to Class 705, which encompasses automated business data processing technologies. PTO BUSINESS METHOD WHITE PAPER at 6. In FY 1999, the 2658 Class 705 applications represented approximately 1% of all applications filed with the PTO. *Id.* at 7. In FY 2000, 7800 Class 705 applications were filed, out of which the PTO issued 899 patents. In FY 2001, the PTO anticipated 10,000 Class 705 applications would be filed, with over 400 patents issued from among them. Joy Y. Xiang, *How Wide Should the Gate of “Technology” Be? Patentability of Business Methods in China*, 11 PAC. RIM L. & POL’Y J. 795, 828 n.103 (2002).

²⁵¹ PTO BUSINESS METHOD WHITE PAPER at iv.

²⁵² See, e.g., Kahin 4/11 at 18-20.

difficulties.²⁵³ Panelists tended to focus upon the application of several traditional patentability criteria – nonobviousness, written description, and enablement – when assessing PTO grants of business method patents.²⁵⁴

a. Nonobviousness

As discussed previously, nonobviousness is at the core of patent law, and prior art is at the core of nonobviousness.²⁵⁵ The PTO recognized that inventors' increased patenting of business methods required changes in the examination process, including a shift in the examiner knowledge base.²⁵⁶ Locating prior art is particularly difficult for business methods. In part this stems from the infrequency with which such patents previously were sought.²⁵⁷ Other factors – the absence of a drive to publish within business method fields (unlike, for example, the sciences), and the fact that commercial practices in question often only exist in the “heads of business persons” – are systemic problems that may

be more unique to business methods.²⁵⁸

Given the centrality of prior art to nonobviousness determinations, the effective identification of non-patent prior art is critical to ensuring that the PTO issues quality business method patents. Accordingly, former PTO Director Dickinson undertook the Business Method Initiative, which had two primary goals: 1) the identification of sources of non-patent literature, and 2) the creation of mandatory fields of search for examiners.²⁵⁹ Identifying sources of non-patent prior art more generally is likely to be an ongoing task for the PTO, as technological advances multiply and the number of patent applications continues to rise.²⁶⁰

Assessing prior art poses an additional challenge for the PTO. Is the automation of an existing business method inherently obvious? The PTO responded to this challenge by implementing another level

²⁵³ See, e.g., Myrick 10/30 at 186-87; Stoll 4/11 at 170. For a recent empirical study concluding that Internet business method patents “were no worse than patents in general in the late 1990s . . . and may have been better than average,” see John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERK. TECH. L. J.— (forthcoming 2003), in draft at http://papers.ssrn.com/sol3/delivery.cfm/SSRN_ID421980_code030727560.pdf?abstractid=421980.

²⁵⁴ See, e.g., Kushan 4/11 at 104, 113; Janis 4/11 at 65-66.

²⁵⁵ See *supra* Ch. 4(II)(A).

²⁵⁶ See generally PTO BUSINESS METHOD WHITE PAPER at 8-10.

²⁵⁷ See, e.g., Gable 3/20 at 116-18.

²⁵⁸ Thomas 4/11 at 111. Recent research, however, cautions against overemphasizing distinctions between business method patents and other patents based on the accessibility of prior art. See John R. Allison & Emerson H. Tiller, *Internet Business Method Patents*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY at 259, 260 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) (“We conclude that criticisms of Internet-related patents that focus on prior art in particular should be taken with some caution, as we find the statistical differences between these patents and more general patents to be small and, if anything, to suggest that Internet-related patents are well supported by prior art references.”), available at <http://books.nap.edu/books/0309086361/html/260.htm#pagetop>.

²⁵⁹ Love 2/27 at 467-68.

²⁶⁰ For example, when the Commission on Patent Law Reform sat over ten years ago, see *supra* Ch. 1, Box 1-5, the Commission recommended that the PTO create its own database, because “the technology develops so rapidly that you really are not going to find in the patent database the real prior art . . .” Taylor 2/27 at 473.

of review of business method patents by a more senior examiner or examination panel, known as a “second pair of eyes.” The PTO recognized that applying patentability criteria to emerging technologies may be difficult or, at minimum, might differ from their application to more established subject matter, and that more senior examiners could assist with the tough judgment calls that ensue. PTO Group Director for Cryptography and Security Technology Center (TC 2100) John Love noted that the allowance rate for Class 705 (covering most computer-implemented business methods) has consistently decreased since the program was introduced and interpreted this as an indication that patent quality has increased.²⁶¹ Presumably, a second review of this nature might heighten the quality of patentability determinations in other areas of emerging technology as well, as recently suggested by the PTO’s 21st Century Strategic Plan.²⁶²

b. Written Description

Panelists expressed concern that business method patents will contain claims that encompass every manner of

implementing a particular business model.²⁶³ In theory, rigorous application of the written description requirement, which ensures that the inventor has invented what the patent application claims, might avoid such results.²⁶⁴ Some of the panelists suggested difficulties with describing business methods, however.²⁶⁵ As one panelist noted, the general concern is the difficulty of providing a consistent vocabulary to describe abstract subject matter such as high-level software patents and business method patents.²⁶⁶ Another panelist framed the issue in terms of the inherent difficulty of “defin[ing] an idea.”²⁶⁷

c. Enablement

Several panelists argued that business method patents, which frequently encompass software-automated or online processes, are not enabling. As discussed previously, enablement ensures the public is in possession of the invention, *i.e.*, it implements the patent system’s disclosure

²⁶¹ John Love 2/27 at 475. Love stated the allowance rate for Class 705 was 55 percent in 2000 (the reforms were in place for the second half of 2000) and 45 percent in 2001. *Id.* at 470-71. Love further stated that the reduction in Class 705 patents issued indicates improved searching on the part of the PTO for prior art and, he hoped, the narrowing of claims so that they more closely capture a patentee’s innovative contribution. *Id.* at 475.

²⁶² United States Patent and Trademark Office 21st Century Strategic Plan, *Patent Quality Improvement: Expansion of the Second-Pair-of-Eyes Review* (April 2, 2003), at <http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm>. See *infra* Ch. 6(III)(A)(2).

²⁶³ Kushan 4/11 at 114. Mr. Kushan, the author of the PTO’s guidelines for computer-implemented inventions, stated that patents containing claims that encompass every manner of implementing a particular business model should not issue and that stringent written description requirements could play a preventative role. Kushan 4/11 at 114.

²⁶⁴ Kushan 4/11 at 114. See generally *supra* Ch. 4(II)(B) (discussing written description requirements). The enablement and utility doctrines might also prevent the improvident granting of such patents. Kushan 4/11 at 114-15.

²⁶⁵ See, e.g., Kahin 4/11 at 112; Young 4/11 at 112.

²⁶⁶ Kahin 4/11 at 112.

²⁶⁷ Young 4/11 at 112.

requirement.²⁶⁸ Without the publication of the underlying source code, however, some panelists questioned whether that requirement was met.²⁶⁹ For example, Mr. Kushan observed that the higher-level discussion of software currently required may not be sufficient to prove the patent works in the manner claimed or to reveal any dependence on a particular implementation.²⁷⁰ Toward that end, Mr. Kushan believes that requiring patentees to post their source code, somewhat analogous to the micro-organism deposits in the biotech area, would help achieve “the goal of satisfying public need and access to an operable invention.”²⁷¹

3. Patentable Subject Matter

Although all panelists agreed that improvement in the application of traditional patentability criteria to business methods was necessary, they disagreed as to whether such improvement would be sufficient. On one side, Mr. Kushan argued that improvement of business method patents must come through keeping the PTO’s examination “focused on the measurement criteria of inventiveness as opposed to the definitional

criteria of eligibility. . . .”²⁷² By contrast, Professor Kahin argued, “we ought to be willing to draw lines around patentable subject matter. And I say this recognizing that this is a chronic policy problem in an age of porous boundaries, that it is hard to maintain lines. But the alternative is to swallow the world, and I don’t think that’s what the patent system should be doing.”²⁷³ A number of panelists discussed the viability or value of a “technicity” requirement for drawing the line regarding patentable subject matter.²⁷⁴

The record offers substantial guidance concerning patentable subject matter more generally.²⁷⁵ On one hand,

²⁷² Kushan 4/11 at 24.

²⁷³ Kahin 4/11 at 20.

²⁷⁴ See, e.g., Thomas 4/11 at 55 (“point of patentable distinction involves . . . manipulation of natural laws . . . concerning physical elements”); Musacchia 4/9 at 26 (urging United States to move toward European and Japanese approaches requiring industrial application and technical features); cf. Hughes 2/28 at 622 (European discussions on software and business methods “could be very revealing to us”). According to the European Patent Office, “in order to be patentable, an invention must be of a technical character to the extent that it must relate to a technical field, must be concerned with a technical problem and must have technical features in terms of which the matter for which protection is sought can be defined in the patent claim.” Available at http://www.european-patent-office.org/news/pressrel/2000_08_18_e.htm. Panelists disagreed as to what this meant as a practical matter. See, e.g., Stoll 4/11 at 162 (noting that “anecdotally many, many attorneys have told me they are patenting both software and business methods in Europe”); Thomas 4/11 at 174 (noting that the UK and French patent offices “have spoken out against business methods, but the German Patent Office seems in favor of them”).

²⁷⁵ The precise boundaries of the patent system’s domain are still unresolved. Although the Supreme Court’s *Chakrabarty* opinion observes that “Committee Reports . . . inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man,’” 447 U.S. at 309, the Court immediately adds, “This is not to

²⁶⁸ See *supra* Ch. 4(II)(B).

²⁶⁹ See also *supra* Ch. 4(II)(B)(3).

²⁷⁰ Kushan 4/11 at 102.

²⁷¹ Kushan 4/11 at 102. For a contrary view, see National Academy of Sciences Board on Science, Technology, and Economic Policy, Conference on the Operation of the Patent System: Insights from New Research 222 (Transcript of Proceedings Oct. 22, 2001) (“the Patent Office doesn’t want the source code, because they have nowhere to store it, and they have nowhere to get access to it in a useful way”), at http://www7.nationalacademies.org/step/transcript1022_PD_F.pdf (Testimony of Robert Sterne).

defenders of business method patents stressed that universality of patentable subject matter has been a significant factor in U.S. technological development.²⁷⁶ They argued that in the absence of clear empirical evidence, the default position should be that an invention is patentable. Stated alternatively, they suggested that the promotion of innovation should be presumed unless empirical evidence to the contrary exists.²⁷⁷ On the other hand, critics argued that business method patents do not foster incentives to innovate, because business methods traditionally evolve in response to competition and internal business needs, without regard to legal rights to exclusivity.²⁷⁸ In other words, it is unclear whether business method patents satisfy “but for” principles.²⁷⁹ Moreover, Yale University President Richard Levin noted possibilities for the exercise of market power and the impairment of follow-on innovation.²⁸⁰

suggest that § 101 has no limits or embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.” *Id.*

²⁷⁶ See Jeffrey R. Kuester & Lawrence E. Thompson, *Risks Associated with Restricting Business Method and E-Commerce Patents*, 17 GA. ST. U. L. REV. 657, 685 (2001); Kuester 4/11 at 44-45; IPO (stmt) 16 (describing patents as a bedrock of the economic incentive to innovate in all technologies).

²⁷⁷ Kuester & Thompson, 17 GA. ST. U. L. REV. at 680-81; Kuester 4/11 at 37-38, 44, 115-16; Nydegger 4/11 at 184.

²⁷⁸ See, e.g., Musacchia 4/9 at 24-26; Young 4/11 at 61, 63-64; Thomas 4/11 at 57-59.

²⁷⁹ See *supra* Ch. 4(II)(A)(2).

²⁸⁰ See R. Levin (stmt) 2 (“There are potentially serious consequences of a low threshold for patenting in emerging technology areas. A patent, after all, grants an exclusive right, and in some cases it can confer power in product and innovation markets. We should be very wary

Recommendation. Given the complexity of the issues and the diversity of views reflected in the Hearing record, the Commission makes no recommendation for judicial or legislative action to reconsider or restrict the patentability of business methods. Nonetheless, in light of the uncertainty surrounding the benefits and the possible competitive downside from extending patent coverage to new fields, future extensions, and any future reconsideration, by courts or by Congress, of patentable subject matter extensions, require – at a minimum – a conscious policy choice, in addition to a searching and rigorous application of the other patentability criteria. In assessing such future issues, decision makers should ask whether the extension of patentability will “promote the Progress of Science and useful Arts” or instead will hinder competition that can function effectively to spur innovation. Such consideration is consistent with the historical interpretation of Section 101, which typically recognizes that granting patent protection to certain things, such as phenomena of nature and abstract intellectual concepts, would not advance the patent system’s Constitutional goals.

of creating unwarranted market power by granting unwarranted patents.”); see also, Langenfeld 2/20 at 18; Thomas 4/11 at 60; Kushan 4/11 at 114; Robert M. Hunt, *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the Economy?*, Q1 BUSINESS REVIEW 5, 14 (2001) (finding reason to question whether business method patents will provide significant incentives to innovate). Hunt also stresses the need for “more careful empirical research on the effects of increasing the availability of patents in high technology industries” to give policymakers “more and better information about the costs and benefits of the ongoing changes in our patent system.” *Id.*

III. CONCLUSION

The Hearings highlighted both the potential benefits and potential harms of patents. Clearly, they help foster innovation. At the same time, the testimony identified a number of potential adverse effects, including greater market power, higher costs and risks for competitors, and higher costs and reduced incentives for independent follow-on innovation. The presence of both potential benefits and potential harms implies a need for making tradeoffs and judicious policy choices. In deciding issues at the interstices of the patent statutes, in amending those statutes, and in making determinations about patentable subject matter, policymakers should strive to take conscious account of the likely effects on innovation and on competition, with the goal of adopting policies that contribute most to consumer welfare over time.

In some cases, “but for” thinking can provide useful guidance for overall policy directions. For example, to the extent that the suggestion test for nonobviousness lacks convincing correlation to the likelihood that invention would occur or that it would be disclosed and developed without the patent, the test raises the potential for conferring exclusionary rights without offsetting social benefit. The Commission, therefore, urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. Failure to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art

may be unnecessarily detrimental to competition.

Competitive considerations help inform other substantive aspects of the patent system. They raise questions about the commercial success test for nonobviousness and confirm the importance that courts evaluate, case by case, whether commercial success is a valid indicator of the nonobviousness of the claimed invention and that patentees bear the ultimate burden of demonstrating that the claimed invention caused the commercial success. They suggest that current disclosure doctrines accord reasonably well with economic goals at a systemic level but that accurate, up-to-date assessments of the predictability of the art and of the abilities of the PHOSITA in evolving industries are important elements for harmonizing the patent and antitrust regimes. They suggest the need to monitor carefully the consequences of *Madey v. Duke University* for the vitality of follow-on innovation and the functioning of the experimental use defense.

Finally, competition concerns suggest the need for a legislative change. The Hearing record indicates that current continuation practice disrupts business certainty and harms competition by permitting applicants to broaden their claims after competitors have developed their products and incurred sunk costs. The Commission recommends that legislation be enacted providing intervening or prior user rights that would protect third parties from hold-ups made possible by continuations.