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Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform

*Kristen Nugent**

INTRODUCTION

A person whose family income is \$75,000 or more is almost twice as likely to be in “excellent” health than someone with family income of less than \$20,000.¹

Nearly twenty-two million persons delayed medical care in the last year because of its cost; over fifteen million additional individuals did not receive the care they needed at all due to the expense.²

Persons in the lowest income group are five times as likely as persons in the highest income group to delay medical care due to cost and about ten times as likely not to get needed medical care.³

A substantial amount of academic literature is dedicated to potential strategies for remedying these inequities in the provision of health care in the United States. Yet, only a small portion of this writing considers the impact of intellectual property rights on the pricing and availability of modern medical advancements. Rather, the published research in this field focuses predominately on the intersection of patent law with medical procedures, biotechnology, and pharmaceutical drugs. Of course, an examination of these areas is undeniably important to determining how to best shape legal institutions to foster the progress of knowledge and the innovation of technology in the medical sciences.

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1. PATRICIA F. ADAMS ET AL., NATIONAL CENTER FOR HEALTH STATISTICS, SERIES 10, NO. 233, SUMMARY HEALTH STATISTICS FOR THE U.S. POPULATION: NATIONAL HEALTH INTERVIEW SURVEY, 2005, VITAL & HEALTH STAT. 4 (2007).

2. *Id.* at 6.

3. *Id.*

However, this article seeks to explore an often-overlooked segment of this debate: whether the current patent system strikes the optimal balance between providing incentives to inventors to bring new medical devices to the marketplace, and promoting public health by making these medical devices available at a reasonable price. If the system is not balanced, then the issue becomes whether there are alternatives to the existing institutions that can better achieve this goal.

In order to answer these questions, this article undertakes a multi-step analysis. Part I offers an overview of current patent law, with an emphasis on medical devices. For the purpose of analogy and contrast, Part I also considers the special rules that apply to medical procedures and drugs. Part II explains how ethical and economic considerations suggest the need for an alternative system in the medical device sector. Part III analyzes the difficulties with implementing a new compensation system for medical devices despite relevant patent and business traditions. Part IV notes some of the unique characteristics of the medical, academic, and research professions that may counteract the concerns discussed in Part III and justify unique treatment of medical devices. Finally, Part V discusses the benefits and drawbacks of several alternatives to the current patent system, including government intervention in the form of grants, awards, and tax breaks; compulsory licenses; shortened patent terms; increased reliance on trade secret protection; or some combination of these options.

Based on this analysis, this article concludes that the medical device industry is amenable to a patent reform system that seeks to balance ethical and economic considerations better than the current regime. A combined system is proposed, whereby medical device inventors would be granted patents offering a reduced period of exclusive control over the device, followed by receipt of reasonable compulsory licensing royalties for the remainder of the patent's traditional twenty-year term. This scheme would be supplemented with additional opportunities to receive government-provided monetary awards and benefits in exchange for earlier dedication of the device to the public domain. Additionally, inventors would continue to have the option of choosing trade secret protection in lieu of patent rights. This article concludes that such an arrangement would most equitably account for the interests and needs of both healthcare device consumers and producers.

PART I—OVERVIEW OF PATENT LAW

A. General Principles

The United States Constitution charges Congress with the responsibility to promote “the Progress of Science and useful Arts, by securing for limited

Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴ The patent laws deriving from this authority are generally justified by a utilitarian rationale.⁵ That is, the government encourages invention and the dissemination of knowledge by granting inventors monopolies over their inventions,⁶ in exchange for disclosure in the patent application of the invention’s description and best means of enablement.⁷ Currently, the monopoly term lasts twenty years from the filing date of the application.⁸

During this period of exclusive control, the patent holder can restrict others from introducing to the market any product that fits within the patent’s claims.⁹ Moreover, the patent owner may charge supra-competitive prices for access to the invention, which allows the inventor to recoup the research and development costs that competitors would not incur if permitted to free-ride off her work.¹⁰ Without this mechanism to recover fixed costs, inventors would have difficulty earning a profit and would lose much of their incentive to create.¹¹ Alternatively, the patent owner may withhold the invention from the public for the duration of the patent period.

To be eligible for this patent protection, the invention must meet several statutory conditions. Under current law, these requirements apply generally, with no statutory text explicitly dictating differential treatment for varying types of technology.¹² First, the invention must fit into one of

4. U.S. CONST. art I, § 8, cl. 8.

5. See, e.g., Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 150-55 (2004) (describing the incentive to invest, incentive to disclose, and incentive to innovate theories for providing patent protection to promote scientific progress). See also *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 5-10 (1966) (noting that the Framers rejected a natural rights theory of intellectual property in favor of a social and economic rationale for the patent system, since the Framers believed that the monopoly grant was at odds with the “inherent free nature of disclosed ideas”).

6. 35 U.S.C. § 154(a)(2) (2000).

7. See 35 U.S.C. § 112 (2000) (requiring that the application of the invention contain a description in such “clear, concise, and exact terms” as to allow a “person having ordinary skill in the art” to construct and use the invention once the patent term is over). 35 U.S.C. § 103(a) (2000) (a “person having ordinary skill in the art” is often referred to as a “PHOSITA”). See also *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 474 (1895) (“The Incandescent Lamp Case”).

8. 35 U.S.C. § 154(a)(2) (2000).

9. See 35 U.S.C. § 271(a) (2000) (providing that anyone who “makes, uses, offers to sell, or sells any patented invention” without authority, infringes the patent); 35 U.S.C. § 281 (2000) (permitting an inventor “remedy by civil action” for patent infringement); 35 U.S.C. § 283 (2000) (providing the courts authority to grant injunctions for patent infringement).

10. See Mireles, *supra* note 5, at 151-52.

11. *Id.* at 152.

12. Some authors have suggested that Patent Office examiners and courts may be holding different categories of inventions to different standards on their own, without express authorization from Congress. See *infra* notes 93-100. This article also considers

the general categories of patentable matter, which includes any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”¹³ Congress intended the patent laws to have a wide scope;¹⁴ thus, while natural phenomena and abstract ideas are not patentable, the medical devices under consideration in this article would clearly fall within the bounds of the law. The second requirement is utility,¹⁵ which in practice is a minimal constraint. The medical devices at issue here are presumed useful, insofar as they perform the functions they are designed to perform and provide at least a minimal social benefit.

The third requirement of novelty reflects the principle that only new inventions merit patent protection.¹⁶ Still, an improvement on an invention covered by a preexisting patent may itself be patented, implicating the doctrine of blocking patents.¹⁷ In these circumstances, the holder of the improvement patent and the original patentee each has the right to exclude the other from practicing the improvement.¹⁸ Of course, the parties may be able to negotiate licensing agreements so that the innovation reaches the general public.¹⁹ However, if the bargaining process breaks down, the improvement will be kept from the market until the original patent’s term expires and the invention enters the public domain.²⁰ This article will explore the implications of blocking patents as they relate to the availability of medical technologies. Finally, under the requirement of non-obviousness, the invention must be a sufficient advancement over all relevant prior art references such that it would not have been obvious to a person having ordinary skill in the art (“PHOSITA”) at the time the invention was made.²¹

This article examines the complexities of the economic theories underlying the current system of patent law, as well as criticisms of these theories, especially in the context of the medical sector. Essentially, the current patent system is justified under utilitarian economic theory as a means of providing incentives for the creation of information when the development and dissemination of knowledge is valuable to society but not

how the patent statute offers special treatment to certain categories of medical technology—namely, medical procedures and drugs—in other aspects of the law. *See infra* Part I.B.

13. *See* 35 U.S.C. § 101 (2000).

14. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

15. *See* 35 U.S.C. § 101 (2000). *See also* UNITED STATES PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE, 2100-20 (2006).

16. 35 U.S.C. § 102 (2000 & Supp. II 2002).

17. Mireles, *supra* note 5, at 168.

18. *Id.*

19. *Id.* at 169.

20. *Id.* at 168.

21. 35 U.S.C. § 103(a) (2000).

necessarily profitable for the originator in the absence of monopoly pricing.²²

Under a patent monopoly, inventors know that their competitors will be barred from free-riding off of the time and money they invest into development by merely copying the end result.²³ At the same time, inventors are not constrained by market forces pushing the price of the innovation down to its marginal costs of production.²⁴ Therefore, while a patent monopoly allows inventors to price goods at a level where they can recover fixed costs of research and development, nothing prevents them from raising the price even higher.²⁵ Consequently, a significant population may value the invention more than its marginal cost but less than its monopoly price.²⁶ Although these people would benefit from obtaining the good, the patent monopoly would price them out of the market, ultimately resulting in net social welfare loss.²⁷ Moreover, to the extent that the inventions would have been created even without patent protection, society suffers a deadweight loss without any countervailing benefit, which undermines the utilitarian justification for patent protection in the first place.²⁸ This article argues that this deadweight loss is particularly dangerous in the medical context, where not only financial interests, but also public health and welfare, are at stake.

B. Medical Procedures and Pharmaceuticals

The previous section outlined the general principles of patent law, which apply to most inventions. However, due to the unique interests implicated in medical procedures and prescription drugs, Congress has deviated from the strict universal application of these principles by enacting special rules

22. See, e.g., Steve P. Calandrillo, *An Economic Analysis of Intellectual Property Rights: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System*, 9 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 301, 303-04 (1998).

23. See *id.* at 303.

24. *Id.*

25. See *id.*

26. *Id.*

27. Calandrillo, *supra* note 22, at 304-05.

28. The term “deadweight loss” in economics generally refers to the loss of efficiency (a deviation from the optimal market equilibrium) that occurs as the result of market distortions like taxes, subsidies, or monopoly pricing. See, e.g., KARL E. CASE & RAY C. FAIR, *PRINCIPLES OF ECONOMICS* 442 (Prentice Hall 5th ed. 1999) (1994). In the context of the patent monopoly, society accepts a loss of competition because the promise of the monopoly will induce inventors to create. Thus, it logically follows that if an inventor would have created the invention even without the patent promise, no new value is added to society that would not have arisen anyway. In this sense, whenever an invention would have been created regardless of patent protection, the utilitarian justification for the current patent regime fails.

and exceptions in these areas. Since medical devices implicate many of these same interests, this section offers a brief overview of some of the more important departures from the general patent regime for health-related inventions. Indeed, the comparison of medical devices to medical procedures and drugs was recognized as appropriate in the past, as patent experts have testified before Congress that “patenting medical devices raises virtually all the same social costs as does patenting medical methods.”²⁹

For one, pharmaceuticals receive special treatment under patent law with respect to the length of the monopoly term. Instead of the standard twenty year term that begins on the date the application was filed for utility and plant patents, the duration for drug patents is calculated on the basis of the time it takes for clinical trials and FDA approval.³⁰ Notwithstanding this “advantage,” the “effective patent life” of the average drug patent is only 11.8 years.³¹ Yet, the pharmaceutical industry is often cited as being particularly reliant on patent protection due to its substantial upfront research and development expenditures.³² The fact that the industry “maintains tremendous incentive to innovate despite having patent duration effectively shortened by approximately one-third . . . [provides] strong reason to believe that the incentive provided by the patent system may be much more than is necessary for this or other industries.”³³ To be sure, this article supports the same contention, and argues that a reduced patent term may be justified for medical devices as well.

Further, granting differential treatment to medical devices is not unprecedented in patent law for the medical sector. For example, Congress enacted a statutory exception for the manufacture, use, or sale of patented inventions “for uses reasonably related to the development and submission of information under Federal law which regulates” drugs in order to protect certain medical researchers from liability.³⁴ Specifically, experimental uses of a patented drug will not constitute infringement if undertaken for the purpose of obtaining FDA approval to get a safe generic version of the product to the market shortly after the patent term expires.³⁵ While the text

29. *Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearing on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 104th Cong. 81 (1995) (statement of Donald R. Dunner, Chair, Section of Intellectual Property Law, American Bar Association).

30. 35 U.S.C. § 156 (2000 & Supp. II 2002). See also Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 290 (2006).

31. Johnson, *supra* note 30, at 290.

32. *Id.*

33. *Id.*

34. 35 U.S.C.A. § 271(e)(1) (2007).

35. Robert M. Portman, *Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress*, 4 U. BALT. INTELL. PROP. L.J. 91, 112

of the law only explicitly mentions drugs, the Supreme Court has construed this statutory exception to apply to medical devices as well.³⁶

Additionally, Congress has attempted to balance competing interests in the context of medical procedure patents. The medical community has consistently opposed patent protection in this area, while other interest groups have objected to limitations either specifically on patents in the medical context or on patentable subject matter generally.³⁷ This conflict led to an amendment to the patent statute prohibiting suit against a medical practitioner or related healthcare entity for performance of a patented medical activity.³⁸

However, several exceptions written into this amendment demonstrate why an amendment alone is insufficient to address all the concerns raised within this article. For instance, an exempted “medical activity” does not include “the use of a patented machine . . . in violation of such patent.”³⁹ Thus, physicians are prevented from using another device in a medical procedure if doing so would constitute an infringement of that patent.⁴⁰ Furthermore, the statutory exception does not extend explicitly to persons involved in activities directly related to “the commercial development, manufacture, sale, importation, or distribution” of a medical device.⁴¹ As a result, it grants a continuing legal remedy to device manufacturers against other persons or entities that infringe or induce others to infringe upon medical procedure patents by offering competing technology.⁴²

In the aggregate, these special rules indicate that Congress is receptive to amending patent law to meet the distinctive needs of the health industry. It is unlikely, however, that Congress will completely abandon the fundamental precepts of patent law discussed in Section A, even when the social interests at issue are substantial. Therefore, it is necessary to examine the considerations associated with the implementation of an alternative system that can build on the patent regime currently in place.

(1996) (describing this exception as congressional action to “diminish rights of patent holders that conflict with the public interest”).

36. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678-79 (1990). See generally Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device, and Drug Laws*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2000).

37. Portman, *supra* note 35, at 113 n.99.

38. 35 U.S.C. § 287(c)(1) (2000).

39. 35 U.S.C. § 287(c)(2)(A)(i) (2000).

40. Portman, *supra* note 35, at 114-15. See also Frank M. Washko, *Should Ethics Play a Special Role in Patent Law?*, 19 GEO. J. LEGAL ETHICS 1027, 1030 (2006).

41. 35 U.S.C. § 287(c)(3) (2000).

42. Portman, *supra* note 35, at 117.

PART II—ETHICAL, ECONOMIC, AND INTERNATIONAL CONSIDERATIONS
AFFECTING PATENT LAW

In overseeing the future direction of patent law, legislatures must balance the ethical and economic policy concerns implicated by it. Unfortunately, these concerns often conflict not only with each other, but internally as well, with respect to the preferable course of action they suggest. Sections A and B of this Part respectively explore the major ethical and economic considerations implicated in shifting to an alternative intellectual property regime for medical devices. Thereafter, although a full survey of applicable international patent law is beyond the scope of this article, Section C provides an overview of how adherence to the most prominent intellectual property law treaty—the World Trade Organization TRIPS agreement—could limit the United States’ ability to undertake drastically transformative measures.

A. Ethical Considerations

The ethical principles underlying the U.S. patent system are widely recognized to be utilitarian.⁴³ Thus, in considering the moral implications of altering the intellectual property regime governing medical devices, this article sets aside any qualms one might have about denying an inventor some Lockean conception of her “natural rights” in her creation.⁴⁴ Instead, this article focuses on striking the appropriate balance between ensuring the widespread and equitable availability of medical care, and constructing the optimal environment for cultivating medical advancements. The complexity of this challenge is reflected in the shift in the American Medical Association’s (“AMA”) position on patenting medical devices over time: half a century ago, the AMA held that patenting medical instruments, appliances, and other devices was unethical.⁴⁵ Today, the prohibition on such patents no longer stands.⁴⁶

As noted above,⁴⁷ the ethical implications of patenting medical

43. See, e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1597 (2003) [hereinafter Burk & Lemley, *Policy Levers*] (“courts and commentators widely agree that the basic purpose of patent law is utilitarian: We grant patents in order to encourage invention.”).

44. See JOHN LOCKE, *TWO TREATISES OF GOVERNMENT* 287 (Peter Laslett ed., Cambridge Univ. Press 1988) (1690). Essentially, Locke’s natural rights theory of property asserts that each individual has an exclusive “property” in her own person, and a corresponding right to the fruits of the labor of her body. Thus, a natural rights theorist might argue that patent protection for medical devices is merited by virtue of the laborer’s inventive endeavor alone. Such arguments are outside the scope of this article, however.

45. Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN’S L. REV. 329, 354 (1997).

46. *Id.*

47. See *supra* notes 34-38 and accompanying text.

procedures have been so substantial that Congress enacted special safe harbor provisions protecting medical practitioners from liability for using a patented method. Indeed, many of these concerns surrounding the patenting of medical procedures translate directly to the medical devices domain.

To begin, the costs associated with patenting medical products raise a myriad of ethical concerns. For instance, the prohibitively high licensing or royalty fees that a patent holder may charge for her product could substantially impair patient access for the duration of the patent monopoly, either because few doctors could afford to acquire the relevant technology or because the individual patients could be priced out of the market.⁴⁸ Also, costs to the healthcare system could rise as teaching hospitals and medical schools that use these patent-protected products could potentially pass the expense of the monopoly prices on to their medical students in the form of higher tuition fees.⁴⁹ This ethical argument can be expressed in an economic framework: even though property rights may create additional incentives to innovate, a social order where these innovations are not widely available may generate lower net social welfare than a system where fewer innovations are created, but where innovations are accessible on a more widespread basis.⁵⁰

Regarding the ethical implications of an innovation's availability, there is a danger that a particular device could become the preferred form of treatment for a specific ailment, such that it would define the standard of care.⁵¹ This kind of standardization could force doctors who treat that ailment to pay whatever price the patentee sets in order to avoid malpractice liability.⁵² An atmosphere where medical decisions are heavily influenced, if not dictated, by monetary affairs, stands in contradiction to the "rather uniformly recognized . . . patients' rights to receive medical care in accordance with their licensed physician's best judgment and the physician's right to administer it . . ." ⁵³ Thus, current patent law has the

48. Weldon E. Havins, *Immunitizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. DET. MERCY L. REV. 51, 62 (1999) (discussing a similar effect for patented medical procedures).

49. Portman, *supra* note 35, at 107.

50. Stanley M. Besen & Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSPECTIVES 3, 6 (1991).

51. Havins, *supra* note 48, at 62-63.

52. *Id.* Havins foresees, at least in the context of medical processes, a situation where doctors are trapped: if they refuse or are unable to purchase the right to perform the relevant procedure (or, by analogy, to buy the relevant device), they risk liability for breach of the duty of care; but if they perform the procedure anyway, they open themselves to infringement suits. *Id.*

53. *United States v. Evers*, 453 F. Supp. 1141, 1150 (M.D. Ala. 1978). See also Portman, *supra* note 35, at 109 ("The physician must decide whether to become a licensee, refer the patient to a licensee, . . . or forgo the procedure [or use of the device]

potential to distort not only the patient's choice of physician, but the physician's choice of treatment.

In addition to limiting treatment options, there is concern that the existence of patent rewards is changing the ethics and dynamics of the medical research field.⁵⁴ The unique characteristics of this sector, which make it particularly amenable to elimination or alteration of the current patent system, are discussed in greater detail below.⁵⁵ Briefly, however, industry insiders have recognized that the means by which patent law allocates credit and potential monetary reward for invention has caused distrust between students and faculty members, altering the traditional mentorship relationship in a way that threatens the progress of science and the useful arts.⁵⁶

Clearly, there are ethical consequences to current patent law that, in the aggregate, suggest that adjustments to the regime could lead to a net increase in social welfare. That is, the financial losses that some industry players may face could be relatively minor and will arguably be outweighed by the improvements in the rapport between researchers and the wider availability of medical devices, both of which benefit society as a whole. Accordingly, it is important to weigh these ethical implications when considering alternatives to the existing patent regime.

B. Economic Considerations

As previously stated, the Constitutional underpinnings of the U.S. patent system are found in the Intellectual Property clause, which provides that government-conferred exclusive rights are permissible for the purposes of promoting science and the useful arts.⁵⁷ If the ultimate goal of the patent system is to benefit society, then arguably the current patent system focuses too heavily on providing economic incentives for creation at the expense of progress in the open exchange of knowledge and public access to medical advancements. In other words, there may be an unintended tradeoff whereby the patent system has increased the total quantity of inventions while neglecting the importance of quality and accessibility, by means of the patent monopoly and the "race to be first." Merely spurring the flow of

altogether The patent has directly interfered with the physician's decision-making process, the patient's treatment, and the patient's choice of medical provider.").

54. See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 174 (2001).

55. See *infra* Part IV.B.

56. See Golden, *supra* note 54, at 174 (reviewing reports of increasing "pathological behavior" among scientists, attributable to the influence of the patent regime and resulting in disrupted mentor-mentee relationships and slowed production of knowledge).

57. See *supra* note 4 and accompanying text.

private investment dollars into technological endeavors is not, after all, the objective of the Intellectual Property clause.⁵⁸

The danger of the patent monopoly implemented in the current patent regime is that it may grant “property rights beyond what inventors legally deserve, or (of more fundamental concern) beyond what best promotes the development and dissemination of technological products.”⁵⁹ Because industry lobbyists generally believe that increased intellectual property protection will increase profits, lobbyists push for ever broader patent protection.⁶⁰ Thus, arguably the patent institution distorts behavior from what is constitutionally desirable and economically efficient. On the other hand, some scholars have contended that the U.S. is a leader in research and innovation because of the broad scope of the protection its patent system offers.⁶¹

Regardless of whether medical research has flourished because of or in spite of the current patent system, the system’s structure leaves it vulnerable to abuse. While manipulation of the patent laws for personal gain leads to inefficiencies and social losses in all categories of inventions, it is particularly detrimental in the medical context because of the negative effects it can have on patient care. For example, a patent holding company or other business entity can purchase the patent rights of struggling or bankrupt companies, even if it lacks the ability or intention to use, improve, or develop the technology it purchases.⁶² Instead, the new patent-holder can use its property right to extract funds from those who do wish to put the knowledge underlying the patent to a socially beneficial or commercial use.⁶³ If the patent owner’s demands are too high, innovation will hit a roadblock: businesses will abandon the project, diverting funding from potentially valuable research endeavors, or pass the expense along to healthcare consumers for whom increases in marginal costs are difficult to absorb.

Although the problem of the “race to be first” permeates patent law generally, certain effects of this phenomenon are specific to the medical context. Priority races occur because only the first firm to invent the

58. See Golden, *supra* note 54, at 104-05 (arguing that patents are intended to provide protection that gives innovators an incentive “to bring forth new knowledge”).

59. *Id.* at 105.

60. *Id.* at 133.

61. See, e.g., Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT’L L. REV. 223, 241 (2002) (comparing U.S. advancement over other nations in the field of biotechnology).

62. Washko, *supra* note 40, at 1032.

63. *Id.* The same logic would also allow patent holding companies to hinder the ability of companies who wanted to make products for socially beneficial, rather than purely economic, reasons.

relevant device will obtain a patent right in it, notwithstanding other firms' investments in developing similar products that fall within the patent's claims.⁶⁴ As a result, both the device and the scientific knowledge underlying it evolve at sub-optimal levels.⁶⁵

Despite this problem, Professor Kitch's prospect theory of intellectual property suggests that it is most sensible to grant the original patentee broad ability to control the development, manufacture, and sale of her invention, since the expertise she acquired in creating the invention put her in a superior position to encourage further use and improvements.⁶⁶ Then again, it is equally likely that under these circumstances both the patent holder and other potential inventors have a reduced interest in producing a more socially useful form of the invention.⁶⁷ The patent owner can continue to charge monopoly prices on the original invention without pursuing additional improvements that would actually merit higher prices. The owner can also block future inventors from practicing their improvements on the original device until the original patent term is over.⁶⁸ In the rapidly changing field of medical technology, both the original invention and the improvement may be obsolete by that time.

In their general critique of Kitch's prospect theory, Professors Merges and Nelson elaborate on these concerns and conclude that rivalrous development is superior to coordinated development both theoretically and empirically.⁶⁹ First, they argue that rivalry sharpens the threatened consequences of passivity.⁷⁰ In support of this contention, they discuss several occasions where firms with control over a technology were complacent with the status quo until competition drove them to embark on new socially beneficial and profitable ventures.⁷¹ Additionally, they claim that the prospect theory overlooks the fact that a firm may focus on the one or few aspects or applications of the protected technology with which it is most familiar, even though outsiders may find other potential functions for the device.⁷² Professors Merges and Nelson contend that it is reasonable to expect that a broad property right will lead to underdevelopment and lost

64. Calandrillo, *supra* note 22, at 329.

65. *Id.*

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

67. Calandrillo, *supra* note 22, at 329-30.

68. See, e.g., Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX L. REV. 989, 1010 (discussing the problem of blocking patents).

69. See generally Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

70. See *id.* at 872.

71. *Id.*

72. *Id.* at 873.

improvements that otherwise would have occurred if a diverse set of researchers had access to the device.⁷³

In sum, there are both economic advantages and disadvantages to the existing U.S. patent regime. While this Section described some of the inadequacies that an alternative system should address, patent law reformists must continually reflect on potential distortions a different regime could cause.

C. International Considerations: The TRIPS Agreement

The current patent system is hindered by companies' obligation to comply with international treaty commitments and the need to keep American companies competitive in a globalized marketplace. However, with respect to at least some of the options discussed in this article, these obstacles are not insurmountable.

The most important treaty to this discussion is Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), the provisions of which the United States adopted as part of the 1994 Uruguay Round of the World Trade Organization ("WTO") negotiations.⁷⁴ This agreement generally provides that patent protection must be available for twenty or more years for all categories of inventions, unless commercial exploitation of the product contravenes public order or morality.⁷⁵ It is unclear, however, if the ethical arguments propounded by this article could ever satisfy the WTO's intended meaning of "morality" sufficient to place medical devices within this exemption.

Regardless of the breadth of the WTO's interpretation of this provision, signatory countries have already demonstrated their ability to work within the general rules of the treaty to deal with related issues, such as ensuring that citizens of impoverished member nations have access to pharmaceuticals without materially diminishing the patent-provided incentive to create them. Indeed, at the Doha Ministerial Conference in 2001, WTO ministers issued a special declaration stating that the terms of TRIPS should not inhibit member nations from pursuing their domestic public health policies and goals.⁷⁶ They also encouraged members to take advantage of flexibilities already written into the TRIPS agreement.⁷⁷ Additionally, the WTO ministers added or extended exemptions and

73. *Id.* at 873-74.

74. See INFORMATION AND MEDIA RELATIONS DIVISION, WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO, 41 (3d ed. 2007), available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf.

75. *Id.* at 43.

76. *Id.* at 82.

77. *Id.*

waivers designed to facilitate the least-developed countries' ability to acquire patented drugs more cheaply.⁷⁸ If necessary, member nations could agree to similarly special treatment for medical devices.

The safeguard provisions in TRIPS already allow some version of a compulsory license scheme,⁷⁹ which is presented in this article as one of the more favorable alternatives to current patent law. Essentially, compulsory licensing schemes attempt to influence the terms of bargaining agreements reached by the original inventor and the improver.⁸⁰ Accordingly, TRIPS does not restrict the reasons for which a government may grant a compulsory license, provided that the potential licensee first tries to negotiate a voluntary license from the patent holder.⁸¹ If negotiations fail, the government can compensate the patent holder for the license at a fair market rate.⁸² Depending on the structure of revisions to U.S. patent law, and barring any conflict with other treaties (such as NAFTA), the need to craft amendments to TRIPS in order to harmonize international law with a domestic compulsory licensing regime would be minimal.

Already, a number of foreign countries have implemented compulsory "dependency license" provisions into their patent statutes.⁸³ An improver may invoke these provisions against the dominant patent holder in the case of blocking patents.⁸⁴ The existence of these compulsory licenses generally serves only to facilitate private bargaining for cross-licensing arrangements, and does not materially alter inventor incentives.⁸⁵ This idea suggests that an appropriately constructed and limited compulsory licensing regime in the United States would impact incentives minimally and avoid violating any international reciprocity obligations.

Later, this article explores several options aside from compulsory

78. *Id.* at 84.

79. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 333 (1994) [hereinafter TRIPS Agreement] (Article 31, "Other Use Without Authorization of the Right Holder").

80. Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 103-04 (1994).

81. See TRIPS Agreement, *supra* note 79, at 333 (Article 31(b)).

82. Gumisai Mutume, *Health and "Intellectual Property"*, 15 AFRICA RECOVERY, 14, 14-15 (June 2001). See also WORLD TRADE ORGANIZATION, TRIPS AND HEALTH: FREQUENTLY ASKED QUESTIONS—COMPULSORY LICENSING OF PHARMACEUTICALS AND TRIPS, Sept. 2006, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Nov. 10, 2007).

83. See Merges, *supra* note 80, at 104-05 (noting that China, France, Italy, Japan, and Sweden are among countries with compulsory license provisions in their patent statutes). The European Union, moreover, recently implemented regulations allowing compulsory licenses in the narrow context of pharmaceuticals exported to least developed nations. See also Commission Regulation 816/06, 2006 O.J. (157) 1.

84. *Id.* at 104.

85. *Id.* at 105.

licenses, although only tangential consideration is dedicated to the implementation of these alternatives from an international perspective. As opposed to these alternatives, however, a compulsory licensing regime emerges as a promising alternative to the current patent institution, given the normative and legal background described in this section.

PART III—CHALLENGES TO ALTERNATIVE COMPENSATION REGIMES FOR MEDICAL DEVICES

The dynamics of the present patent system are ingrained in the nation's inventive culture; one could expect resistance to change due to the force of historical precedent alone. Consequently, advocating changes only to the medical device sector alleviates some political barriers but intensifies others. Sections A and B of this Part examine how to justify differential treatment for medical device patents and how to determine what inventions would fall within the exception's domain. Section C surveys the broader claim that a selective alternative compensation regime could skew inventor and investor incentives in the medical device industry in an undesirable way.

A. Classifying "Medical Devices"

One of the first hurdles to implementing a special category of patent protection for medical devices is establishing how and when to classify a given device as "medical." For instance, should the tools used in elective procedures like cosmetic surgery be released into the public domain before the traditional patent term has expired, along with the devices used to save lives or alleviate pain? The ethical pull for universal access to the latter class of inventions is obviously much stronger, and inventors drawn to research in the latter category are arguably less likely to be financially motivated. But what if a plastic surgery device also could be used for reconstructive purposes? Or what if the technology behind or applications of an invention could span multiple disciplines?⁸⁶ One can foresee circumstances where firms would argue that their device does not fall within the medical technology exception and thus deserves the traditional patent term.

On a related note, the question arises as to who should make the determination of whether the medical device classification applies. The average judge likely lacks the appropriate technical background to make fine distinctions in close cases, but leaving the decision strictly to the U.S.

86. On this question, see, e.g., Qin Shi, *Patent System Meets New Sciences: Is the Law Responsive to Changing Technologies and Industries?*, 61 N.Y.U. ANN. SURV. AM. L. 317, 336 (2005).

Patent and Trademark Office (“PTO”) would further burden the agency and leave applicants without the traditional protection of the courts.⁸⁷

B. Singling Out Medical Devices

As this article will illustrate, the medical sector has unique characteristics that make it particularly amenable to special treatment. As discussed above in the context of medical procedures and drugs, there is precedent for congressional action in this area. Nevertheless, the question remains: why single out medical devices for special treatment, as opposed to any and all socially valuable inventions? Certainly, representatives of many other industries also could claim that specially tailored rules would foster innovation in their respective fields as well. Meanwhile, consumers of their products could argue that the current law grants an overly expansive award, or that a reduction in monopoly power is ethically required. As several scholars note, making distinctions between inventions threatens the cohesion of the patent system and encourages interest groups to pressure Congress to change the laws to their advantage.⁸⁸

Many schemes for redesigning the patent system contemplate demarcating categories into which inventions would be placed and treated accordingly. For instance, divisions could be based on economic and technical traits, such as the invention’s cost of production, the income it generates, or the degree to which it introduces or utilizes pioneering functions or knowledge.⁸⁹ Of course, such information is often difficult to obtain *ex ante*.⁹⁰ In contrast, categorization based on broad industrial sectors lacks the precision of a more refined system, but is easier and less expensive to administer.⁹¹ It also reflects the idea that devices within a given industry frequently share finer economic and technical traits.⁹² Determining whether the entire patent system ought to be overhauled and all inventions segregated into discrete categories is beyond the scope of this article. For now, it is sufficient to recognize that under virtually any classification system, medical devices considered *en bloc* have characteristics sufficiently unique to justify affording them differential treatment.

In fact, many scholars argue that a degree of “technological-specificity” already exists in the patent system due to the actions of the PTO and the

87. *Id.* at 336-37.

88. Golden, *supra* note 54, at 184.

89. Johnson, *supra* note 30, at 299.

90. *Id.*

91. *See id.* at 299-300.

92. *Id.*

courts, even if Congress does not explicitly authorize it.⁹³ For example, Professor Wagner distinguishes between “micro-specificity” and “macro-specificity” in the patent system.⁹⁴ Micro-specificity is a schema whereby the legal rules applied to an invention vary depending on particular technological circumstances, regardless of the broad category of industry in which the invention lies.⁹⁵ Under a system of macro-specificity, on the other hand, the applicable legal rules are distinct across different industries, but remain similar for all the technologies within a given industry.⁹⁶ Wagner contends that micro-specificity both positively and normatively describes and justifies current patent law.⁹⁷ In support of this contention, he notes that the PHOSITA standard allows for flexible application of the law from innovation to innovation.⁹⁸ Additionally, he argues that categorization of inventions on the basis of the general nature of the technology or industry participants is too imprecise to respond to changes in specific technology.⁹⁹

In contrast to the micro-specificity approach, scholars such as Professors Burk and Lemley advocate a patent system characterized by macro-specificity, particularly as a political means of promoting biotechnology innovation.¹⁰⁰ Although the proposals in this article more closely align with Burk and Lemley, it is important to note that scholars have endorsed various types of technological specificity which may already be inherent in the system.

C. *Effects on Incentives*

Under a utilitarian rationale, sufficient incentives to innovate are central to encouraging the creation of new and useful inventions. Therefore, when considering alternative patent systems, it is necessary to examine not only the typical progression of the inventive process, but also the effects on the desire to invent in the first place.

According to some patent law scholars and practitioners, the discovery trajectory of cutting-edge innovations commences with a groundbreaking discovery that has potentially broad applications, which defines and

93. See, e.g., Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1185 (2002) [hereinafter Burk & Lemley, *Is Patent Law Technology-Specific?*]; R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003).

94. Wagner, *supra* note 93, at 1345.

95. *Id.*

96. *Id.*

97. *Id.* at 1347.

98. *Id.*

99. Wagner, *supra* note 93, at 1347.

100. Burk & Lemley, *Is Patent Law Technology-Specific?*, *supra* note 93, at 1191.

establishes the new field.¹⁰¹ Then, discoveries within this new field are refined further and improved incrementally.¹⁰² Simultaneously, other fields of inquiry progress in a similar manner.¹⁰³ Ultimately, these distinct but related fields intersect, inspiring even more advanced inventions with greater commercial potential.¹⁰⁴ As a result, the patent system arguably gains efficiency when it displays horizontal consistency between different industries.¹⁰⁵ In effect, “[t]echnology-specific incentives may appear attractive at first, but as the technology evolves, the incentive specifically instituted may become out-of-sync with the discovery process, obviating its incentive appeal.”¹⁰⁶

The literature analyzing the “discovery-trajectory” phenomenon criticizes proposals to adjust factors, such as the length of the patent term, to increase the number of patents, arguing that it would be “an unpredictable and wasteful exercise.”¹⁰⁷ Specifically, this literature suggests that the importance of “the inventor’s own interest in and means for industrial application, the ripeness of the invention for commercial exploitation, the profit margin of the relevant market, and the difficulty and competitiveness of the art” render increasing patent incentives imprudent.¹⁰⁸ These same factors support this article’s proposal that a reduction in patent protection may be appropriate.

Nonetheless, basic economic theory suggests that, notwithstanding external conditions that may mitigate the net effect of change, reducing or otherwise altering the patent term is likely to skew investor and inventor incentives.¹⁰⁹ Thus, the most fundamental objections against reform of the current patent regime are that changes to the system would negatively impact the incentive to invest and incentive to disclose.

1. Incentive to Invest

The incentive to invest theory operates on the premise that patent law fosters private investment in two fundamental ways. First, it promises

101. Shi, *supra* note 86, at 331.

102. *Id.*

103. *Id.* at 332.

104. *Id.* at 331.

105. *Id.* at 332.

106. Shi, *supra* note 86, at 332.

107. *Id.* Shi finds that the correlation between the number of patents issued to an inventor and the likelihood that he will invent in the future is nonlinear. *Id.* at 332.

108. *Id.*

109. See, e.g., James Langenfeld, *Intellectual Property Protection and Antitrust: Steps Toward Striking a Balance*, 52 CASE W. RES. L. REV. 91, 97-98 (2001) (explaining that reduction in intellectual property protection will lead to a corresponding decrease in incentives to innovate, leading to an eventual loss into net social welfare).

individual researchers compensation, in the form of being able to set the market price for the good, as a reward for dedicating their time and money to developing the invention. Since knowledge and ideas are classic public goods, inventors who do not have the right to exclude others from practicing their inventions risk competitors free-riding off of their initial investments, obtaining the end result without having to incur the costs.¹¹⁰ A lack of invention protection leads to a market failure wherein inventors cannot recover their costs of development and thus have lower incentives to create in the first place.¹¹¹ Patent protection helps inventors to recoup their investments by prohibiting copying during the patent term so that the patentee can raise the device's price at or above a level sufficient to meet both fixed and marginal costs.¹¹² Therefore, if medical products did not provide patent protection, individuals with high inventive capital would realize they could maximize their earnings in a field with traditional patent protection, thus skewing incentives in a manner that encourages inventors to explore non-medical fields. Of course, this result presupposes that all non-economic motivations to innovate are held constant between industrial sectors, which, as the discussion below will show, is an inappropriate assumption.

Second, patent rights operate as an “intermediate marketable product—a government-issued currency”¹¹³ that allows smaller or start-up firms to attract the private investment they need to develop and market their innovations. The inventive process is time sensitive, financially risky, and carries no guarantee of commercial success. Yet, patent rights shift the risk-reward calculus in favor of investing capital in an enterprise. In the event the research and development process produces a commercially valuable medical device, the inventor will be able to exclude competitors from the market, therefore increasing the likelihood the investors will realize a return on their principal. The patent rights also can be licensed or sold in order to recover capital. Without patent law, investors will arguably lose this important government-sponsored signal of value, which could divert resources to other industries.¹¹⁴

2. Incentive to Disclose

The patent application requires disclosure of the best manner in which the public can construct and use the device once it enters the public

110. Mireles, *supra* note 5, at 151-52.

111. *Id.*

112. *Id.*

113. Golden, *supra* note 54, at 168.

114. *Id.* at 169-70.

domain.¹¹⁵ Proponents of the current patent system argue that without this disclosure requirement, creators have no reason to ever share the knowledge underlying their innovations with the public. Instead, it would be in their interest to withhold the information—whether by trade secret, contract, or other protection—possibly indefinitely, in order to maintain their monopoly position.¹¹⁶ Under the current law, however, society can build upon the knowledge contained in the patent to make improvements to existing inventions and can construct the patented invention without duplicative experimentation once the patent term is over.¹¹⁷

PART IV—JUSTIFYING DIFFERENTIAL TREATMENT

While acknowledging the validity of opponents' objections to an alternative compensation system, this Part delineates a series of responses and countervailing considerations that arguably offset, limit, or even eliminate the potential problems related to developing alternative compensation regimes discussed in Part III. Section A begins by addressing the "incentive to invest" and "incentive to disclose" issues directly and by describing additional factors outside the domain of patent law that motivate economically productive behavior. Section B then illustrates how normative conduct within the medical profession suggests that the promise of patent protection often is of secondary value in providing incentive for creative behavior. Taken together, the Sections of this Part make a credible case for instituting alternative intellectual property treatment for medical devices.

A. Responses to the Economic Arguments

Some authors have noted a lack of reliable empirical data demonstrating that the patent system advances scientific and technological knowledge and innovation in the way economic theory suggests it should.¹¹⁸ Others have taken the criticism a step further, claiming that patents on medical technology may "actually stifle innovation and dissemination of these inventions to the public."¹¹⁹ Even the National Institutes of Health has cautioned that "intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and

115. 35 U.S.C. § 112 (2000). *See also supra* note 7 and accompanying text.

116. *See* Havins, *supra* note 48, at 62 (explaining the incentive to disclose theory in the context of medical process patents, and criticizing it on the grounds that, in the absence of patent protection, another practitioner would be likely to develop the same procedure anyway).

117. Mireles, *supra* note 5, at 153-54.

118. *See, e.g.,* Havins, *supra* note 48, at 61.

119. Washko, *supra* note 40, at 1027.

product development.”¹²⁰ Indeed, it is generally recognized that different industries rely on patents to varying extents, suggesting that the rigid patent term under the current patent law can lead to deadweight monopoly loss without offsetting innovative gain. This is especially likely where, as with the medical device sector, the invention would have been created anyway.¹²¹

1. Incentive to Invest

In response to the “incentive to invest” argument that patent rights allow small businesses to attract the private investment they need to develop their innovations, Golden’s criticisms of this theory in the biotechnology context apply to the medical device industry as well. For instance, Golden contends that biotechnology stocks are subject to wild, short-term swings regardless of their patent position.¹²² This volatility casts into doubt the effectiveness of patents in stabilizing investments.¹²³ Likewise, even if stocks in medical device companies are not as prone to speculative high-risk buying and selling as biotech stocks, their prices nevertheless fluctuate due to investor over-enthusiasm and fear, misinformation and misunderstandings about the company’s activities, or announcements unrelated to the company’s patent holdings.¹²⁴ Golden summarizes some additional flaws in the “incentive to invest” rationale as follows:

The stimulation of fights over intellectual property rights—such as through patent litigation that distracts from, and increases the cost of, the pursuit and development of innovations—could slow progress more than the spur of prospective patent speeds it. Furthermore, the erosion or corruption of public sector values, as a result of increased focus on obtaining private property rights, could weaken an established and effective (and predominately publicly funded) system for producing scientific and technological advance. Finally, patent monopolies could distort the direction of research and eventually clog the ‘small company’

120. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (proposed May 25, 1999).

121. Johnson, *supra* note 30, at 284-85 (suggesting that a patent system which provides incentives beyond the inducement threshold can lead to abuses such as the strategic delaying of competition) (citing Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32:2 MGMT. SCI. 173, 174-76 (1986)).

122. Golden, *supra* note 54, at 170-71.

123. *Id.*

124. See, e.g., Amy Tsao, *The Healthiest Play in Medical Devices*, BUSINESSWEEK, June 18, 2004, available at http://www.businessweek.com/bwdaily/dnflash/jun2004/nf20040618_5362_db014.htm?chan=search (describing sector analysts’ cautious approach of investing for the long-term in entities with multi-year histories of profits as opposed to smaller companies that may experience rapid short-term growth).

dynamism of the . . . industry itself, leading ultimately to its domination by giant companies with large concentration of vested intellectual property rights¹²⁵

As applied to medical devices, reduced patent litigation should translate to more investment money dedicated to research and development, cheaper prices for consumers, and a reaffirmation of the communal values discussed in Section B of this Part. These results could even inspire further public and private expenditures when investors witness the success of the traditional knowledge-sharing dynamic at work.

2. Incentive to Disclose

With respect to the argument that the patent application provides “incentive to disclose,” it is important to recognize that although the information contained in the application will eventually reach the public domain, the process of filing the application distorts the researcher’s incentive to submit relevant findings for peer review.¹²⁶ A statutory bar precluding the issuance of a patent for public disclosures made more than one year prior to filing, in combination with possible fear that other experts’ scrutiny could expose flaws in the work, may prompt the patent applicant to limit disclosure and evaluation of the innovation to the patent examiner.¹²⁷ Of course, medical devices will be evaluated for safety before entering the market. However, the secrecy that permeates the invention immediately prior to filing the application postpones effective peer review and limits the forcefulness of the “incentive to disclose” theory.

Furthermore, while the medical technology industry and research universities frequently work together to develop innovations, members of the academic community have criticized the tendency of businesses to privatize information.¹²⁸ This privatization has stifled the free exchange of knowledge that previously characterized academia and facilitated progress.¹²⁹ Indeed, these fears are not purely speculative, as universities, due at least in part to the influence of the industry, are taking advantage of the patent system and pursuing licensing and technology transfer schemes more frequently.¹³⁰

125. Golden, *supra* note 54, at 172. These flaws apply equally to the concerns of this article.

126. Portman, *supra* note 35, at 106.

127. *Id.*

128. Golden, *supra* note 54, at 134 (explaining the conflict in the context of the biotechnology industry).

129. *Id.*

130. *Id.* at 142-43 (noting, however, that “even after obtaining the rights to exclusive patent monopolies, government laboratories and universities have favored widespread granting of non-exclusive licenses,” suggesting a concern for the public interest still drives much of this research).

Studies within the biotechnology sector suggest that the intrusion upon the traditional expectations of information sharing could have a demoralizing effect on researchers.¹³¹ The behavior of researchers outside the bounds of patent law suggests that the “incentive to disclose” is weak justification for a robust patent system.¹³² This rationale demonstrating the shortcomings of the “incentive to disclose” theory should apply to the patenting of medical devices as well, since these devices originate with researchers who possess similar social and academic concerns.

Moreover, even though the knowledge behind the issued patent enters the public domain, the ability to put that knowledge to any socially or commercially useful purpose is limited during the term of the patent monopoly.¹³³ This limitation undermines the “incentive to disclose” rationale as well. Furthermore, the law prohibits firms from manufacturing devices that read onto the patent’s claims.¹³⁴ Thus, inventors could withhold any improvements on the original invention from the market if the blocking patent holders are unable to negotiate a licensing arrangement.¹³⁵ Indeed, for minor improvements that would be socially useful but which would not merit independent patent protection, the information might never be known.

Arrow’s information paradox predicts that the original patent owner will not be able to price an improver’s idea unless the owner first hears of the improvement.¹³⁶ However, once the improver discloses the unpatented improvement information, the original owner is free to use it without payment.¹³⁷ Enterprising companies may also engage in attempts to design around the patent’s claims, generating an invention that serves substantially the same purpose as the original and wasting investment dollars that could

131. *See id.* at 152-63 (discussing the motivations of life science professionals).

132. *See id.* at 165-66 (noting that researchers publish their discoveries for reasons other than patent protection).

133. 35 U.S.C. § 271(a) (2000) (granting the patent holder the power to exclude others from making or using the patented invention during the patent term).

134. *Id.*

135. Lemley, *supra* note 68, at 1050-51 (describing the “rather absolute power” the inventor has to control any improvement to her invention during the term of her patent).

136. *Id.* at 1051. Kenneth Arrow, currently at Stanford University, won the 1972 Nobel Prize in Economics and the 2004 National Medicine of Science for his extensive contributions to the field. His work has centered on social choice, risk-bearing, and decision-making under imperfect information conditions; his “information paradox” is foundational to theories of the economics of information. *See generally* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609 (Nat’l Bureau of Econ. Research ed., Princeton Univ. Press 1962).

137. *Id.*

be put to a more socially useful purpose.¹³⁸ Thus, there are several ways in which the “incentive to disclose” theory is undermined.

3. Additional Factors

Market forces may provide the potential inventor with the anticipation of income sufficient to incentivize creation, even in the absence of any government-initiated incentive system or patent. Perhaps the most important of the market forces is the “first mover advantage.” Scholars have identified several ways in which the first mover advantage can manifest itself, potentially rendering patent protection unnecessary.

First, there will often be natural barriers to entry into a particular market, in addition to those that the originating companies can erect within the bounds of the law.¹³⁹ Second, the original inventor’s control over the market without patent protection will be extended during the period in which potential copiers learn about the existence of the new device and consider manufacturing a competing version.¹⁴⁰ Third, once the competitor makes the decision to manufacture the product, it must complete the substantial tasks of analyzing and reverse engineering the device, purchasing the equipment needed to construct it, and hiring or training engineers familiar enough with the relevant technology to guide this process.¹⁴¹

Scholars note that the first mover advantage is most robust when the relevant industry is characterized by high fixed costs and low marginal costs of production.¹⁴² Indeed, the medical device industry exhibits such characteristics,¹⁴³ suggesting that even in the absence of patent protection, the prospect of first mover advantages would propel innovation. Even proponents of reducing or eliminating the current patent system acknowledge that when deciding whether to undertake a certain project,

138. Mireles, *supra* note 5, at 153.

139. Calandrillo, *supra* note 22, at 319 (citing F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 384-87 (Rand McNally & Co. 1973) and JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 400-01 (MIT Press 1988)).

140. *See id.* at 319-20 (citing F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 385 (Rand McNally & Co. 1973)).

141. *See id.* at 320 (citing F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 385 (Rand McNally & Co. 1973) and JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 400 (MIT Press 1988)).

142. *Id.* at 320-21 (citing STEVEN SHAVELL, ECONOMIC ANALYSIS OF THE LAW, Instructor’s Guide § 7, at 5 (2004)).

143. *See, e.g.*, National Innovation Centre, Innovation Know-How Guide to Production and Distribution In-Use, <http://www.nic.nhs.uk/InnovationKnowHow/InnovationAssistant/Tracks/Production/In-Use/Maintaining+Supply.htm> (last visited Nov. 10, 2007) (“Often medical device production carries high fixed costs partly due to strict regulatory and quality requirements. This means that a key challenge is to increase the sales and therefore production volumes to offset these high initial costs and create a sustainable business.”).

firms will factor into their calculation the probability that copying rivals will appropriate their expenditures on research and development.¹⁴⁴ However, the strong possibility of first mover advantages weighs in favor of pursuing innovation.

The patent system encourages a race-to-invent mentality in which the “winner” obtains exclusive rights to sell the good for the duration of the patent term.¹⁴⁵ The “winner’s” competitors receive nothing, regardless of the extent of their research or how close they came to making the same patentable invention. However, an approach based on market forces alone could allow these competitors to realize the benefit of their investments. For instance, innovation leaders will have a head start over market newcomers who will be building from scratch and will have to dedicate time and money to acquiring the machinery, personnel, and knowledge necessary to compete.¹⁴⁶ This environment encourages the most efficient trajectory of production. In such an environment, firms have reason to research and innovate in order to reap the benefits awarded to the original suppliers in the market, while diminishing the need to rush the process in order to be absolutely first and win the monopoly. This lack of haste in research and development should result in higher quality devices.

The first mover advantage is one of the most important responses to the claim that innovators need patent protection to recover their fixed costs of production. However, several other business-based phenomena can also lead to increased profit margins, thus providing incentive for inventive behavior even absent a regime of legal protection. For instance, if two firms sell equivalent products, the firm with more efficient management, better marketing and sales efforts, superior customer service, and a better reputation is likely to see higher gross revenue and net profit.¹⁴⁷

This concept applies to the first-mover advantage insofar as first-comers will have more time to perfect these capacities, and consumers are more likely to continue to do business with a company they trust. Additionally, a firm that develops a device internally will have up-to-date manufacturing capacity, familiarity with the technology to facilitate quicker improvements, and the “kind of holistic understanding” of the device and its market that a competitor who merely copies the invention will lack.¹⁴⁸ While such factors alone may not be sufficient to supplant the entire patent system, when taken into account along with the other characteristics of the medical

144. See Calandrillo, *supra* note 22, at 325.

145. See 35 U.S.C. § 271(a)-(b) (2000) (holding liable as an infringer anyone who “without authority makes, uses, offers to sell, or sells” or who “actively induces infringement” any patented invention during the patent term).

146. Calandrillo, *supra* note 22, at 319.

147. See Johnson, *supra* note 30, at 277, 279.

148. See *id.* at 279.

device industry discussed below, they solidify the case for lessening current protections and considering alternative forms of compensation.

B. Characteristics of the Industry

Both globally and historically, the medical profession has disfavored attempts by its members to hinder the dissemination of knowledge or discoveries that could benefit patient well-being, particularly when the motivation is personal financial gain.¹⁴⁹ Of course, this stance is in conflict with the business segment of the medical device industry, which is more profit-oriented.¹⁵⁰ Indeed, the AMA deems the open exchange of information and the publication of research results to be an obligation and an ethical duty:

This tradition enhances patient care, leads to the early evaluation of new technologies, and permits the rapid dissemination of improved techniques Prompt presentation before scientific organizations and timely publication of clinical and laboratory research in scientific journals are essential elements in the foundation of good medical care.¹⁵¹

Scholars and analysts concur with the AMA's assessment, noting that the norms of openness, cooperation, and collegiality that permeate the scientific community help overcome the free-rider problem, lead to the earlier validation of the results of research endeavors, and minimize unnecessarily duplicative studies.¹⁵²

A public good-oriented structure of the research community complements the public service values inherent to the medical profession. Golden describes this as the "inventor class," characterized by "values that prize the advancement and wide dissemination of scientific and technical knowledge, and, less altruistically, support a 'credit economy' in which personal achievement is tied to status, reputation, and empire building."¹⁵³ Researchers and academics advance their careers by obtaining grants and awards, beating their peers to discoveries and innovations, and publishing seminal works. Accordingly, the potential for personal monetary gain

149. See, e.g., Portman, *supra* note 35, at 95, 97-98.

150. See *id.* at 104.

151. COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS § 9.08 (1994).

152. Paul A. David, *The Economic Logic of "Open Science" and the Balance between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, in *THE ROLE OF SCIENTIFIC AND TECHNICAL DATA AND INFORMATION IN THE PUBLIC DOMAIN: PROCEEDINGS OF A SYMPOSIUM* 19, 21-22 (Julie M. Esanu and Paul F. Uhler, eds., Nat'l Academic Press 2003) (adding that intellectual property rights, by promoting secrecy and priority races, can have the opposite effect of postponing research corroboration efforts and failing to control redundant experimentation).

153. Golden, *supra* note 54, at 144.

through patent protection may be less of an inducement for those who choose to undertake medical device research rather than enter other industries.¹⁵⁴ Since the “combined incentives of ethical duty, professional recognition, and career advancement have traditionally been enough incentive for medical research,”¹⁵⁵ there should be no material decline in innovative behavior. This proposition is particularly true when factoring in the potential of considerable economic windfall that exists even in the absence of patent protection for major discoveries and creations, as discussed in Section A above.

PART V—ALTERNATIVE COMPENSATION SCHEMES

Assuming this article’s supposition is correct and the medical device industry is amenable to accommodating changes in intellectual property protection and compensation, the next question is what type of alternative compensation system would best balance the interests of healthcare consumers, physicians, and the medical device industry. This Part investigates five possible avenues for reform: government grants, awards, and tax breaks; compulsory licenses; shortened patent terms; trade secret protection; or some combination of the above. Undoubtedly, any of the proposed solutions would encounter some intense political resistance. While this article takes the political feasibility of enactment into account, this factor is not determinative in the way it might prove to be in practical application.

A. Government Grants, Awards, and Tax Breaks

In theory, replacing patent protection with a government reward system could remedy many of the current regime’s shortcomings. A properly designed reward system would offer financial stimulus to innovate, similar to the stated purpose of the patent monopoly, but without the corresponding restrictions on the use and dissemination of what is created.¹⁵⁶ Under this regime, the government would pay inventors a monetary award that reflects the value society assigns to the product and the reasonable investments in developing it.¹⁵⁷ In return, the invention and related information would enter the public domain, obtainable by anyone at the marginal cost of production or dissemination.¹⁵⁸ Because inventors would receive

154. *See id.* at 144-45. Golden believes that because of the lack of material rewards during the early parts of their careers, these scientists’ claims to be motivated by the desire cure or treat disease and advance scientific knowledge are plausible. *Id.* at 154.

155. Washko, *supra* note 40, at 1030-31.

156. Calandrillo, *supra* note 22, at 306-07.

157. *Id.*

158. *Id.*

appropriate compensation and the availability of the device would approach its socially optimal level, net social welfare could be improved over the current system.¹⁵⁹

Furthermore, a reward system could help to solve some of the negative consequences of the “race to be first” problem discussed above. For instance, even if a company did not receive a government reward for creating the foundational invention, it could utilize the technology to make further improvements that would both benefit society and make the company eligible for new government rewards or superior position in the marketplace. As a corollary matter, if the firm had already sunk costs into trying to develop the original invention, only to have another company win the award first, those investments would still give the firm a competitive advantage over others and would allow the resources to be reapplied to the pursuit of the improvements.

While a government reward system has appeal in the abstract, it suffers from many practical problems that would likely render it unfeasible.¹⁶⁰ The most obvious impracticality is the difficulty of calculating the appropriate amount of money with which to reward each inventor.¹⁶¹ While proponents of these plans have argued that an independent commission could tie valuation to market demand, others have countered that creating a new government entity would be an unnecessary and additional expense, since it would lack the specialized familiarity with the relevant markets that subsists naturally in private businesses.¹⁶² There is also the possibility of a reduced incentive to innovate if the expected returns from the government award are less than the expected returns from monopoly pricing.

Of course, some inventors might prefer the assured money of a reward system over the risk that a different cheaper invention will come along and diminish the market value of the patented product. To further dispel the concern of under-investment, the government could promise to give additional compensation to those inventions that unexpectedly exceed the original projected market value used to calculate the initial award.

However, determining the source of funding for this program is an even more fundamental problem, assuming that the government could determine the appropriate amount of money to present to each inventor. Although proponents of a reward system argue that the administrative costs would be comparable to those of the current patent regime,¹⁶³ there is no comprehensive study of the probable costs of such a transition. Thus, such

159. *Id.* at 307-08.

160. *See, e.g., id.*

161. Calandrillo, *supra* note 22, at 308.

162. *Id.*

163. *Id.* at 337.

claims are speculative and should be treated with caution. Furthermore, while it does seem likely that the increased public access, the decreased prices for medical devices, and the accelerated technological development that would come from a properly functioning reward system would offset any increase in taxes,¹⁶⁴ it is unclear if the public would perceive it this way. Rather, any increase in taxes would probably be met with resistance. Finally, whether tax rates are increased or tax revenue is shifted to the reward program from other areas, there would be an implicit subsidy whereby wealthy individuals in good health bear a higher burden of paying the costs and receive less value from the system than less financially fortunate individuals in poor health who consume more medical devices and services. However, this type of subsidization is currently in practice—for example, through Medicare deductions from paychecks and risk pooling via health insurance plans—so it would not be an impossible endeavor to arrange tax plans for a medical device program in a similar manner.

In addition to funding problems, the public's desire to see the government tied up in healthcare policy issues raises another concern. Society generally has greater faith in the market than the government to allocate resources efficiently. Critics of government reward systems worry that such state intervention could inhibit creative independence.¹⁶⁵ While this may be less problematic in the realm of the sciences than in the arts, there is still the potential for distortions to arise. For example, when Congress allocates funds, they may be swayed by powerful interest groups for particular causes or inclined to disproportionately fund “glamorous” or “popular” media-friendly projects (such as AIDS or breast cancer research, for instance), even though other areas of research are less exposed, and therefore in greater need of funding. Electing a post hoc reward system as opposed to an ex ante funding mechanism may mitigate the problem somewhat by allowing researchers to read the market and commence work in areas they anticipate will be lucrative. Even with this arrangement, however, problems could arise if a supposedly independent commission systematically over-valued certain types of medical devices, or if the method of calculating reward amounts failed to incorporate intensity of need or preference into a market-based formula.

As an alternative to an award system, government grants have been proposed. Of course, a discussion of government grants would not be complete without consideration of the Bayh-Dole Act, which controls part of the broader legal regime surrounding current patent law.¹⁶⁶ The passage

164. *Id.* at 337-38.

165. See Robert M. Hurt & Robert M. Schuchman, *The Economic Rationale of Copyright*, 56 AM. ECON. REV. 421, 425-26 (1966).

of the Bayh-Dole Act (“Act”) allows universities and small firms to hold patents on inventions developed with federal funds.¹⁶⁷ In doing so, the Act reflects congressional recognition that the sciences will advance more quickly if business, academia, and government coordinate their actions.¹⁶⁸ Although the government reserves a non-exclusive right under the Act to employ an invention developed with government money and can require licensing if the patent-holder does not practice the invention within a reasonable time, the institutional beneficiary maintains the rights of a traditional title owner.¹⁶⁹ With the resultant additional money to support expensive technological research, universities are able to engage in projects that their budgets would not otherwise support and to retain experts in the applied sciences fields who might otherwise work in the more lucrative private sector.¹⁷⁰

While the Act may encourage institutional inventors to develop better commercial applications of their patented articles, by granting these entities patent monopolies it also results in the same problems of restricted public access inherent in the patent system generally.¹⁷¹ These restrictions seem particularly unfair given that the public has already paid for the technology through the initial government grant.¹⁷² Furthermore, blurring the line between the public sector and private business could have negative implications for the socially oriented disposition of academia and government.¹⁷³ Thus, to the extent the Bayh-Dole Act conflicts with the goals of alternative systems discussed in this Part, it quite clearly contradicts the typical bargain of acceptance of taxpayer money in exchange for public availability and dissemination of the results, which is what this article believes gives a reward program its appeal in the first place. As such, it serves as an example that, like the traditional patent regime, alternative compensation schemes also must ensure that the inventor’s rewards are proportionate to the sacrifices that society makes to stimulate the inventions. Because it fails in this respect, the Act should be repealed.

In addition to government grants and awards, scholars have also supported tax credits as an alternative way to fund research and

166. See Bayh-Dole (University and Small Business Patent Procedures) Act, 35 U.S.C.A. §§ 200-212 (2007).

167. Mireles, *supra* note 5, at 142-43.

168. *Id.*

169. *Id.* at 160.

170. *Id.* at 157.

171. *Id.* at 147.

172. Mireles, *supra* note 5, at 143.

173. *Id.* at 157.

development indirectly.¹⁷⁴ However, ex ante tax credits, like grants and other forms of government subsidy, tend to exacerbate the difficulty of determining an appropriate amount to award, because the benefit is given before the developer produces anything tangible.¹⁷⁵ Nevertheless, government grants and tax subsidies would encourage research and development efforts for a wider array of innovations by shifting the risk from the inventor to the government, and by increasing the financial base for projects whose social value is greater than their projected business value.¹⁷⁶ By offering the award ex ante, the government is in a position to require that the output of the government-funded research enter the public domain.¹⁷⁷

Presently, the government already subsidizes this behavior to a certain extent, and it is not unrealistic to think this role could be expanded. This expansion could shift the quid pro quo from one where the government reward (of a patent monopoly) follows disclosure of the invention, to one where the government reward (of a subsidy or grant) precedes the creation of the device, which the inventor is then obligated to make publicly available. Such a system would deal directly with many of the ethical and economic concerns discussed in this article.

In performing and funding research, the government (insofar as it represents its national constituency and acts consistent with its constitutional charge) seeks primarily to advance the “national interest” in scientific and technological progress. At the level of the twenty-billion-dollar-per-year enterprise known as the National Institutes of Health (“NIH”), this “national interest” is viewed as consisting of developing knowledge and technology that is either to be put into the public domain, or to be entrusted to someone who will use it to produce articles of public use. Accordingly, the government can be viewed as seeking to use public funding and patent protection to maximize the development of knowledge-based products that are either available for free or freely offered on public markets.¹⁷⁸

Although the shortcomings of extreme government intervention may preclude subsidies, grants, and awards from displacing the patent system altogether, they could nonetheless prove to be useful tools if applied in conjunction with other alternatives to the current patent regime.

174. See Golden, *supra* note 54, at 138 (calling tax credits a “classic example” of how the government can fulfill its task “to try to mediate the relationship between industry and academia to optimize scientific and technological progress” in a manner other than direct funding).

175. Johnson, *supra* note 30, at 274.

176. *Id.* at 274-75.

177. *Id.* at 275.

178. Golden, *supra* note 54, at 132-33 (footnotes omitted).

B. *Compulsory Licenses*

Under the present system, patent rights are enforced by a property rule, rather than a liability rule.¹⁷⁹ In other words, the patent owner has the right to completely enjoin an infringer from using the protected invention, which in turn allows her to set her own price for licenses.¹⁸⁰ One possible alternative to the current property rule patent regime is a regime that employs a liability rule: namely, a compulsory licensing scheme. Under a liability rule system, courts determine the value of the performance or good on the basis of objective market criteria, in order to calculate the compensation that must be paid to the injured party in the event of an infringement.¹⁸¹ Generally, compulsory licensing schemes implement a liability rule in the case of improvement inventions that infringe original patents.¹⁸²

Within these systems, injunction tends to be an appropriate remedy only when the bargaining environment is conducive to ensuring that the right to practice the invention ultimately will subsist with the highest-valuing users. Typically, such circumstances exist when there are a small number of interested parties who can easily identify each other, transaction costs are low, and courts would have a difficult time setting a fair price for a damages award due to the complexities of the asset and relevant business context.¹⁸³

Thus, awarding injunctive relief is sound policy only in limited contexts. The medical device industry, however, seems to lack the characteristics that would make it appropriate economically or socially. First, although major firms will have the means and incentives to track down the owners of patents they wish to license, the medical technology industry is characterized by a large number of players. This complicates the patent holder's decision of to whom, when, and at what price to license. Furthermore, although they are not "interested parties" in the sense of desiring the right to manufacture the device on their own, patients and doctors have a legitimate interest in whether the technology is available at an affordable price. The licensing market, however, fails to recognize this interest because collective action problems hinder these groups from promoting their needs as effectively as individual yet powerful firms.¹⁸⁴

179. *Merges*, *supra* note 80, at 77-78.

180. *Id.* at 77.

181. *Id.*

182. *Id.* at 103-04.

183. *Id.* at 78.

184. See generally MANCUR OLSON, JR., *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (Harvard Univ. Press 1965) (widely considered the foundational work on the theory of collective action problems). Specifically, the broad geographical dispersion of patients and doctors as a group makes cohesive organization and

Second, transaction costs will likely be high in most exchanges, given the information costs related to the complexity of the medical device technology involved. These costs include: (1) the chance for opportunistic and strategic behavior, especially when rights overlap (as in the case of blocking patents); (2) the expense of policing adherence to the terms of the agreement and enforcing it through the legal system; and (3) the divergent and often conflicting motivations of the transacting entities.¹⁸⁵

Third, while parties may in good faith differ in their ex ante estimations of the value of the technology, not to mention their strategic bargaining postures, an expert-led court should be able to determine a fair approximation of market value for the medical device. Moreover, in the context of compulsory licensing, where there were gross discrepancies between the anticipated and actual value of the invention, the court could make adjustments ex post. Thus, it appears that rights in medical devices could be secured by a liability rule as well as, or even superior to, a property rule.

This idea holds true despite the fact that a basic understanding of Robert Coase's theorem would suggest that a compulsory licensing system is not necessary in the patent context. Coase's theorem provides that regardless of who holds the property right initially, interested parties should be able to bargain to allow for the most efficient allocation of resources, whether by trading, transferring, or licensing the rights.¹⁸⁶ Coase himself recognized, however, that this holds true only in the absence of transaction costs.¹⁸⁷ However, in the biomedical industry context, as indicated immediately above, such transaction costs generally are presumed to be substantial and may include any of the following: the existence of bundling rights, strategic behavior, varying degrees of competence and experience in business and negotiation, conflicting party motivations (especially where concerns of financial profit are juxtaposed against those of social welfare improvement), and differing abilities to handle excess costs.¹⁸⁸ In such conditions, firms may fail to reach a licensing agreement, even if it would benefit the parties as well as society.

Fragmented patent rights, leading to patent thickets¹⁸⁹ and patent anti-

cooperation difficult, while each individual has an incentive to free-ride off the efforts of others, enjoying the benefits of lower medical device prices without contributing any time or resources toward attaining them.

185. See generally Jürg Niehans, *Transaction Costs*, in 4 *The New Palgrave Dictionary of Economics and the Law* 677–80 (John Fatwell, et al. eds., 1987). Traditional examples of transaction costs include the expenditure of resources for obtaining information about a potential exchange, bargaining to suitable terms, and policing compliance.

¹⁸⁶ Ronald H. Coase, *The Problem of Social Cost*, 3 *J.L. & ECON.* 1, 5 (1960).

187. *Id.* at 7.

188. Mireles, *supra* note 5, at 173-74.

189. The term "patent thicket" refers to a technological field where the relevant patent rights

commons,¹⁹⁰ further exacerbate the barriers to successful license negotiation. The end result is that one or both parties may believe that transaction costs would overwhelm the net gain from otherwise efficient licensing arrangements.¹⁹¹ This belief causes too few potential licensees to seek the license in the first instance and a shortage of licensors supplying the demand that does exist.¹⁹² Research suggests that especially high transaction costs leading to market failure are more likely when the subject of the license is a major innovation, and when the licensor modifies the license for each individual licensee.¹⁹³ In these circumstances, “it is much simpler to grant roughly identical licenses to all who will pay a standard rate.”¹⁹⁴

Another concern is that a compulsory license scheme allows the court or a third-party agency to fix the terms of the agreement, rather than allowing the parties to do so themselves. The parties to the transaction may be more likely than courts to accurately appraise the device at issue because with new technology, the parties’ subjective perception of the asset’s potential for success in the marketplace can overshadow the more objective measures a court would use in making value judgments.¹⁹⁵ To the extent that the parties’ familiarity with the technology and expertise about industry needs gives them a comparative advantage over courts in pricing devices, such subjectivity is desirable.

As noted previously, however, the parties’ subjective valuation of the device can be detrimental to achieving compromise when one or both misestimate the technology’s worth. This could be a good faith error, part of a bargaining strategy, or a combination of both.¹⁹⁶ However, a court or agency using indicators such as the item’s fixed and marginal costs of

are owned by multiple actors, leading to coordination problems when trying to assemble the necessary rights to conduct further research. ORG. FOR ECON. CO-OPERATION AND DEV. (OECD), GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 15 (2002), available at <http://www.oecd.org/dataoecd/42/21/2491084.pdf>.

190. The “tragedy of the anti-commons” occurs when too many people hold private rights in a particular property, with each able to block the others’ use such that the property as a whole is underutilized. See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

¹⁹¹ Lemley, *supra* note 68, at 1054-55.

¹⁹² *Id.*

¹⁹³ Merges & Nelson, *supra* note 69, at 874 (citing D. TEECE, THE MULTINATIONAL CORPORATION AND THE RESOURCE COST OF INTERNATIONAL TECHNOLOGY TRANSFER 44 (Ballinger Publishing Co. 1976) (finding that transfer costs constitute nearly one fifth of the total project costs in the international transactions studied)).

¹⁹⁴ *Id.* at 874-75.

¹⁹⁵ Merges, *supra* note 80, at 99-100.

¹⁹⁶ Lemley, *supra* note 68, at 1058-59. See also Merges, *supra* note 80, at 89-90. Merges acknowledges these obstacles to efficient bargaining but believes they are most problematic in the context of blocking patents, where he argues application of the doctrine of reverse equivalents would be a superior solution. *Id.* at 91-98.

production, the demand for comparable devices currently on the market, and expert testimony should be in a good position to formulate a fair royalty rate. Furthermore, as noted above, in the occasional cases of serious misalignment between the ex ante estimated value and the actual value in the market place, a court could hear petitions for readjustment of the licensing fee ex post.

In the past, Congress has considered employing a compulsory license scheme in place of the current patent regime. For instance, in response to H.R. 1127, a 1995 bill that proposed a complete moratorium on medical device and process patents, experts testified in favor of requiring medical patent owners to “license the technology at a reasonable royalty”; they believed such a policy to be more narrowly tailored than complete termination of patent protection as a means of handling the problems that the bill sought to address.¹⁹⁷ This article finds that if patent law for medical devices were to be modified, introducing a compulsory licensing system appears to be one of the most viable alternatives. As such, Congress should reconsider the issue, especially in light of the technological changes that have taken place since it was last discussed in 1995.

C. Shortened Patent Terms

The current patent system gains credibility merely because of its historic existence, which provides the benefits of familiarity and predictability to potential inventors.¹⁹⁸ Thus, if policymakers fear the repercussions of a complete institutional overhaul, they still have the alternative of refining and reducing current patent monopoly rights to better reflect the economic needs of the medical device industry.¹⁹⁹ After all, the length of the patent term, originally derived from the length of apprenticeships, is essentially arbitrary. The current twenty-year term stands only because of historical precedent and international treaties devised in accordance with that duration.²⁰⁰

Part of the appeal of revising patent protection through manipulation of the patent term is its simplicity of implementation and administration. While more complex solutions offer greater opportunities for clever lawyers to exploit the laws in their clients’ favor, changes to duration involve unambiguous black letter rules that will apply categorically.²⁰¹ Furthermore, should any initial change to the term prove inefficient in its

197. Katopis, *supra* note 45, at 358-59 (quoting William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 651, 664 (1995)).

198. See, e.g., Calandrillo, *supra* note 22, at 357.

199. See *id.* at 358.

200. Johnson, *supra* note 30, at 283.

201. See *id.* at 289.

effects on incentive, “duration has the prospect of allowing infinite gradations in making the slight adjustments to the size of the patent reward.”²⁰²

The length of the patent term can be tailored to the specific financial requirements of the medical device industry and the needs of society in multiple ways. Several scholars have suggested terms of varying length depending on characteristics of the invention itself or the industry in which it is categorized.²⁰³ Proponents of this plan recommend that policymakers derive these categories based on two criteria: first, “inventions that share economic characteristics that are determinants of optimal patent life” should be grouped together; and second, the categories should be clearly defined and delineated such that there is little room for debate as to the grouping into which a given invention falls.²⁰⁴ Under this approach, the economic and functional characteristics that distinguish medical devices from other types of technology would place them into the subset of inventions that should have patent terms on the shorter end of the scale.

Another solution involves expanding monopoly maintenance fees²⁰⁵ in a manner that would alter the patent owner’s calculus of whether preserving the monopoly is worth the extra cost.²⁰⁶ Such a proposal poses the danger that the title holders would simply pay the fees and then pass the cost along to consumers in the form of higher prices. Still, if this strategy were implemented, any fees collected could be redistributed in the form of research grants that would obligate the recipient to dedicate their results to the public domain. A reduced patent term also could be combined with other forms of compensation, such as a compulsory license after the shortened strict monopoly period ends.

D. Trade Secret Protection

Presently, firms sometimes decide that taking advantage of trade secret law is a viable alternative to seeking a patent. While one can logically assume that in the complete absence of patent law, more firms would choose trade secret protection, this article does not suggest that abolishing the current patent regime and relying only on trade secrets is economically indicated or socially desirable.

202. *Id.*

203. *See, e.g., id.* at 286. *See also* Burk & Lemley, *Policy Levers*, *supra* note 43, at 1632 (focusing on differentiating between industries and tailoring the applicable law accordingly via doctrines related to patent scope).

204. Johnson, *supra* note 30, at 292.

205. *See* 37 C.F.R. § 1.20(e)-(g) (2007) (outlining the current schedule of maintenance fees, which assesses progressively higher levels beginning in the fifth year of patent protection).

206. *See* Johnson, *supra* note 30, at 286.

While trade secret laws can vary slightly from state to state,²⁰⁷ the basic tradeoff is the same. The duration of the trade secret can be unlimited, as long as the information is not widely known by the relevant public and the owner takes reasonable precautions to maintain this confidentiality.²⁰⁸ By opting for this potentially infinite protection rather than the set twenty-year patent monopoly, the owner risks a competitor discovering the secret, creating the invention, and entering into the marketplace; thus dissolving the original owner's right to protection.²⁰⁹

Therefore, reliance on trade secrets undermines one of the main benefits of patent law—the public disclosure of information about the innovation. Others can utilize disclosed information about the invention to build improvements upon the original immediately or to make competitive equivalent products once the patent term is over. The time and effort spent deconstructing and analyzing a medical device, for which the method of manufacture or means of operation is a trade secret, on the other hand, are nonproductive expenditures.

While society may gain additional competition and better products through reverse engineering, the process poses problems. Unfortunately, the cheaper it is to reverse engineer a competitor's device, the more tempting it is for a firm to relinquish efforts at original product development, with a net effect that fewer medical devices would be made. This article has demonstrated how business dynamics like the first mover advantage can mitigate disincentives to create in these situations.²¹⁰ It seems unlikely, however, for trade secret protection alone to always facilitate the optimal level of creation in the medical device context. Furthermore, the competitive nature of the medical device industry, where rival firms work on similar problems with similar knowledge bases, increases the possibility that others will independently create a device that performs the same function as the one for which trade secret protection is

207. Although a substantial majority of the states have adopted the Uniform Trade Secrets Act ("UTSA"), the cause of action for trade secret misappropriation has its origins in common law. Since this case law sometimes affects modern judicial interpretation of the provisions of the UTSA, and since some states have only adopted the model code in part or not at all, different states with different precedent or laws which may construe the terms, obligations, and rights stemming from the statute in divergent ways. *See, e.g.*, Michael Risch, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1, 6-8 (2007).

²⁰⁸ *See* Risch, *supra* note 207, at 11.

209. Under the UTSA, a trade secret is information "that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UNIF. TRADE SECRETS ACT §1.4., 14 U.L.A. 538 (1968).

210. *See supra* Part IV.A.3.

sought. Thus, one can expect that industry participants would be reluctant to rely solely on trade secret law to protect their interests.

E. Combining Alternative Compensation Systems

The previous four Sections of this Part highlighted the merits of several alternative means of incentivizing and rewarding inventive efforts, but in each case noted that replacing the current system with the proposed alternative alone was unlikely to suffice. This Section, however, argues that a synergetic effect will occur when elements from two or more of the possible alternative regimes are incorporated into intellectual property policy for medical devices. Rather than give a cursory review of all of the possible combinations of the aforementioned four options, this Section focuses on what appears to be the most promising arrangements based on the foregoing discussions.

In a combination system, the discretionary use of a reward system would remedy any lost incentive due to replacement of the current law with a decreased patent term or compulsory license. If limited to the medical device sector, the monetary amount the government would need to generate would be considerably less than if the reward system were to replace the overall patent law structure. Furthermore, the reward would not have to be as large under a combined regime because the limited patent term and/or revenues from compulsory license fees would cover most fixed costs and provide part of the incentive to create. This, in turn, would prevent research efforts from being diverted to non-medical technology avenues. It would also be more politically feasible than a massive tax increase.

As mentioned above, the federal government currently devotes considerable expenditures to research in the medical device industry. Adjusting the relative amount or direction of rewards in response to the needs of the system and introducing new tax breaks for the industry are fairly easy changes to make politically. For these reasons, this article concludes that any new compensation system should feature such government-sponsored incentives, provided the conferral is subject to conditions that hasten the rewarded invention's entrance into the public domain.

An abrupt and complete elimination of the current patent regime for medical devices is a risky endeavor, both politically and economically. A more practicable option is to retain the current patent structure nominally, but amend it to include additional provisions regarding the treatment of medical devices that advance the normative goals discussed in this article. Specifically, this article proposes a drastically reduced grant of exclusive

monopoly power,²¹¹ followed by a period of compulsory licensing for the remainder of the traditional twenty-year term. The monopoly period allows the inventor to secure first-mover advantages and recover fixed costs, but the onset of compulsory licensing ensures that the patent owner will continue to have the incentive to maintain its competitive advantage through reasonable pricing, uniformly high quality of manufacture, and sound business practices. Such a system should benefit consumers without materially altering the incentives of the industry, particularly when combined with possible compensation through rewards and tax subsidies. Furthermore, entities that are not confident in the proposed system would continue to have the option to rely on trade secret protection.²¹²

CONCLUSION

This article explores the possibility of patent reform in the specific context of the medical device industry. It notes that the current patent regime is not efficiently balancing the social and economic issues at stake in this area of the law, and establishes that applying special rules to medical devices would not be wholly unprecedented. The article then considers possible arguments both for and against implementation of an alternative compensation regime in the medical device context, eventually making the case that the expected benefits of an appropriately tailored new regime would outweigh the potential costs of change. Finally, after evaluating the relative merits and drawbacks of several different types of alternative compensation schemes, this article concludes that the optimal option would be a combined system. Under such a system, the patent holder receives monopoly control over the invention for a brief term, after which point she must license the right to manufacture, sell, or use the invention for a reasonable fee throughout the remainder of the traditional twenty-year patent duration. Discretionary use of federal funds and tax subsidies are also permissible under this scheme to correct for any market failures and provide additional incentives where needed.

There are several advantages to this proposal. First, compared to other possible measures of restructuring patent law, the combined system that

211. Based on the rapid evolution of medical technology, this article estimates the ideal exclusivity period to be approximately five years. A congressional committee examining this issue would have the means to more thoroughly evaluate relevant economic factors and revise the length of the strict monopoly period accordingly.

212. The rapid evolution of medical technology and high probability of the technology's obsolescence within a reduced term of exclusivity suggests few firms would favor trade secret protection. *See supra* Part V.D. A guaranteed monopoly with continuing returns from licensing fees may well be preferable to one which, although potentially infinite in duration and capable of realizing substantial initial returns, ultimately leaves an owner vulnerable to competition.

retains the traditional twenty-year patent monopoly duration is likely to face reduced interest group resistance. Although some major manufacturing firms would oppose any diminution of their monopoly rights, the proposal merely alters the nature of patent protection rather than eliminating it altogether. Therefore, other firms may determine that the cost of lobbying the legislature to retain the current regime would exceed their expected losses from the change. Moreover, entities such as consumers' rights groups and social justice advocates focusing on healthcare issues will exert countervailing pressure on their representatives in support of the change. Second, there does not appear to be any valid constitutional objection to this article's proposal; there is no constitutional mandate that patent protection take any particular form, provided it lasts only for "limited times." Congress is empowered to formulate a law such as the one proposed here if it determines that it will better promote progress in the medical device industry. While the work contained herein may have application to other areas by analogy, one of the reasons this article is able to support the recommended reforms is because of the distinctive dynamics of the medical device industry. Thus, although there may be a need for broader patent reform, this article's more modest objective is only to explore the issues and possible avenues for change in one particular segment of the law. Nonetheless, policymakers and academics alike are encouraged to reflect on the concerns, arguments, and potential solutions addressed above when contemplating either industry-specific or general patent reform.