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Bad Medicine: Economic Disadvantage and Claim Limitation in an Ailing Patent Office

Elisabeth Marie Koehnemann
University of Georgia School of Law

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BAD MEDICINE: ECONOMIC DISADVANTAGE AND CLAIM LIMITATION IN AN AILING PATENT OFFICE

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I. INTRODUCTION

"The protection of our intellectual property is an obsession with me. Because if we invent it, and all that goes into it, that's how we're going to compete in the world."

- Sen. Barbara Mikulski¹

As the gatekeeper for domestic patent rights, the United States Patent and Trademark Office (PTO)² is an important catalyst for economic growth in the United States.³ In an effort to improve patent quality and streamline the patent process in the twenty-first century, the PTO recently developed policy initiatives and rules that limit the number of claims an applicant can file.⁴ Although well intentioned, these new provisions hinder an applicant's ability to obtain patent protection for the full scope of his or her invention.⁵ Thus, any rule changes intended to increase PTO efficiency need to be carefully balanced against the negative impact such rules might have on innovation.⁶

For today's businesses, success depends on intangible information-based industries which now represent major aspects of the American economic landscape.⁷ These industries require constant innovation in order to maintain

¹ *Commerce, Justice, Sci., and Related Appropriations Agencies for Fiscal Year 2008 Hearing of the Commerce, Justice, and Sci. Subcomm. of the S. Appropriations Comm.*, 110th Cong. 48 (2007) (statement of Sen. Barbara Mikulski, Chair, Subcomm. on Commerce, Justice, Sci., and Related Agencies).

² The provisions of the patents laws are laid out in Title 35 of the United States Code and give authority for the PTO to examine and grant patents. See 35 U.S.C. §§ 1-376 (2000).

³ Alfonso G. Chan, *A Proposed Defense to Patent Infringement*, 1999 COMP. L. REV. & TECH. J. 79, 79 (1999).

⁴ See U.S. PATENT AND TRADEMARK OFFICE, 2007-2012 STRATEGIC PLAN 32-33 (2007) [hereinafter STRATEGIC PLAN], available at <http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf> (listing twenty-six action initiatives comprising the five-year plan); Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (revising rules of practice in examination of claims in patent applications); discussion *infra* Part III.A (discussing effect of new rules on strategic claiming practices).

⁵ See *infra* Part III.A.

⁶ See FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3 at 11 n.48 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (noting that some experts believe that without patent protection, innovation in the pharmaceutical industry would increase approximately 60%).

⁷ See WESTON ANSON ET AL., FUNDAMENTALS OF INTELLECTUAL PROPERTY VALUATION: A PRIMER FOR IDENTIFYING AND DETERMINING VALUE 234 (2006) ("In the case of Microsoft, the value of its intangible assets and intellectual property is more than 90%; for Merck it is 80% of the total capitalization.").

their position in a world market where technologic knowledge increases exponentially.⁸ The necessity of a patent system has been obvious to Americans since the founding of our country.⁹ Since that time, the ingenuity of American inventors, coupled with a patent system that encourages and rewards innovation, has transformed America into the world's preeminent technological and economic nation.¹⁰ Modern patent protections provide an environment in which a patentee can profit from his invention free from competition.¹¹ This promotes economic vitality through investment, research, scientific development, and the commercialization of new inventions.¹² In exchange for this protection, the

⁸ See Gordon E. Moore, *Cramming More Components onto Integrated Circuits*, 38 *ELECTRONICS* 8 (1965), available at <http://download.intel.com/research/silicon/moorespaper.pdf> ("The complexity for minimum component costs has increased at a rate of roughly a factor of two per year . . . Certainly over the short term this rate can be expected to continue, if not to increase. Over the longer term, the rate of increase is a bit more uncertain, although there is no reason to believe it will not remain nearly constant for at least 10 years."); Ray Kurzweil, *The Law of Accelerating Returns*, Mar. 7, 2001, <http://www.kurzweilai.net/articles/art0134.html?printable=1> ("It is important to note that Moore's Law of Integrated Circuits was not the first, but the fifth paradigm to provide accelerating price-performance. Computing devices have been consistently multiplying in power (per unit of time) from the mechanical calculating devices used in the 1890 U.S. Census, to Turing's relay-based 'Robinson' machine that cracked the Nazi enigma code, to the CBS vacuum tube computer that predicted the election of Eisenhower, to the transistor-based machines used in the first space launches, to the integrated-circuit-based personal computer. . . .").

⁹ More than 200 years ago, the need for a patent system was addressed in the Constitution. U.S. CONST. art. I, § 8, cl. 8 (declaring Congress's power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

¹⁰ The United States ranked first in a recent global economic competitiveness report. See WORLD ECON. FORUM, *THE GLOBAL COMPETITIVENESS REPORT 2007–2008*, at 10, 12 (2007) (concluding that the United States is the world's most competitive economy given its combination of highly innovative and sophisticated companies, efficient financial markets, high university enrollment, and strong intellectual property protection); Richard M. Jones, *Competitiveness Index: Where America Stands*, FYI: THE AIP BULLETIN OF SCIENCE POLICY NEWS, Jan. 24, 2007, <http://www.aip.org/fyi/2007/011.html> (noting that the Council on Competitiveness has determined that sixteen of the top twenty-five most innovative companies in the world are American companies). With that said, several macroeconomic imbalances and repeated fiscal deficits threaten the economic competitive edge that the United States has over other countries. World Economic Forum, at 12–13.

¹¹ A patent grants the patentee the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States. . . ." 35 U.S.C. § 154(a)(1) (2000). See also Robert E. Thomas, *Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws*, 43 AM. BUS. L.J. 689, 694 (2006) ("Without the potential to at least recover development costs, an inventor may not attract sufficient financing or be willing to invest the resources needed to complete the project.").

¹² See ROGER SCHECHTER & JOHN THOMAS, *PRINCIPLES OF PATENT LAW* § 1.3.1, at 9–12 (2d ed. 2004) (introducing patent policy).

inventor discloses his invention to the public and society benefits from the increased availability of information in the public domain.¹³

Such a system potentially reduces social benefits through transfer of wealth from consumers to producers by increasing prices from competitive to monopoly level¹⁴ and inhibiting the use of scientific or technological knowledge for further research.¹⁵ Yet, patent protection seeks to minimize these effects through various legal mechanisms. In order for an invention to be patentable, it must be novel, useful, and non-obvious.¹⁶ Additionally, a patent is granted only for a term "beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed."¹⁷ This essential system is regulated by a complex code of action that inventors must obey in order to obtain patent protection.¹⁸ Because the PTO promulgates this code,¹⁹ every inventor and thus the economy to which they contribute is dependent on the efficacy of the rules.

This Note considers the claims limitation aspect of the new rules in the context of economic valuation of intellectual property and appropriate motivation for innovation. Part II examines the provisions of the new rules and the policies the PTO is attempting to further with their promulgation. Part III demonstrates the practical realities of patent prosecution and the detrimental impact a delayed or ineffective patent prosecution system will have on the United States economy, both domestically and abroad. More specifically, this Part addresses the particular patent valuation factors which disparately impact industries and applicants especially vital to domestic innovation and prosperity. Additionally, Part III

¹³ See 35 U.S.C. § 112 (2000) (describing the "full and clear disclosure" required to obtain a valid patent); MANUAL OF PATENT EXAMINING PROCEDURE § 2162 (8th ed., rev. 6, 2007) (explaining that "the patentee must disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention" and that the patent disclosure requirement allows the information contained in the patent to become "a part of the information available to the public for further research and development").

¹⁴ See RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 276, 279–80 (6th ed. 2003) (efficiency consequences of monopoly); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 250 (1994) ("Economic rents are common in the economy. They are enjoyed wherever an economic actor has a cost advantage that competitors cannot match, for legal or other reasons."); see also SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 97–112 (2004) (discussing intellectual property as an incentive mechanism).

¹⁵ See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 870 (1990) ("Since some of the follow-on efforts of inventors could result in something not simply slightly different but significantly better than the patented technology, broad patents could discourage much useful research.").

¹⁶ See 35 U.S.C. §§ 101–103 (2000) (statutory criteria for patentable inventions).

¹⁷ *Id.* § 154(a)(2).

¹⁸ See *id.* §§ 111–122 (patent application requirements).

¹⁹ See *id.* §§ 1–13 (establishment of the PTO).

presents alternatives available to the PTO to relieve the currently overwhelming application backlog with a focus on improving administrative factors rather than altering a functioning patent system. This Note concludes that claim limitation rule changes, such as those proposed by the PTO, will inhibit patent applicants from obtaining comprehensive patent protection and negatively impact innovation vital to the American economy.

II. BACKGROUND

To address the growing problems in the PTO, this Part will begin by providing a brief overview of the patent prosecution process in general. Next, the administrative difficulties being faced by the PTO, the primary causes of these difficulties, and the solutions to these difficulties proposed by the PTO will be discussed. This Part will also describe the particular economic and innovative consequences arising from such proposed solutions.

A. NUTS AND BOLTS OF OBTAINING A PATENT

Before issuing as an enforceable patent, each application must go through an extensive examination process, known as “prosecution.”²⁰ This process includes review of the application’s disclosure and a search of a large body of relevant technological information, known as “prior art,”²¹ by trained personnel at the PTO, known as examiners, to determine whether each claim is patentable.²² To obtain a patent, an applicant must provide a written description of the invention in sufficient detail for a person skilled in the relevant area of technology to make and use the invention.²³ In addition, the applicant must provide one or more claims that define what the applicant regards as his or her invention.²⁴ A claim, unlike the written description, is designed to provide public notice of precisely what the patent owner has a right to exclude others from making, using, or selling.²⁵

²⁰ See SCHECHTER & THOMAS, *supra* note 12, § 7.2, at 222–34 (introduction and mechanics of patent prosecution); see also Raymond Van Dyke, *E Wars – Episode One: The Patent Menace*, 6 COMP. L. REV. & TECH. J. 1, 17 (2001) (checklist for obtaining a patent).

²¹ Prior art constitutes all information that has been made available to the public that might be relevant to a patent claim’s novelty or nonobviousness. See SCHECHTER & THOMAS, *supra* note 12, §§ 4.3–4.4, at 85–141, § 5.2, at 145–51.

²² *Id.* § 7.2.3, at 225–27.

²³ 35 U.S.C. § 112 (2000).

²⁴ *Id.*

²⁵ SCHECHTER & THOMAS, *supra* note 12, § 6.2, at 200.

A patent's claims are the most critical elements of the application because they define the metes and bounds of protection.²⁶ A fundamental goal of claim drafting is to encompass all possible embodiments of the invention disclosed in the specification because any embodiment not claimed is dedicated to the public and cannot be recovered by the applicant.²⁷ Adequate protection of patent validity in the litigation context requires presenting claims in many statutory classes, as different types of claims provide for a different scope of protection, apply against different parties, and have different defenses.²⁸ For example, on a basic level, a new chemical compound can often be patented through claims directed to methods of using the composition and methods of making the composition.²⁹ Even within one statutory class, the applicant will need to present a claim set varying from broad to narrow.³⁰ Narrow claims increase the likelihood of validity if new prior art is discovered, while broad claims increase likelihood that attempts to design around will fail.³¹

If the PTO believes the application fulfills the statutory patentability requirements, it will allow the application to issue as a granted patent.³² Yet, in over 80% of cases, the examiner rejects claims as unpatentable in the first communication to the applicant,³³ known as a "first office action,"³⁴ and provides

²⁶ See 37 C.F.R. § 1.75(a) (2007) ("The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery."); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) ("The scope of every patent is limited to the invention described in the claims contained in it, read in the light of the specification. These so mark where the progress claimed by the patent begins and where it ends that they have been aptly likened to the description in a deed, which sets the bounds to the grant which it contains.").

²⁷ JEFFREY G. SHELDON, *HOW TO WRITE A PATENT APPLICATION* § 6.5.1 (2007).

²⁸ See generally M. HENRY HEINES, *PATENT EMPOWERMENT FOR SMALL CORPORATIONS* 47 (2001) (suggesting successful patent enforcement requires creativity in drafting claims); ROBERT C. FABER, *LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING* § 7:2 (5th ed. 2007) ("For fullest protection wherever an invention is capable of being claimed in more than one of the different ways, it is recommended that that be done.").

²⁹ See SHELDON, *supra* note 27, § 6.5.4 (explaining the significant advantages associated with method claims as compared to other types of claims).

³⁰ See SCHECHTER & THOMAS, *supra* note 12, § 6.2.2.1, at 206 (discussing how patent applicants should use dependent claims to narrow a claim when necessary). In general, a narrow claim specifies more detail than a broad claim. Broad claims encompass more "intellectual territory" and are more vulnerable to invalidation. GREGORY A. STOBBS, *BUSINESS METHOD PATENTS* 489 (2003).

³¹ SCHECHTER & THOMAS, *supra* note 12, § 6.2.2.1, at 206.

³² 35 U.S.C. § 151 (2000).

³³ K. Matthew Dames, *The Patent System on Tilt: IBM Seeks to Change the Game*, INFO. TODAY, Oct. 16, 2006, available at <http://newsbreaks.infotoday.com/nbreader.asp?ArticleID=18422> (quoting Brigid Quinn, deputy director of the PTO's public affairs office, stating that "80% of all applications are rejected after the initial review").

³⁴ See DONALD S. CHISUM ET AL., *PRINCIPLES OF PATENT LAW: CASES AND MATERIALS* 104-15

the applicant with a detailed explanation of how the claims lack patentability.³⁵ In response to an initial rejection, the applicant may amend the claim or present reasons why the rejection is improper.³⁶ If the claims are still found unpatentable after reevaluation by the examiner, the rejection is made final and prosecution is closed.³⁷ Though some patents issue in less than a year and others can take decades to issue,³⁸ applicants must wait almost two years on average for a first office action and almost another year after that for the prosecution to be closed.³⁹ Such an extended examination process is due to many intermingled factors, the most apparent being the number of applications flooding the PTO each year.⁴⁰

B. AGENCY IN DISTRESS: CURING AN AILING PATENT OFFICE

The PTO is facing a crisis of numbers: in excess of 440,000 patent applications were filed in the 2006 fiscal year;⁴¹ more than doubling the number filed ten years before.⁴² While this would seem to be good news for innovation,⁴³

(3d ed. 2004) (discussing the formalities of patent prosecution).

³⁵ 37 C.F.R. § 1.104(c) (2007).

³⁶ *Id.* § 1.111(b).

³⁷ *Id.* § 1.113.

³⁸ See Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 71–72 (2004) (describing the distribution of prosecution time including a patent with a total prosecution time of more than forty-four years).

³⁹ See U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2006, at 123 (2006), available at <http://www.uspto.gov/web/offices/com/annual/2006/2006annualreport.pdf> (describing pendency statistics by technology center).

⁴⁰ See Brian E. Mack, *PTO Rulemaking in the Twenty-first Century: Defining the Line Between Strategic Planning and Abuse of Authority*, 75 FORDHAM L. REV. 2105, 2106 (2007) (discussing how the dramatic increase in U.S. patent applications in recent years has created a substantial backlog of unexamined patent applications).

⁴¹ The PTO fiscal year ends on September 30th. 31 U.S.C. § 1102 (2000).

⁴² See U.S. PATENT AND TRADEMARK OFFICE, U.S. PATENT STATISTICS, CALENDAR YEARS 1963–2006 (2007), available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf (demonstrating that the number of patent applications and patent grants have increased by approximately 114% and 61%, respectively, in the past ten years).

⁴³ Patent grant rate has often been linked to intellectual progress and development. See ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 5 (2004), available at <http://www.oecd.org/dataoecd/48/12/24508541.pdf> (“The increasing use of patents to protect inventions by businesses and public research organisations is closely connected to recent evolutions in innovation processes, the economy and patent regimes.”). But see James E. Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* (MIT Dep’t of Econ., Working Paper No. 00-01, 2000), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=206189 (discussing how patent protection may reduce overall innovation and social welfare in dynamic industries, such as software); Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473, 505–06 (2005) (“It is plausible that patenting increased after 1982 because the patent system became more reliable, and therefore more likely to

given the increased application rates, it is reasonable to expect future application filings to increase by 36,000 applications each year.⁴⁴ Countries with a higher growth rate tend to receive more patent applications, so the substantial increase in U.S. patent filing should be viewed as a positive economic indicator of the innovation in the diverse domestic economy.⁴⁵ In addition to an increased number of patent applications, the average time required to process an application has grown to over two and a half years.⁴⁶

Notably, from an efficiency standpoint, of the nearly half a million patent applications received by the PTO annually, less than 200,000 actually issue as patents.⁴⁷ Because not all applications result in issued patents,⁴⁸ the dramatic increase in application filings has caused the number of pending patent applications to more than double in the past five years.⁴⁹ Over 700,000 of the 1,000,000 applications pending at the end of 2006 had not even received a first

confer . . . benefits and cost reductions. . .”).

⁴⁴ See U.S. PATENT STATISTICS, CALENDAR YEARS 1963–2006, *supra* note 42 (showing that from 2003–2004, 2004–2005, and 2005–2006, the number of patent applications filed increased by 26,096, 25,369, and 35,125 applications respectively).

⁴⁵ BISWAJIT DHAR & C. NIRANJAN RAO, WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTERNATIONAL PATENT SYSTEM: AN EMPIRICAL ANALYSIS 50 (2002), *available at* http://www.wipo.int/about-ip/en/studies/pdf/study_b_dhar.pdf.

⁴⁶ See John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U.L. REV. 77, 98 (2002) (noting that patents in 1976–78 sample averaged 2.23 years in prosecution as compared to 2.77 years in prosecution for the 1996–98 sample).

⁴⁷ U.S. PATENT STATISTICS, CALENDAR YEARS 1963–2006, *supra* note 42. Yet, the utility of relying on published patent grant rates when making patent reform decisions is questionable due to difficulties in calculating patent grants rates. See Ron D. Katznelson, *Bad Science in Search of “Bad” Patents*, 17 FED. CIR. B.J. 1 (2007/2008) (discussing complications involved in grant rate calculation); Mark A. Lemley & Bhaven N. Sampat, *Is the Patent Office a Rubber Stamp?* 4–9 (Stanford Public Law Working Paper No. 999098, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=999098 (identifying data controversies in calculating patent grant rates).

⁴⁸ Since 2002, approximately forty to fifty percent of patent applications have resulted in issued patents. See PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006, *supra* note 39, at 120 (reporting patent applications which were either abandoned or received first office actions in 2006). Applications that do not result in issued patents are either abandoned or pending before an examiner. See U.S. GENERAL ACCOUNTING OFFICE, PATENTS: INFORMATION ABOUT THE PUBLICATION PROVISIONS OF THE AMERICAN INVENTORS PROTECTION ACT 12–13 (2004), *available at* <http://www.gao.gov/new.items/d04603.pdf> (discussing patent status as issued, abandoned, or pending). Applications may be abandoned by express request of the applicant or failure to reply in a timely and sufficient matter. See MANUAL OF PATENT EXAMINING PROCEDURE § 711.01–.02(c) (explaining patent prosecution abandonment procedure).

⁴⁹ Compare PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006, *supra* note 39, at 124 (reporting 1,077,042 patent applications pending at the end of fiscal year 2006), with U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2001, at 110 (2001), *available at* <http://www.uspto.gov/web/offices/com/annual/2001/01performreport.pdf> (reporting 613,173 patent applications pending at the end of fiscal year 2001).

office action.⁵⁰ Increased delay in patent prosecution means a shorter period of protection for applicants, especially since the patent term is measured from the filing date rather than issue date.⁵¹ Additionally, the uncertainty of not knowing the full scope of the invention until years later when the patent issues withholds a social benefit because it prevents fully informed market decisions by both the inventor and competitors during the pendency period.⁵²

For several years, the PTO has been struggling to reduce its backlog of applications that have not been examined.⁵³ In response, the PTO developed the 21st Century Strategic Plan,⁵⁴ which included several initiatives targeted toward timeliness, increased technology use, and employee training.⁵⁵ Pursuant to this plan, a record 1,218 patent examiners were hired in 2006.⁵⁶ While this resulted in a record number of reviewed patent applications that year, the percentage of applications reviewed by examiners that were ultimately approved in 2006 reached a record low.⁵⁷ Even if annual hiring goals are met, an estimated 800,000 patent applications will be awaiting a first office action by the end of 2007,⁵⁸ and it is projected that 1.4 million patent applications will be pending a first office action by 2012.⁵⁹ Since the volume of patent applications will continue to exceed the PTO's capacity to timely examine them,⁶⁰ the United

⁵⁰ PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006, *supra* note 39, at 122.

⁵¹ 35 U.S.C. § 154(a)(2) (2000) (providing term of patent protection begins on date of grant and ends twenty years from filing date of application); *see also* Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes – Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 127–28 (2005) (“Thus, the period between the date an application is filed and the date the patent ultimately issues is essentially a dead period for the patentee, regardless of the invention’s intended usage. An extended dead period shortens the available ‘live’ period for the patent.”).

⁵² *See* Osenga, *supra* note 51, at 120–21 (discussing some of the private and social losses caused by speed and quality problems present in the PTO).

⁵³ *See* John Doll, USPTO Acting Commissioner for Patents, 2005 Patent Practice Update at National Association of Patent Practitioners Meeting (July 19, 2005), http://www.napp.org/D011_Presentation.ppt (discussing 2004 pendency rates in the USPTO).

⁵⁴ STRATEGIC PLAN, *supra* note 4, at 6.

⁵⁵ *United States Patent and Trademark Modernization Act of 2003: Hearing before the Subcomm. on Courts, the Internet and Intellectual Property*, 108th Cong. 61 (2003) (statement of James E. Rogan, Director, United States Patent and Trademark Office); *see also* STRATEGIC PLAN, *supra* note 4, at 32–34 (listing the initiatives of the PTO’s 21st Century Strategic Plan).

⁵⁶ Press Release, U.S. Patent and Trademark Office, Fiscal Year 2006: A Record-Breaking Year for the USPTO (Dec. 22, 2006), *available at* <http://www.uspto.gov/web/offices/com/speeches/06-73.htm> (reporting record-breaking numbers related to 2006 hiring goals).

⁵⁷ Press Release, U.S. Patent and Trademark Office, Deputy Under Secretary of Commerce Announces FY 2008 Budget Proposal for USPTO (Feb. 5, 2007), *available at* <http://www.uspto.gov/web/offices/com/speeches/07-09.htm>.

⁵⁸ Erik Sherman, *Patent Politics*, IP LAW & BUSINESS, Aug. 2007, at 44.

⁵⁹ STRATEGIC PLAN, *supra* note 4, at 11.

⁶⁰ *See* Stephen Becker, *Patent Pileup: The Patent Office Can’t Clear Its Backlog by Shifting Work to*

States Government Accountability Office believes that the PTO must drastically increase reform efforts, beyond hiring, to reduce the backlog.⁶¹

C. 37 C.F.R. 1.75(B) AND THE CLAIM LIMITATION RULE CHANGES

The PTO is authorized to establish regulations to govern operations within the office in order to facilitate and expedite the processing of patent applications.⁶² In January 2006, the PTO exercised this authority and proposed to revise the rules of practice relating to the examination of claims in patent applications in order to make the process more effective and efficient.⁶³ The original proposal sought stringent limitations on claims,⁶⁴ but the proposal was modified in response to several hearings and extensive public commentary.⁶⁵

Inventors, LEGAL TIMES, Apr. 3, 2006, at 58 (“In recent town-hall meetings, John Doll, the commissioner for patents, unveiled a plan to hire 1,000 additional examiners, who would then be trained for eight months in a new academy. However, the PTO has calculated that even this effort would barely make a dent in the backlog and quality problems. . . .”). But see Steven J. Moore, *Hampering Ingenuity Through Changes in the Rules; The New USPTO Proposed Regulations*, INTELL. PROP. TODAY, Apr. 2006, at 33 (referring to USPTO claims that increased hiring alone will not reduce the backlog as “sheer poppycock”).

⁶¹ See U.S. GOV'T ACCOUNTABILITY OFFICE (GAO), U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 1-23 (2007), available at <http://www.gao.gov/new.items/d071102.pdf> (analyzing effect of patent examiner hiring and attrition rates on growing backlog of unexamined patents). In response to the GAO report, the PTO plans to review current production goals to “encourage a completely fresh look at production in a manner that will motivate employees, improve its work environment, and enhance the quality and efficiency of the patent examination process.” Press Release, U.S. Patent and Trademark Office, USPTO Will Begin Study of Patent Examiners’ Production Goals (Oct. 4, 2007), available at <http://www.uspto.gov/web/offices/com/speeches/07-42.htm>.

⁶² See 35 U.S.C. § 2(b) (2000) (specific powers of PTO). But see *Tafas v. Dudas*, No 1:07cv846 (JCC), 2008 WL 859467 (E.D. Va. Apr. 1, 2008) (finding the PTO Rule-making Authority is limited to procedural changes, whereas the claim limitation rule discussed here is substantive).

⁶³ Press Release, U.S. Patent and Trademark Office, USPTO Proposes Measures To Improve Patent Examination (Jan. 3, 2006), available at <http://www.uspto.gov/web/offices/com/speeches/06-01.htm>.

⁶⁴ See Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61-01 (Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1) (proposing initial examination of only representative claims expressly designated by applicant for initial examination); Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1) (requiring that second or subsequent continued examination filings be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted and that all patentably indistinct claims be submitted in a single application).

⁶⁵ The National Association of Patent Practitioners (NAPP) opposed the PTO’s suggestions to address the backlog by adjusting the patent application filing rules by placing limits on claims because the changes would “leave a large number of questions open, make adequate protection for patents

1. *Provisions of the Final Rules.* The final rules, published in August 2007, limit the number of claims that can be presented for initial examination in a single application and the number of continuation applications, requests for continued examination of applications, and continuation-in-part applications.⁶⁶ Among other significant changes, the revised rules require an applicant to file an examination support document that covers all of the claims in an application if the application contains more than five independent claims or more than twenty-five total claims (known as the “5/25 rule”).⁶⁷ While certainly easing the PTO’s examination burden, such changes dramatically affect applicants for U.S. patents through increased prosecution costs and decreased patent protection.⁶⁸ Some commentators believe these rules might require applicants to reduce the scope of claims applied for and accept inadequately narrow claims due to the limited opportunity for presentation of claims.⁶⁹

Indeed, within twenty-four hours of publication of the final rules, a disgruntled inventor challenged the authority of the PTO in an action for a preliminary injunction.⁷⁰ During an October 31, 2007 hearing, the court issued

more difficult, yet achieve only marginal improvement in . . . the backlog problem.” See E-mail from NAPP, to USPTO (May 3, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/napp.pdf (responding to request for comments regarding claims practice). For further comments from the public, see U.S. Patent and Trademark Office, *Comments Regarding Claims Practice*, http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/claims_comments.html (last visited Mar. 2, 2008). The USPTO responded to the flood of comments by not expressly limiting the number of claims that would be examined in an application. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,721 (to be codified at 37 C.F.R. pt. 1).

⁶⁶ See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. at 46,716–843 (revising rules of practice in examination of claims in patent applications).

⁶⁷ See *id.* at 46,724 (“An applicant must file an examination support document in compliance with [37 C.F.R.] § 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits of the application if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims.”). An independent claim is completely self-contained, while a dependent claim refers back to an earlier claim to incorporate all limitations in the previous claim and include its own limitations. CHISUM ET AL., *supra* note 34, at 91.

⁶⁸ See *infra* Part III.A–D.

⁶⁹ See, e.g., Thomas, *supra* note 11, at 727–28 (arguing that regulations that severely limit when continuation applications can be filed may restrict an applicant’s ability to claim and defend meritorious inventions).

⁷⁰ Complaint, *Tafas v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007) (No. 1:07cv846), 2007 WL 3359672 (alleging that the new rules are inconsistent with various provisions of the Patent Act and with the U.S. Constitution). *Tafas* was consolidated with a subsequent injunction action by GlaxoSmithKline (GSK). See Verified Amended Complaint, *SmithKline Beecham Corp. v.*

an order temporarily enjoining the PTO from implementing the new rules, which were set to become effective the next day.⁷¹ The *Tafas* court concluded that the potential negative impact on the plaintiffs resulting from the implementation of the new rules was greater than the possible problems created by the new continuation rules since the claim rules do not absolutely limit the number of claims allowed.⁷²

Several months later, the court granted the summary judgment motion against the PTO and found the proposed limitations to the number of claims per patent to be substantive changes and thus improper extensions of PTO authority.⁷³ With respect to the final rules creating the 5/25 rule, the court noted that 35 U.S.C. § 112 “expressly permits an applicant to file ‘one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention,’ ” and further noted that “[s]ince 1938, the CCPA has consistently held that the Patent Act does not place any mechanical limits on the number of claims an applicant may file.”⁷⁴ The PTO had argued that the changes were only procedural and is considering an appeal.⁷⁵

Previously, there was no limit on the number of claims allowed in a patent application so long as the required excess claims fee was paid, providing an economically coercive way to minimize large numbers of claims in an application.⁷⁶ In contrast, the disincentive under the new rules is a requirement that an applicant wishing to file more than five independent claims or more than twenty-five total claims will be required to file an Examination Support Document (ESD).⁷⁷ The ESD would include a statement by the applicant that a

Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) (No. 1:07cv1008), 2007 WL 3231881. The action was supported by numerous amicus curiae briefs. *See, e.g.*, Brief of American Intellectual Property Law Association as Amici Curiae Supporting Plaintiffs, *Tafas*, 511 F. Supp. 2d 652 (No. 1:07cv846) (focusing on irreparable harm caused by the retroactive impact of applying the new rules to pending patent applications and lack of adverse impact to PTO if implementation is delayed).

⁷¹ *Tafas*, 511 F. Supp. 2d at 658, 671.

⁷² *See id.* at 665–66 (finding that there is a strong likelihood of success on the rules governing continuations of patent applications, but not on the claims rule issue); Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,724 (to be codified at 37 C.F.R. pt. 1) (discussing how the new 34 C.F.R. § 1.75(b) requires a prior art search and reference list be filed if the claim count exceeds the 5/25 limit).

⁷³ *Tafas v. Dudas*, No. 1:07cv846 (JCC), 2008 WL 859467 (E.D. Va. 2008).

⁷⁴ *Id.*

⁷⁵ Zusha Elinson, *Judge Strikes Down Patent Office's New Rules*, DAILY REPORT, Apr. 4, 2008, at 1.

⁷⁶ *See* MANUAL OF PATENT EXAMINING PROCEDURE § 714.10 (8th ed., rev. 6, 2007) (“Applicant is required to pay excess claims fees for each claim that is in excess of 3 in independent form or in excess of 20 (whether dependent or independent).”).

⁷⁷ Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg.

pre-examination search was conducted and a listing of pertinent references resulting from the search.⁷⁸ The rule would not only apply to applications filed on or after the effective date of the rule, but would also be retroactive and include any application that is pending but has not received an examination.⁷⁹ These additional disclosure requirements will significantly increase the costs associated with claiming more than the 5/25 threshold number.⁸⁰

Additionally, the ESD process exposes applicants to increased inequitable conduct liability.⁸¹ Inequitable conduct allegations arise from an applicant's intentional misrepresentation of a material fact or failure to disclose material information in his or her patent application.⁸² Such allegations may cause the resulting patent to be declared unenforceable.⁸³ The ESD requires an applicant to make a series of affirmative representations regarding his or her search of prior art that is likely to have a direct bearing on whether an examiner is convinced that the claims are patentable.⁸⁴ However, the PTO fails to define the scope of that

at 46,724.

⁷⁸ *Id.* at 46,741. The ESD would also identify all claim limitations disclosed in the prior art and particularly point out how each claim is patentable over the cited references. *Id.* at 46,741–72. An applicant may, without an ESD or justification, “present up to fifteen independent claims and seventy-five total claims to a single patentably distinct invention via an initial application and two continuation or continuation-in-part applications that are filed and prosecuted serially. . . .” *Id.* at 46,721. For an explanation of continuation applications, see MANUAL OF PATENT EXAMINING PROCEDURE § 201.07 (8th ed., rev. 5, 2006) (“A continuation is a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented.”); *id.* § 201.08 (“A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application.”).

⁷⁹ Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. at 46,716.

⁸⁰ See ICF INTERNATIONAL, CERTIFICATION ANALYSIS UNDER THE REGULATORY FLEXIBILITY ACT: CHANGES TO PRACTICE FOR CONTINUED EXAMINATION FILINGS, PATENT APPLICATIONS CONTAINING PATENTABLY INDISTINCT CLAIMS, AND EXAMINATION OF CLAIMS IN PATENT APPLICATIONS 16 (June 29, 2007), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcertificationanalysis.pdf> (noting that the patent search required by the ESD alone would cost between \$1,000 and \$2,500).

⁸¹ Jeffrey G. Sheldon, *Ethical Obligations of Patent Practitioners: Do You Know the Rules?*, 923 P.L.I. PAT. COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES 513, 521 (2008).

⁸² SCHECHTER & THOMAS, *supra* note 12, § 7.7.1, at 258.

⁸³ *Id.*

⁸⁴ See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. at 46,741–44 (explaining the ESD requirements).

search.⁸⁵ Thus, the resulting potential for a practitioner to be accused of inequitable conduct could cause the applicant to behave in a manner so as to avoid the necessity of filing an ESD.⁸⁶

2. *Policy Behind the Changes.* According to the PTO, the recent changes to the patent application system will allow the office to conduct a more thorough and reliable examination of patent applications.⁸⁷ The idea is that the ESD will assist the examiner in determining patentability by providing the most relevant prior art before actually conducting a prior art search,⁸⁸ thus dividing the responsibility for patent quality between applicants and the PTO.⁸⁹ The reactions to the new rules have been mixed, though most commentary suggests that the rules will impede the ability of applicants to procure comprehensive patent protection and substantially increase filing costs.⁹⁰

The PTO's main goals for the recent rule changes, increasing patent office efficiency and decreasing the application backlog,⁹¹ are based on the belief that pendency times for a patent application are highly correlated with the number of

⁸⁵ See *Tafas v. Dudas*, 511 F. Supp. 2d 652, 667 (E.D. Va. 2007) (“[According to plaintiff GSK,] the ‘rule does not indicate whether the applicant must conduct electronic searches, manual searches, or both; in which countries’ databases the applicant must search; or which libraries it must search.”).

⁸⁶ See *id.* at 668 (acknowledging the difficulty a “reasonably prudent person” would encounter in complying with the ESD requirements). In a 2006 symposium, PTO representatives acknowledged that the ESD practice involves submissions which “in the current law of inequitable conduct, nobody’s going to want to do.” Letter from David E. Boundy, Vice President, Cantor Fitzgerald L.P., to Steven S. McMillin, Deputy Director, U.S. Office of Management and Budget, at 4 & n.10 (July 3, 2007), available at <http://www.whitehouse.gov/omb/oira/0651/comments/461.pdf> (on file with author) (referring to recorded web video of Duke University Law School’s Fifth Annual Hor Topics in Intellectual Property Law Symposium).

⁸⁷ See Defendant’s Opposition to Plaintiffs’ Motion for a Temporary Restraining Order and Preliminary Injunction, *Tafas v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007) (No. 1:07cv846), 2007 WL 3231880 [hereinafter *PTO GSK Opposition*] (describing PTO goal to “increase application quality, reduce the backlog, and improve examination efficiency”).

⁸⁸ Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. at 46,721.

⁸⁹ U.S. Patent and Trademark Office, *Measure to Improve Patent Quality and Reduce Pendency* (Aug. 20, 2007), <http://www.uspto.gov/main/homepagenews/bak2007aug20.htm>.

⁹⁰ While some responses have been as vehement as “It is time for Patent Counsel to rally the troops, grab the pitchforks, and head for the sands of battle . . . in the Eastern District of Virginia,” Posting of John White to PLI Patent Blog, <http://www.pli.edu/patentcenter/blog.asp?view=plink&id=119> (Oct. 17, 2007, 16:38 EST), most responses have been more sedate. See generally *Comments Regarding Claims Practice*, *supra* note 65 (collecting public comments submitted to the PTO regarding the proposed claim designation rule).

⁹¹ See Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 62 (Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1) (“The Office’s current practice for examination of claims in patent applications is less efficient than it could be because it requires an initial patentability examination of every claim in an application.”).

claims and prior art references contained in the application.⁹² Despite acknowledging that the initial examination of large numbers of claims may sometimes be necessary in certain applications, the PTO believed that excessive claims required a disproportionate amount of the already limited time available to review applications.⁹³ While over 40% of new applications in the 2004 fiscal year had more than twenty claims,⁹⁴ only 1.2% of all nonprovisional applications in 2005 included more than ten independent claims.⁹⁵ Based on this data, the PTO concluded the rule changes would allow for the examination of every independent claim in 98.8% of the applications filed without any additional effort by the applicant.⁹⁶

D. EFFECT OF CLAIM NUMBER ON PATENT VALUE AND IMPORTANCE

A policy analysis should emphasize more important patents, which are identified through their inherent value.⁹⁷ Hypothetical measures of patent value include the number of claims in an application, number of citations made to other patents, "citations received" through references made by subsequent patents to the patent at issue, number of continuation applications filed, and whether the patent was ultimately litigated.⁹⁸ The average number of claims is a strong indicator of patent value for three primary reasons. First, because multi-claim patents are costly to file because of increased filing fees⁹⁹ and attorney's fees, the number of claims in an application can be an indicator of patent value.¹⁰⁰ Second, given the high cost of litigation, patents which are litigated are also typically considered valuable patents.¹⁰¹ Thus, the correlation between number of claims and litigation implies that claim number is a strong predictor of a patent's value.¹⁰²

⁹² John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 438–39, 448–51, 459 (2004).

⁹³ U.S. Patent and Trademark Office, *Proposed Rule Changes to Focus the Patent Process in the 21st Century*, <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html> (last visited May 18, 2008).

⁹⁴ *Id.*

⁹⁵ Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. at 62, 66.

⁹⁶ *Id.* at 62.

⁹⁷ See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1508–11 (2001) (arguing that an effective patent system focuses its resources on valuable patents rather than "bad patents").

⁹⁸ See John R. Allison et al., *supra* note 92, at 448–56 (examining the key characteristics of litigated patents as indicators of patent value).

⁹⁹ Under the old rules, an applicant who wished to file more than twenty claims or more than three independent claims had to pay an additional fee per claim. 37 C.F.R. § 1.16(h)–(i) (2007).

¹⁰⁰ Allison & Lemley, *supra* note 46, at 104.

¹⁰¹ Allison et al., *supra* note 92, at 441.

¹⁰² See John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent*

Litigated patents include significantly more claims than non-litigated patents: an average of 13.2 claims for the latter patents and 19.8 claims for the former.¹⁰³

Third, higher patent maintenance rates correspond to higher patent values.¹⁰⁴ Obtaining a patent is a costly process.¹⁰⁵ Most expenses associated with a patent are incurred during the prosecution process through attorney and filing fees, with estimates ranging from \$10,000 to \$30,000 per patent.¹⁰⁶ The incredible expense of acquiring a patent does not end with issuance, as maintenance fees must be paid throughout the life of the patent.¹⁰⁷ To prevent expiration of a patent, a patentee must pay \$900 three and a half years after issuance, \$2,300 seven and a half years after issuance, and \$3,800 eleven and a half years after issuance.¹⁰⁸ In deciding whether to maintain a patent and incur the substantial costs of patent maintenance, the number of claims in the patent plays a significant role, as the patent maintenance fee generally increases with the number of claims.¹⁰⁹ Studies of patents have shown that a patent with a higher number of independent claims

Prosecution, 53 VAND. L. REV. 2099, 2132 (2000) ("The number of claims filed is directly related to the cost of prosecution, and can serve as a proxy for either complexity of the subject matter or for the importance of the patent to the applicant."). Some commentators have said that the average number of claims and other such characteristics are poor predictors of whether a patent is likely to be litigated. See David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1722 (2007) (rejecting patent characteristics as value predictors based on weak statistical significance). However, these claims have been rebutted by other scholars. See John R. Allison & Thomas W. Sager, *Valuable Patents Redux: On the Enduring Merit of Using Patent Characteristics to Identify Valuable Patents*, 85 TEX. L. REV. 1769, 1794 (2007) (describing Adelman and DeAngelis's criticisms as "substantially misplaced").

¹⁰³ Allison, *supra* note 92, at 451.

¹⁰⁴ Jonathan A. Barney, *A Study of Patent Mortality Rates: Using Statistical Survival Analysis to Rate and Value Patent Assets*, 30 AIPLA Q. J. 317, 331 (2002).

¹⁰⁵ Lemley, *supra* note 97, at 1498.

¹⁰⁶ *Id.* at 1498–99 (reviewing prosecution cost estimates).

¹⁰⁷ See MANUAL OF PATENT EXAMINING PROCEDURE § 2520 (8th ed., rev. 6, 2007) (explaining patent practitioner maintenance fee procedure).

¹⁰⁸ 37 C.F.R. § 1.20(e)–(g) (2007). These fee values do not apply to design, plant, or small entity patents. *Id.* The maintenance fees required by the USPTO were increased by approximately 3% in September 2007 to reflect fluctuations in the Consumer Price Index. See 35 U.S.C. § 41(f) (2002); U.S. Patent and Trademark Office, *Fee Modernization Act of 2003: Purpose and Need for Proposed Statutory Changes to 35 U.S.C. 41—Fees*, available at <http://www.uspto.gov/web/offices/com/strat21/feepurpose.htm> (last visited Feb. 26, 2008) (stating the thirty-nine fee increase is recommended by the PTO to "ensure that there is no delay in the implementation of the USPTO's new initiatives aimed at improving the quality of granted patents and trademark registrations, increasing efficiency through e-Government programs, and reducing pendency in processing applications for patents and for the registration of trademarks").

¹⁰⁹ Barney, *supra* note 104, at 332.

is worth more to its owner by providing comprehensive protection of the invention and proof of validity in the litigation context.¹¹⁰

The number of claims in a patent relates not only to the intrinsic value of the patent but also both to the relevant industry for the patent and to the characteristics of the applicant. Typically, “[the number of] claims [in a patent] are positively correlated with the applicants’ cash flow and capital intensity.”¹¹¹ Individuals file fewer claims than any entity, and non-profits file the most claims (though this statistic is suspect due to the low number of non-profit patents analyzed).¹¹² The number of claims also differs across technology areas.¹¹³ Accordingly, industries with high total claims per application were medical devices (17.05), pharmaceutical (14.99), and biotechnology (13.30).¹¹⁴ United States-based inventors are strongly represented in the medical device, pharmaceutical, and biotechnology fields in comparison to inventors from other countries.¹¹⁵ Thus, the number of claims in an application can indicate a later issuing patent’s economic value.

III. ANALYSIS

*If the CEO of Walmart was troubled by the success of his company, the inability of his company to handle the multitude of customers, and the inability to spend all of the money he was making, I don't think that he would put a sign in the fornt [sic] window of every Walmart stating: "Effective November 1st we will only be selling brooms."*¹¹⁶

As described in Part II.D, the PTO’s claim limitation rules have a significant impact on the behavior of applicants who are pursuing patent protection. This Part describes the practical and economic effects of these strategic changes in applicant behavior that disparately impact sectors especially important to the U.S. economy. This Part concludes with reasonable solutions that, if adopted by the PTO, may avoid such negative effects.

¹¹⁰ *Id.*

¹¹¹ James Bessen & Michael J. Meurer, *Lessons for Patent Policy From Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 21 (2005).

¹¹² Allison & Lemley, *supra* note 102, at 2145 & n.131, 2174.

¹¹³ *Id.* at 2131–32.

¹¹⁴ *Id.* at 2161.

¹¹⁵ *Id.* at 2121–24.

¹¹⁶ Posting of Anon to Patently-O Blog, <http://www.patentlyo.com/patent/2007/08/dr-tafas-files-.html> (Aug. 23, 2007, 10:53 EST).

A. APPROPRIATE APPROACH OR ABUSE OF AUTHORITY: A PRACTICAL AND STRATEGIC ANALYSIS

Although the PTO has argued that the proposed rules discussed in Part II.C. do not present an absolute bar to the presentation of claims, the practical effect is that applicants wishing to pursue these options face significant and burdensome obstacles. It is expressly the PTO's duty, not the duty of applicants, to examine applications and discover prior art.¹¹⁷ By requiring an ESD, the PTO has impermissibly shifted the burden of discovering relevant prior art to the applicant. The ESD option is not only expensive but also provides statements on the record that can potentially be used by an accused infringer for both invalidity and inequitable conduct defenses.¹¹⁸

Additionally, the PTO rationale that five independent claims provide sufficient protection for the majority of applicants¹¹⁹ fails to consider that complete patent protection is achieved through liberal allowance of dependent claims, which incorporate every limitation of an independent claim with further limitation.¹²⁰ Patent applicants probably will not feel confident that the examiner will find allowable subject matter by reviewing a limited number of initial claims. Scholars have noted that from the PTO's viewpoint, an advantage of dependent claims is that they require less time to examine, and applicants using them should be given a financial incentive for doing so.¹²¹

¹¹⁷ See 35 U.S.C. § 131 (2002) ("The Director shall cause an examination to be made of the application and the alleged new invention . . .").

¹¹⁸ See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,725 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). The new rules, specifically § 1.75(b)(4), establish a process where two applications with patentably indistinct claims will be treated together, which would restrict applicants to ten selected claims for purposes of determining whether ESD is required. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. at 46,725.

¹¹⁹ See *id.* at 46,788 (explaining why the PTO believes that the rule requiring an applicant to file an ESD if his or her application contains more than five independent claims will not have a substantial negative impact on individual and small entity investors seeking patent protection).

¹²⁰ See FABER, *supra* note 28, §§ 2.9–2.10 (recommending that patent applicants draft broader independent claims which include all of the necessary limitations, and then specifically claim the various embodiments of the invention through individual claims). But see SHELDON, *supra* note 27, § 6.5.8.1 (recommending that new practitioners draft parent independent claims to have no more than five dependent claims).

¹²¹ FABER, *supra* note 28, § 2.9 ("Note that, when any claim is allowed, all dependent claims, which are dependent on the allowed claim can also be allowed without further examination for novelty or obviousness, other than to make sure they are dependent claims and satisfy 35 U.S.C. § 112.").

Ultimately, the new patent application rules may even increase examination burdens on the PTO. Under the proposed rules, practitioners are forced to concurrently file separate applications in order to claim all embodiments of their invention.¹²² This policy could increase the PTO's workload if more than one examiner needs to become familiar with the same subject matter. The increased workload created by the proposed rules will offset or eliminate any backlog reduction.¹²³ The PTO should not pass a rule for the purpose of reducing its workload, especially a rule that limits the actual function of the PTO: managing the patent registration system for the American public.

B. APPROPRIATE APPROACH OR ABUSE OF AUTHORITY: AN ECONOMIC ANALYSIS

In addition to the basic costs imposed on patent applicants in acquiring patents,¹²⁴ many of the proposed rule changes would impose significant new financial burdens on both the applicants¹²⁵ and the PTO itself. First, the rule changes may create substantial budget issues for the PTO because the intended reduction in patent applications translates directly to revenue loss.¹²⁶ The claim limitations will reduce the largest factor in determining patent maintenance fees: the number of claims.¹²⁷ Maintenance fees are over three-fourths of the total fees generated by a patent and require minimal administrative costs from the PTO.¹²⁸ The incremental revenue for claims comes at a relatively low examination cost for the PTO; claims in a single application are necessarily closely related,¹²⁹ and therefore, the examination burden for claims in an application increases at a lesser rate than the increase in fees collected from those additional claims.¹³⁰ Thus, the

¹²² See Brenda Sandburg, *PTO Proposed Rule Could Force Drug Firms to File More Patent Applications*, THE PINK SHEET, Aug. 21, 2007, available at <http://www.fdalegislativewatch.com/2007/08/pto-proposed-ru.html>.

¹²³ Even further, the PTO has already spent more than 25,000 hours preparing its employees for the implementation of the final rules. See *PTO GSK Opposition*, *supra* note 87, at 18 (detailing PTO preparation before the November 1, 2007 implementation of the rules).

¹²⁴ See *supra* notes 105–08 and accompanying text.

¹²⁵ A recent study prepared for the PTO estimated the final claims rules will result in incremental costs ranging from \$872 to \$13,993 per application. ICF REPORT, *supra* note 80, at 25.

¹²⁶ Boundy, *supra* note 86, at 3–5. See also American Bar Association, Section of Intellectual Property Law Report to the House of Delegates, available at <http://www.abanet.org/intelprop/1061egis/ptouserfee.doc> (discussing PTO budgetary issues and the effects of decreased PTO revenue).

¹²⁷ Boundy, *supra* note 86, at 4–5.

¹²⁸ *Id.*

¹²⁹ See 37 C.F.R. § 1.141(a) (2007) (“Two or more independent and distinct inventions may not be claimed in one national application. . . .”).

¹³⁰ The PTO charges a fixed \$310 fee for applications filed with twenty-claims or fewer, and each additional claim is \$50. United States Patent and Trademark Office, FY 2008 Fee Schedule, effective Sept. 30, 2007, available at <http://www.uspto.gov/go/fees/fee2007september30.htm#patapp>. Fees

applications that would be curbed by the new claim rules are among the more profitable ones for the PTO.

Second, the new rules are likely to significantly increase the cost of patent prosecution to the applicant. If the proposed rules are implemented by the PTO, in addition to increasing the immediate costs of reviewing all pending applications,¹³¹ the costs of prosecuting applications are also likely to significantly rise.¹³² In the past, only 1,255 applicants, about half of a percent of all applicants, took advantage of accelerated examination by filing ESD-type documents.¹³³ If applicants are historically averse to filing such documents, requiring an ESD will certainly impact applicant patterns under the new rules. The PTO estimates the cost of preparing an ESD at \$2,500,¹³⁴ but ESDs are more difficult to prepare than novelty opinions.¹³⁵ Unlike the traditionally obtained preliminary novelty opinions, which recite the scope of a prior art search and pertinent items found,¹³⁶ the pre-application prior art search required by the ESD procedure would cost between \$8,000 and \$10,000 for each wider ranging search.¹³⁷ Cost estimates for the more complex ESD range from \$6,000 to \$15,500 per application.¹³⁸ The

are cut in half for small entities. *See id.*

¹³¹ *See* Declaration of David Kappos, on Behalf of IBM, in Support of the AIPLA Amicus Brief, *Tafas v. Dudas*, 511 F.Supp.2d 652 (E.D. Va. Aug. 22, 2007) (arguing against retroactive application of the new rules due to the incredible cost IBM will incur to review over 25,000 pending patent applications to ensure compliance). Notably, IBM, like many information technology companies, has been a strong supporter of "patent reform," including the new rules. Letter from Manny W. Schecter, IBM Associate General Counsel, to USPTO (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/ibm.pdf.

¹³² The new rules will impose costs for reviewing all pending applications and require higher attorney fees for ESD preparation, in many cases. *See* ICF REPORT, *supra* note 80, at 16–18 (discussing monetary cost of the proposed rules).

¹³³ Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 63 (Jan. 3, 2006).

¹³⁴ *See id.* at 66 (citing an AIPLA study of the seventy-fifth percentile charge of a patent novelty search, analysis, and opinion).

¹³⁵ *See* E-mail from Steven M. Hoffberg, Dep't of Commerce, to USPTO (May 1, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/hoffberg.pdf (arguing that the PTO's \$2,500 ESD estimate underestimates the true cost for obtaining an ESD).

¹³⁶ LEGAL OPINION LETTERS: A COMPREHENSIVE GUIDE TO OPINION LETTER PRACTICE § 9.10 (M. John Sterba ed., 3d ed. 2003).

¹³⁷ *See* Lemley, *supra* note 97, at 1510 (estimating cost of prior art searches based on actual search costs and increased legal fees from increased disclosure of prior art).

¹³⁸ *See* Letter from NAPP, to USPTO, *supra* note 65, at 11–12 (estimating ESD cost based on forty hours of work at \$150 per hour); Letter from William B. Slate, to USPTO, at 11 (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/b_l.pdf (estimating ESD cost based on \$18,000 cost of "Validity/Invalidity Only Opinion" minus the \$2,500 if all novelty search work can be applied to the ESD).

decision to select fewer claims or prepare an ESD requires a good knowledge of prior art. While conducting a pre-filing prior art search is good practice,¹³⁹ the timing and extent of searching ought to be decided by applicants.

C. DISPARATE IMPACT ON AREAS UNIQUELY VITAL TO THE AMERICAN ECONOMY

Search costs and higher application fees created by the rules changes will fall disproportionately on individuals and small businesses,¹⁴⁰ which have a significant impact on American innovation and progress.¹⁴¹ Large corporations can adapt by filing more applications because they already file a large number of applications, each addressing very narrow inventions arising from a common commercial invention.¹⁴² Individuals and small businesses do not have that luxury because they do not have enough resources to engage in such tactics.¹⁴³ Even though the PTO attempted to reduce the burden on small entities in regards to the new claim rules,¹⁴⁴ the estimated cost of an ESD for a small entity still looks to be in the range of \$2,563 to \$13,121.¹⁴⁵

¹³⁹ See *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (describing prior art search as “a prudent and nowadays common preliminary to well organized research”).

¹⁴⁰ See *infra* pp. 363–65. However, only 0.04% of the total affected applications will be from small entities. ICF REPORT, *supra* note 80, at 28. Specifically, the claims requirements are predicted to affect only 0.44–0.54% of small entity initial applications. *Id.* at 26.

¹⁴¹ Independent inventors are responsible for many of the most important inventions of the last century: “atomic energy, penicillin, microwave technology, the FM radio, magnetic recording, holography, fiber optics, and insulin.” H.R. REP. NO. 102-382, at 32 n.31 (1991), *as reprinted in* 1991 U.S.C.C.A.N. 1320, 1328.

¹⁴² See generally *Patent Law and Non-profit Research Collaboration: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 107th Cong. 57 (2002) (statement of Jon D. Grossman) (“In fact, it is common for large corporations to have a steady stream of new patents issue in their respective patent portfolios.”).

¹⁴³ See generally Jeff A. Ronspies, *Does David Need a New Sling? Small Entities Face a Costly Barrier to Patent Protection*, 4 J. MARSHALL REV. INTELL. PROP. L. 184, 195–204 (2004) (discussing how the economic disparity between small entities and large corporations may lead individual and small entity inventors to believe the cost of patent protection far exceeds the profits expected).

¹⁴⁴ Small entities are exempt from identifying all of the limitations of the claims disclosed by each reference in the ESD. See *Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications*, 72 Fed. Reg. 46,716, 46,743 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (allowing a small entity to claim an exemption from the requirement in 37 C.F.R. § 1.265(a)(3) for an identification of all of the limitations of each of the claims that are disclosed by the references cited in the listing of the references).

¹⁴⁵ *Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications*, 72 Fed. Reg. at 46,798.

The new rules will not only reduce the scope of patent protection available to technology companies (which traditionally rely on numerous claims for full protection), but independent inventors and small entities will also be less likely to file based on their limited financial resources.¹⁴⁶ Thus, the rules will disproportionately impact inventions especially vital to the national economy.¹⁴⁷ Even if the actual percentage of applications affected is small, the damage would be more significant because it targets the inventions that need the most careful patent protection.

Moreover, limiting the ability to claim complex inventions will fall disproportionately on pharmaceutical and software companies. The pharmaceutical industry is concerned about PTO policies that inhibit their ability to fully protect their discoveries.¹⁴⁸ The Senior Vice President of Pharmaceutical Research and Manufacturers of America, Ken Johnson, said in a statement regarding the patent changes that “what makes this a serious issue is the fact [that] adequate patent protection is the lifeblood behind development of new treatments” at a time when it can take over a decade to develop a drug at great cost to the industry.¹⁴⁹

D. ALTERNATIVES TO THE NEW CLAIM RULES

There has been extensive discussion about how to reform the U.S. patent system, leading to an overwhelming number of potential solutions.¹⁵⁰ In addition to rule changes limiting continuations and number of claims in an application, the PTO has proposed further examination reform through “accelerated examination” procedures,¹⁵¹ an online peer review pilot program to improve

¹⁴⁶ Mack, *supra* note 40, at 2148–49.

¹⁴⁷ See CALIFORNIA HEALTHCARE INSTITUTE, IMPACT OF PATENT LAW CHANGES ON BIOMEDICAL INVESTMENT AND INNOVATION 4–6 (2007), available at <http://www.chi.org/industry/reports.aspx> (follow hyperlink under “2007 CHI Reports”) (“As proposed, the rules would have a devastating effect on mid-sized and start-up biotechnology, pharmaceutical, and medical technology companies.”); BIOTECHNOLOGY INDUSTRY ORGANIZATION, THE ECONOMIC CONTRIBUTIONS OF THE BIOTECHNOLOGY INDUSTRY TO THE U.S. ECONOMY (2000), available at <http://www.bio.org/speeches/pubs/ernstyoung.pdf>

¹⁴⁸ See Katrina Megget, *Patent Changes and the Pharma Industry*, IN-PHARMATECHNOLOGIST.COM, Aug. 30, 2007, <http://www.in-pharmatechnologist.com/news/ng.asp?id=79375> (discussing how pharmaceutical companies must find strategies to deal with the changes in the patent rules).

¹⁴⁹ See *id.* (estimating an average cost of \$1 billion to develop a new drug).

¹⁵⁰ See Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 51–76 (2007) (surveying patent reform proposals under consideration by Congress).

¹⁵¹ See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 Fed. Reg. 36,323, 36,324 (June 26, 2006) (“The USPTO is revising its procedures for applications made special under the accelerated examination program with the goal

access to available prior art,¹⁵² and Information Disclosure Statement procedure changes to encourage new applicants to provide the most relevant information in early stages of the patent application review process.¹⁵³ These changes are meant to work “synergistically” with the final rules.¹⁵⁴ Yet, the PTO seems to be taking a fairly statistical approach to fixing its problems instead of looking aggregately at what would make a patent application examination more efficient.

The rules changes proposed by the PTO are unnecessary when something as simple as increasing fees has an impact on the number of applications filed and the number of claims filed per application.¹⁵⁵ Further increasing excess claim fees would lead to more applicants voluntarily decreasing the number of claims presented. This would allow the PTO to improve its application backlog without adopting new rules that will likely limit the ability of applicants to properly protect their inventions. Another option is fully funding the PTO. Although legislation is being considered to allow the PTO to keep all its revenue,¹⁵⁶ the PTO should lobby Congress to get more revenue than it collects to offset the losses from past years.¹⁵⁷ The increased revenue would allow the PTO to continue workforce expansion¹⁵⁸ and improve workforce attrition.¹⁵⁹

of completing examination within twelve months of the filing date of the application.”).

¹⁵² See John J. Doll, *Pilot Concerning Public Submission of Peer Reviewed Prior Art*, OFFICIAL GAZETTE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE: PATENT AND TRADEMARK OFFICE NOTICES (June 26, 2007), available at <http://www.uspto.gov/web/patents/patog/week26/OG/TOC.htm#ref12> (discussing the feasibility of “collaborative, online process in which members of the public pool together their knowledge and locate potential prior art”).

¹⁵³ See Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808 (July 10, 2006) (discussing proposed changes to the patent filing rules to make special procedures to require preexamination search of prior art).

¹⁵⁴ *PTO GSK Opposition*, *supra* note 87, at 20.

¹⁵⁵ See *supra* Part II.D.

¹⁵⁶ Final Judiciary Comm. Report to Accompany S. 1145, A Bill to Amend Title 35, United States Code, to Provide for Patent Reform, 110th Cong. 34–35 (2008), available at <http://www.ipo.org> (follow “Law, Policy, and Advocacy” hyperlink; then follow “Legislative Action Center” hyperlink; then follow “Patent Reform” hyperlink) (discussing end of PTO fee diversion in section 15).

¹⁵⁷ See A REPORT BY A PANEL OF THE NATIONAL ACADEMY OF PUBLIC ADMINISTRATION FOR THE U.S. CONGRESS AND THE U.S. PATENT AND TRADEMARK OFFICE: US PATENT AND TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY 40 (2005), available at <http://www.napawash.org/Pubs/PTO8-25-05.pdf> (noting that the USPTO lost more than \$741 million of its fee revenue between FY1992 and FY2004).

¹⁵⁸ See *id.* at 41–49 (discussing the impact of fee availability limits on USPTO staffing loads).

¹⁵⁹ See Review of U.S. Patent and Trademark Office Operations Involving Analysis of Government Accountability Office, Inspector General, and National Academy of Public Administration Reports: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 109th Cong. 12 (2005) (statement of Rep. Howard L. Berman, Ranking Member, Subcomm. on Courts, the Internet, and Intellectual Property), available at http://commdocs.house.gov/committees/judiciary/hju23324.000/hju23324_0.htm (“Only 45% of the PTO workforce has five or more years of service, and in

Because of the variety of non-patent methods available for protecting technology, the burden-increasing rule changes may cause some firms to pursue alternative protection mechanisms.¹⁶⁰ This would be socially detrimental because some alternate tactics do not disclose the technology to the public domain.¹⁶¹ Also, while the PTO dropped a 1998 proposal to absolutely limit the number of allowed claims in a patent application in response to negative commentary,¹⁶² the implementation of the new rules might justify even more extreme rules—such as restricting the number of applications allowed per year or further restricting allowances to a single claim—if the backlog were to still worsen.

IV. CONCLUSION

Whether or not the claim limitation rules proposed by the PTO are finally implemented, the significant problems present within the PTO will still burden the already sluggish patent prosecution system. The new rule changes will make the PTO's job easier by shifting more of the time and expense burden of examining a patent application to the applicant. The implementation of the new rules may result in fewer applications being filed or allowed, with narrower patent coverage on any patents ultimately awarded. A reduction in patent filings will ultimately have a negative effect on the American people because this will likely lead to less innovation and disclosure of inventions to the public.

It is better to adapt the PTO procedures than to encourage inventors to file less often.¹⁶³ Given the significance of these changes, the PTO should not adopt new rules unless and until the Court decides the legal challenges relating to the

an agency where it takes roughly five or six years before an employee becomes fully productive, this is a troublesome statistic.”).

¹⁶⁰ See, e.g., Seán M. Coughlin, *Is the Patent Paradox a Result of a Large Firm Perspective?: Differential Value of Small Firm Patents Over Time Explains the Patent Paradox*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 371, 380–81 (2007) (discussing non-patent tactics employed by large firms); Ronspies, *supra* note 143, at 203–04 (discussing alternatives to costly patent process potentially used by small entities, including trade secret protection or no protection at all).

¹⁶¹ See Ronspies, *supra* note 143, at 204 (noting that “the very nature of trade secret protection undercuts the intent of the patent system because innovations kept as trade secrets do not readily become available for others to build upon”).

¹⁶² See Changes to Implement the Patent Business Goals, 64 Fed. Reg. 53,772, 53,774–75 (Oct. 4, 1999) (withdrawing proposal to place limits on the number of claims that will be examined in a single application).

¹⁶³ Alternatives are available despite the PTO claim that weaker rule changes would be inadequate to achieve their backlog reduction goals. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,816–23, 46,824–26, 46,833–34 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

proper rulemaking authority,¹⁶⁴ or Congress acts to address the issues through the pending patent reform legislation. Without a proposal arising from extensive commentary from not only the PTO but also patent practitioners and attorneys, adopting unreasonable new rules with questionable statutory authority would be a harmful and inefficient maneuver for the U.S. patent system.

Elisabeth Marie Koehnemann

¹⁶⁴ The aspect of the claim limitation rules that makes it less susceptible to challenge is that it does not limit the number of continuations or claims definitively, but rather the new rules simply force applicants making numerous claims to justify their approach and pay additional fees both to the PTO and their practitioner.

