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U.S. Patent and Trademark Office Reforms: Regulatory Impacts Upon Innovation and Competition

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U.S. Patent and Trademark Office Reforms: Regulatory Impacts Upon Innovation and Competition

Summary

The interest of the 110th Congress in the patent system has been evidenced by the advancement of substantial reform bills in both the House and Senate. Alongside these congressional proposals, the United States Patent and Trademark Office (USPTO) has engaged in a significant rulemaking effort in recent years. This process culminated in new rules that would make several significant changes to the patent acquisition process.

First, the rules would limit the number of "continued applications" that could be filed, absent a petition and showing by the patent applicant of the need for such applications. Stated generally, a continued application is one that has been re-filed at the USPTO, commonly following an examiner's rejection. The USPTO has justified this limitation on the basis that the increasing number of continued examination filings is hampering its ability to review new applications.

Second, the rules would limit the number of "claims" that can be filed in a particular patent application, unless the applicant supplies the USPTO with an "Examination Support Document" in furtherance of that application. The USPTO asserts that these rules would lead to a more effective examination process.

Critics of the new rules contend that they will negatively impact the ability of innovators to obtain effective proprietary rights. Legal challenges to the rules resulted in the October 31, 2007 decision in *Tafas v. Dudas*. There, the U.S. District Court for the Eastern District of Virginia issued a preliminary injunction against the USPTO. Although this ruling is temporary in nature, its immediate impact is that the USPTO may not implement its rules until the court makes a final determination. The *Tafas v. Dudas* litigation is ongoing at the time of the publication of this report.

In addition, the USPTO has proposed reforms that would impose additional applicant disclosure obligations with respect to "Information Disclosure Statements" filed in support of a particular patent application. The USPTO has not yet taken action concerning this rule.

Should Congress conclude that the current situation with respect to claims and continued application practice at the USPTO is satisfactory, then no action need be taken. If Congress wishes to intervene, however, a number of options present themselves. In the 110th Congress, H.R. 1908 would expressly provide the USPTO with regulatory authority to specify the circumstances under which a patent applicant may file a continued application. Other possibilities include providing the USPTO with substantive rulemaking authority and more specific reforms directed to the relevant substantive provisions of the Patent Act.

Contents

Patents and Innovation Policy 3
The Mechanics of the Patent System 3
Innovation Policy 4

Continued Application Practice Reform 6
Continued Application Practice 6
The USPTO Continued Application Rules 8

Patent Claiming Practice Reform 11
Patent Claiming Practice 11
The USPTO Claim Rules 13

The *Tafas v. Dudas* Litigation 16

IDS Practice Reform 18

Congressional Issues and Alternatives 19

U.S. Patent and Trademark Office Reforms: Regulatory Impacts Upon Innovation and Competition

Legislative interest in the patent system has been evidenced by the advancement of substantial reform bills in both houses of the 110th Congress.[1] Some of the reforms currently under consideration by Congress would impact the United States Patent and Trademark Office (USPTO). Among these proposals are the adoption of patent opposition proceedings,[2] changes to the rules governing the publication of pending patent applications,[3] and third party submission of information to the USPTO that may be pertinent to the decisions whether to allow a patent to issue or not.[4]

Alongside these congressional proposals, the USPTO itself has engaged in a substantial rulemaking effort in recent years. This process culminated in new rules that would make several significant changes to the patent acquisition process. First, the rules would limit the number of "claims" that can be filed in a particular patent application, unless the applicant supplies the USPTO with an "Examination Support Document" in furtherance of that application.[5] Second, the rules would limit the number of "continued applications" that could be filed, absent a petition and showing by the patent applicant of the need for such applications.[6] In addition, the USPTO has proposed reforms that would impose additional applicant disclosure obligations with respect to "Information Disclosure Statements" filed in support of a particular patent application.[7]

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[1]*See* CRS Report for Congress, "Patent Reform in the 110th Congress: Innovation Issues," by John R. Thomas & Wendy H. Schacht.

[2]H.R. 1908 at § 6; S. 1145 at § 5.

[3]H.R. 1908 at § 9; S. 1145 at § 7.

[4]H.R. 1908 at § 9; S. 1145 at § 7.

[5]*See* Department of Commerce, Patent and Trademark Office, Final Rule "Change to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 *Federal Register* (August 21, 2007), 46716 (hereinafter "USPTO Rules").

[6]*Id.*

[7]Department of Commerce, USPTO, "Changes to Information Disclosure Statement Requirements and Other Related Matters," 71 *Federal Register* 38,808 (July 10, 2006) (hereinafter "IDS Notice"). In addition to the reforms with respect to claiming, continued applications, and IDS practice, the USPTO has also proposed changes to the rules governing claims that define alternative inventions, *see* Department of Commerce, USPTO,

(continued...)

The USPTO rules concerning claims and continued applications are controversial. Some patent professionals are concerned that the rules would make the process of patent acquisition more costly, impede the ability of innovators to protect their inventions adequately, and ultimately harm innovation. Some have also opined that the rules are inconsistent with the provisions of the governing patent legislation, the Patent Act of 1952. On the other hand, other observers believe that current claiming and continued application practices are subject to abuses that can potentially place undue burdens upon the USPTO during its examination tasks, be harmful to competitive industry, and at times work against the public interest.[8] These observers favor reforms that would limit what they see as applicant abuses of the current system.

Criticisms of the USPTO rules have led to legal challenges before the U.S. District Court for the Eastern District of Virginia. The result was the October 31, 2007, order in *Tafas v. Dudas*, that issued a preliminary injunction against the USPTO.[9] Although this ruling is temporary in nature, its immediate impact is that the USPTO may not implement its rules until the court makes a final determination. The *Tafas v. Dudas* litigation is ongoing at the time of the publication of this report.

Congressional response to the claims and continuing application rules has thus far been limited. In the 110th Congress, H.R. 1908 would expressly provide the USPTO with regulatory authority to specify the circumstances under which a patent applicant may file a continuing application.[10] That bill passed the House on September 7, 2007, as the "Patent Reform Act of 2007." No other pending legislation — including S. 1145, the Senate legislation also titled the "Patent Reform Act of 2007" — addresses the new USPTO rules.

This report reviews the USPTO rules that would restrict claims and continuing applications. It begins by offering a summary of the patent system and the role of patents in innovation policy. The context, details, and legal challenges to the new USPTO rules are then explained. The report then offers both the policy justifications for the new rules, as well as concerns that patent professionals and other observers have expressed over their effectiveness and impact. The report closes by identifying congressional issues and options.

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[7](...continued)
"Examination of Patent Applications That Include Claims Containing Alternative Language," 72 *Federal Register* 44,992 (August 10, 2007), and has also provided for accelerated examination in certain circumstances, *see* Department of Commerce, USPTO, "Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination," 71 *Federal Register* 36,323 (June 26, 2006).

[8]*See* Mark A. Lemley & Kimberly A. Moore, "Ending Abuse of Patent Continuations," 84 *Boston University Law Review* (2004), 63.

[9]The district court's opinion resulted from two separate lawsuits, Tafas v. Dudas, Case No. 1:07cv846 (E.D. Va. 2007), and Smithkline Beecham Corp. v. Dudas, Case No. 1:07cv1008 (E.D. Va. 2007), that were consolidated.

[10]H.R. 1908, § 14.

Patents and Innovation Policy

The Mechanics of the Patent System

The U.S. Constitution provides Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries . . . ."[11] In accordance with the Patent Act of 1952 (the "Patent Act"),[12] an inventor may seek the grant of a patent by preparing and submitting an application to the USPTO. USPTO officials known as examiners then determine whether the invention disclosed in the application merits the award of a patent.[13]

In determining whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[14] In particular, the application must enable persons skilled in the art to make and use the invention without undue experimentation.[15] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[16]

The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must meet four primary requirements. First, the invention must fall within at least one category of patentable subject matter. According to the Patent Act, an invention which is a "process, machine, manufacture, or composition of matter" is eligible for patenting.[17] Second, the invention must be useful, a requirement that is satisfied if the invention is operable and provides a tangible benefit.[18]

Third, the invention must be novel, or different, from subject matter disclosed by an earlier patent, publication, or other state-of-the-art knowledge.[19] Finally, an invention is not patentable if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[20] This requirement of "nonobviousness"

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[11]U.S. Constitution, Article I, Section 8, Clause 8.

[12]P.L. 82-593, 66 Stat. 792 (codified at Title 35 of the United States Code).

[13]35 U.S.C. § 131 (2006).

[14]35 U.S.C. § 112 (2006).

[15]*See* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

[16]*See* High Concrete Structures, Inc. v. New Enterprise Stone and Lime Co., 377 F.3d 1379, 1382 (Fed. Cir. 2004).

[17]35 U.S.C. § 101 (2006).

[18]*Id. See* In re Fischer, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[19]35 U.S.C. § 102 (2006).

[20]35 U.S.C. § 103(a) (2006).

prevents the issuance of patents claiming subject matter that a skilled artisan would have been able to implement in view of the knowledge of the state of the art.[21]

If the USPTO allows the patent to issue, its owner obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[22] Those who engage in those acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[23] The patent statute also provides for an award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[24]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[25] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights do not enforce themselves. Patent proprietors who wish to compel others to respect their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds. The Court of Appeals for the Federal Circuit (Federal Circuit) possesses nationwide jurisdiction over most patent appeals from the district courts.[26] The Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[27]

Innovation Policy

Patent ownership is perceived to encourage innovation, which in turn leads to industry advancement and economic growth. One characteristic of the new knowledge that results from innovation is that it is a "public good." Public goods are non-rivalrous and non-excludable, for use of the good by one individual does not limit the amount of the good available for consumption by others, and no one can be prevented from using that good.[28]

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[21] *See* KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007).

[22] 35 U.S.C. § 271(a) (2006).

[23] 35 U.S.C. § 283 (2006). *See* eBay Inc. v. MercExchange L.L.C., 126 S.Ct. 1837 (2006).

[24] 35 U.S.C. § 284 (2006).

[25] 35 U.S.C. § 154(a)(2) (2006). Although the patent term is based upon the filing date, the patentee obtains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[26] 28 U.S.C. § 1295(a)(1) (2006).

[27] 28 U.S.C. § 1254(1) (2006).

[28] *See* Dotan Oliar, "Making Sense of the Intellectual Property Clause: Promotion of Progress
(continued...)

The lack of excludability in particular is believed to result in an environment where too few inventions would be made. Absent a patent system, "free riders" could easily duplicate and exploit the inventions of others. Further, because they incurred no cost to develop and perfect the technology involved, copyists could undersell the original inventor. Aware that they would be unable to capitalize upon their inventions, individuals might be discouraged from innovating in the first instance. The patent system corrects this market failure problem by providing innovators with an exclusive interest in their inventions, thereby allowing them to capture their marketplace value.[29]

The patent system purportedly serves other goals as well. The patent law encourages the disclosure of new products and processes, for each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.[30] At the close of the patent's twenty-year term,[31] others may employ the claimed invention without regard to the expired patent. In this manner the patent system ultimately contributes to the growth of the public domain.

Even during their term, issued patents may encourage others to "invent around" the patentee's proprietary interest. A patentee may point the way to new products, markets, economies of production and even entire industries. Others can build upon the disclosure of a patent instrument to produce their own technologies that fall outside the exclusive rights associated with the patent.[32]

The regime of patents has also been identified as a facilitator of markets. Absent patent rights, an inventor may have scant tangible assets to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been disclosed to a prospective licensee might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make transactions concerning information goods more feasible.[33]

Through these mechanisms, the patent system can act in a more socially desirable way than its chief legal alternative, trade secret protection. Trade secrecy guards against the improper appropriation of valuable, commercially useful and secret information. In contrast to patenting, trade secret protection does not result in

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[28](...continued)
as a Limitation on Congress's Intellectual Property Power," 94 *Georgetown Law Journal* (2006), 1771.

[29]*See* Dan L. Burk & Mark A. Lemley, "Is Patent Law Technology-Specific?," 17 *Berkeley Technology Law Journal* (2002), 1155.

[30]35 U.S.C. § 112 (2006).

[31]35 U.S.C. § 154 (2006).

[32]*See* Rebecca Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 *University of Chicago Law Review* (1989), 1017.

[33]Robert P . Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

the disclosure of publicly available information. That is because an enterprise must take reasonable measures to keep secret the information for which trade secret protection is sought. Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.[34]

The patent system has long been subject to criticism, however. Some observers have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of innovation. The desire to obtain a lead time advantage over competitors, as well as the recognition that passive firms may lose out to their more innovative rivals, may provide sufficient inducement to invent without the need for further incentives.[35] Other commentators believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[36]

Because the relationship between the rate of innovation and the availability of patent rights is not well-understood, we lack rigorous analytical methods for studying the impact of the patent system upon the economy as a whole. As a result, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation. Thus, each of these arguments for and against the patent system remain open to challenge by those who are unpersuaded by their internal logic.

Continuing Application Practice Reform

Continued Application Practice

The Patent Act allows inventors to file "continued applications."[37] Stated generally, a continued application is one that has been "re-filed" at the USPTO, commonly following the rejection of some or all of its claims. Continued patent applications allow inventors to extend the period of examination at the USPTO in order to negotiate further with a patent examiner, amend claims, submit new claims, and gain additional time to prepare evidence to be submitted to the USPTO in support of their applications, among other potential benefits.[38]

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[34]David D. Friedman *et al.*, "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives* (1991), 61.

[35]*See* Frederic M. Sherer, *Industrial Market Structure and Economic Performance* (1970), 384-87.

[36]*See* John R. Thomas, "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," *University of Illinois Law Review* (2001), 305.

[37]35 U.S.C. § 120 (2006). Continued applications are also commonly termed "continuing" applications.

[38]See Gary C. Ganzi, "Patent Continuation Practice and Public Notice: Can They Coexist?," 89 *Journal of the Patent and Trademark Office Society* 545, 574-80 (July 2007).

Under current patent practice, several different types of continued applications exist. A "continuation" application discloses the same subject matter as the original application.[39] A "continuation-in-part" application, or CIP, adds some additional subject matter to the original application.[40] Finally, a "request for continued application," or RCE, allows applicants to request additional examination of an application without the need to file a continuation application.[41]

A simple example illustrates continuation practice. Suppose that an inventor files a patent application on January 1, 2000. After the USPTO examiner subsequently issues a "final rejection" of that application, the inventor files a continuation application on February 1, 2004. The continuation application includes the same disclosure as the 2000 application. By filing it, the inventor may continue to assert to the USPTO that a patent should issue on that invention. If the USPTO approves the continuation application, it will issue as a patent that expires on January 1, 2020 — twenty years from the date of filing of the original or "parent" application.

Section 120 of the Patent Act imposes several technical requirements that must be met with respect to continuation applications. First, the continuation application must be filed prior to the patenting, abandonment, or termination of proceedings of its predecessor application. Second, the predecessor and continuation application must have at least one inventor in common. Third, the continuation application must expressly identify the predecessor application.[42]

Finally, to be entitled to the benefit of the predecessor application, claims within the continuation application must be fully supported by the technical disclosure found within the predecessor application. Claims that reference "new matter" found in the continued application, but not in the predecessor application, are entitled only to the actual filing date of the continued application. As noted earlier, such an application is termed a "continuation-in-part," or CIP.[43]

It should be appreciated that an applicant may file a continuation application even though the "parent" application has resulted in an issued patent itself. Even in circumstances where the USPTO examiner has allowed all of the claims of a patent application to issue, the inventor may nonetheless file a continuation application. He may do so in order to obtain broader claims, to obtain claims that more closely track his competitor's products, or for any other reason.

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[39]*See* Transco Products Inc. v. Performance Contracting Inc., 38 F.3d 551, 555 (Fed. Cir. 1994).

[40]*Id.*

[41]35 U.S.C. § 132(b) (2006).

[42]35 U.S.C. § 120 (2006).

[43]*See also* Leesona Corp. v. Varta Batteries, Inc., 522 F. Supp. 1304, 1335 n.153 (D. Del. 1981) ("by definition continuation-in-part applications add matter not disclosed in earlier applications. But, in the face of intervening art, any "new matter" disclosed in a continuation-in-part application cannot be accorded a filing date earlier than the date of filing of the continuation-in-part application.").

Continued applications are widely used in modern patent practice. In 2006, about 29.4% of the applications filed at the USPTO were continued applications, as compared to approximately 18.9% in 1990 and approximately 11.4% in 1980.[44] Furthermore, the relevant provisions of the Patent Act place no numerical limits upon the number of continued applications that may be filed. Many existing U.S. patents have relied upon a chain of four, five, or even greater number of continuations, CIPs, and RCEs.[45]

The USPTO Continued Application Rules

As part of its rules announcement of August 21, 2007, the USPTO imposed some limitations upon the number of continued applications that could be filed absent a petition by the applicant. In particular, the USPTO rules stipulate that applicants may file only two continuations or CIPs, plus one RCE, with respect to an original application as a matter of right. In order to file additional continued applications, the applicant must submit a petition showing an amendment, argument, or evidence that could not have been previously submitted.

The USPTO issued the rules on August 21, 2007, and followed them with an additional "clarification" memorandum on October 10, 2007.[46] The rules were to apply to applications filed after November 1, 2007. In addition, the rules were to apply to applications that had been filed at the USPTO prior to November 1, 2007, provided that they had not yet been reviewed by the USPTO.

The USPTO rationalized its rule in part on the basis of administrative efficiency. As explained by the USPTO:

> The volume of continued examination filings . . . is having a crippling effect on the Office's ability to examine "new" (i.e., non-continuing) applications. . . . The cumulative effect of these continued examination filings is too often to divert patent examining resources from the examination of new applications disclosing new technology and innovations, to the examination of applications that are a repetition of prior applications that have already been examined and have either issued or become abandoned.[47]

The USPTO has also explained that the public interest lies in knowledge of the scope of patent claims. According to the USPTO, the filing of a sequence of continued

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[44]USPTO Rules, *supra*, at 46,718.

[45]*See, e.g.*, Hyatt v. Dudas, 492 F.3d 1365, 1367 (Fed. Cir. 2007) (observing that the five applications at issue in the litigation were "all continuation applications with lineages that can be traced back for decades.").

[46]USPTO, "Clarification of the Transitional Provisions Relating to Continuing Applications and Applications Containing Patentably Indistinct Claims" (October 10, 2007) (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/clmcontclarification.pdf]).

[47]USPTO Rules, *supra*, at 46,718. *See also* Bruce A. Kaser, "Patent Application Recycling: How Continuations Impact Patent Quality & What the USPTO Is Doing About It," 88 *Journal of the Patent and Trademark Office Society* (2006), 426.

applications leaves the public "with an uncertainty as to what the set of patents resulting from the initial application will cover."[48]

Academics have also criticized continued application practice. Mark Lemley and Kimberly Moore, then members of the Berkeley and George Mason law school faculties respectively,[49] stated that continued application practice has introduced a number of deleterious consequences into the patent law:

> First, at a minimum, continuation practice introduces substantial delay and uncertainty into the lives of a patentee's competitors, who cannot know whether a patent application is pending in most circumstances. Second, the structure of the PTO suggests that continuations may well succeed in "wearing down" the examiner, so that the applicant obtains a broad patent not because he deserves one, but because the examiner has neither incentive nor will to hold out any longer. Third, continuation practice can be — and has been — used strategically to gain advantages over competitors by waiting to see what product the competitor will make, and then drafting patent claims specifically designed to cover that product. Finally, some patentees have used continuation practice to delay the issuance of their patent precisely in order to surprise a mature industry, a process known as "submarine patenting."[50]

On the other hand, critics of the USPTO rules explain that continuation practice has a number of beneficial attributes. First, some observers believe that continued application practice allows inventors to pursue a cautious, deliberate strategy before the USPTO, allowing them to obtain robust patent rights. This tactic may be appropriate in view of recent judicial opinions that have emphasized the doctrine of "prosecution history estoppel."[51] Broadly stated, this principle allows courts to consider negotiations between the applicant and the examiner when determining the scope of rights associated with a particular patent. In view of these judicial developments, some patent practitioners believe that it is unwise to make certain concessions to the examiner during the course of prosecution. The ability to file a continued application supports this strategy by allowing additional opportunities for discourse between the applicant and examiner.[52]

Second, critics of the USPTO rules state that continued applications allow innovative firms to procure patent claims that relate to the products that they will ultimately market. For example, a pharmaceutical and biotechnology firm may file

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[48]USPTO Rules, *supra*, at 46,718.

[49]Professor Lemley has since joined the faculty of the Stanford Law School, while Professor Moore has been appointed as a Circuit Judge of the United States Court of Appeals for the Federal Circuit.

[50]Mark A. Lemley & Kimberly A. Moore, "Ending Abuse of Patent Continuations," 84 *Boston University Law Review* (2004), 65.

[51]*See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 532 U.S. 722 (2002).

[52]*See* Letter to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from Michael Kirk, Executive Director, American Intellectual Property Law Association (April 24, 2006), at 5 (available at [http://www.uspto.gov/web/offices /pac/dapp/opla/comments/fpp_continuation/aipla.pdf]).

a patent application incorporating claims directed towards a broad category of compounds. At the time of the initial filing, however, that firm may not have conducted the extensive testing and research that is often needed to identify the particular member of that category that will be brought to market. Under current law, once that particular compound has been identified, the firm may file a continuation application specifically claiming it.[53]

Should administrative rulemaking impose limitations upon continuing applications, some observers believe that pharmaceutical and biotechnology firms in particular may potentially be unable to obtain claims that both cover their marketed products and be able to withstand validity challenges on a reliable basis.[54] This tendency could potentially diminish the effectiveness of patent protection within industries where the patent system is widely acknowledged as crucial to innovation.[55]

Third, critics of the USPTO rules have asserted that some examiners at times do not understand the invention presented to them in particular applications. The use of continued applications is, in their view, necessary to obtain a competent examination.[56] In addition, some observers believe that certain examiners have encouraged the filing of continued applications in order to inflate statistics pertaining to their workplace productivity.[57]

Patent Claiming Practice Reform

Patent Claiming Practice

In addition to addressing continued applications, the USPTO Rules also announced changes to claiming practice. As noted previously, the Patent Act requires each patent to include "one or more claims particularly pointing out and

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[53]*See* Letter to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from David E. Korn, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (May 2, 2006), at 3 (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/phrma_con.pdf]).

[54]*Id.*

[55]*See* Claude E. Barfield & Mark A. Groombridge, "Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy," 10 *Fordham Intellectual Property, Media and Entertainment Law Journal* (1999), 185.

[56]*See* Letter to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from Marc S. Adler, President, Intellectual Property Owners (May 3, 2006), at 3 (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/ipo_con.pdf]).

[57]*See* Memorandum to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from Graciela Cowger, Director, Oregon Patent Law Association (May 3, 2006), at 3 (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/opla_con.pdf]).

distinctly claiming the subject matter which the applicant regards as his invention."[58] The claims set forth the proprietary rights that the patent owner asserts for itself. In particular, the words of a patent's claims are compared to the physical features of an accused product to determine whether infringement has occurred.[59] As well, the teachings of earlier publications, patents, and other relevant "prior art" is compared to a patent's claims in order to decide whether the patented invention has been anticipated or would have been obvious.[60]

Claims may be drafted in either "independent" or "dependent" format. A dependent claim references an earlier claim, but then provides additional limitations upon the scope of that claim. Claims 1 and 2 of U.S. Patent No. 4,161,079, which relate to traps for mice and other pests, provides an example of independent and dependent claims:

> 1. A trap for rodents or like pests comprising:
> an enclosure for the pest to enter;
> means for ensnaring the pest in the enclosure;
> a charge of separately covered bait material mounted to the enclosure;
> means for uncovering said covered bait material within the enclosure, said means for uncovering being operable externally of said enclosure;
> whereby covered bait material may be stored for a long period of time and yet easily released when desired.
>
> 2. The invention of claim 1 wherein:
> said enclosure includes a window through which a user may look to see if a mouse or like pest is entrapped therein.

The use of dependent claims is largely a drafting convenience for patent applicants. In the mouse trap example, rather than reciting each of the features of claim 1 once more, claim 2 merely references them but also incorporates an additional limitation.[61]

In practice, most patents contain multiple claims. Each claim is ordinarily viewed as presenting a separate statement of the patented invention. It is possible that the patent proprietor's competitor may infringe some of the patent's claims, but not others, depending upon the precise wording of the claim. Similarly, a court may declare that some of the patent's claims are invalid, but uphold other claims, in view of novelty, nonobviousness, or other legal requirements to obtain a patent.[62] For the most part, then, each claim in a patent affords the patent owner separate proprietary rights that must be judged on its individual merits.[63]

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[58]35 U.S.C. § 112 (2006).

[59]*See* Roger E. Schechter & John R. Thomas, *Intellectual Property: The Law of Copyrights, Patents, and Trademarks* § 20.2 (2003).

[60]*Id.* at § 16.4.

[61]Schechter & Thomas, *supra,* at § 18.2.2.1.

[62]*See* 35 U.S.C. § 282 (2006).

[63]Schechter & Thomas, *supra,* at § 18.2.

Determinations as to the precise number of claims that a particular patent contains falls largely within the discretion of the individual who drafted the patent. As Paul Janicke, a member of the University of Houston law faculty, has explained:

> No limit is placed on the number of claims that can be included in an application. Most good patent attorneys write many of them of varying scope, in case the broadest turn out to be invalid because they cover some unknown piece of prior art, and in case the narrowest fail to provide commercially effective scope because they are easily designed around. Each claim is judged for validity and infringement as though it were a sort of mini-patent unto itself. To win an infringement case, the patentee need only establish infringement of one claim that the defendant is unable to invalidate. Such a system encourages the most diverse possible claiming. It is a good system for protecting inventions.[64]

The USPTO fee schedule provides some financial incentives to limit the number of claims in a particular patent. The basic filing fee for patent applications is currently $310.[65] For each independent claim in excess of three, the USPTO imposes a surcharge of $210. In addition, for each claim in excess of 20, whether dependent or independent, the USPTO imposes a surcharge of $50.[66] As a result, incorporating large numbers of claims within a patent may lead to a substantial increase in the official fees associated with its acquisition.

Empirical studies have arrived at varying results on the average number of claims per patent, depending on the sampling technique employed and the time frame under consideration. Patent lawyer Peter L. Giunta reported an average of 3.09 independent claims and 18.15 total claims per patent issued in 2003.[67] John Allison and Mark Lemley, members of the faculties of the University of Texas and Stanford University respectively, sampled 1,000 patents issued between 1976 and 1978, and another 1,000 patents issued between 1996 and 1998. Allison and Lemley reported an average of 9.94 claims per patent for the 1970's patents, and 14.87 claims per patent for the 1990's patents.[68] Both the Giunta and Allison-Lemley studies agreed that the average number of claims per patent has increased over time.

It should be appreciated, however, that some patents incorporate considerably more claims than average. For example, in the well-known patent litigation

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[64]*See* Paul Janicke, "Heat of Passion: What Really Happened in *Graver Tank*," 24 *American Intellectual Property Law Association Quarterly Journal* (1996), 1.

[65]It should be appreciated that the USPTO will ordinarily charge additional fees during the course of the patent acquisition process beyond the assessment for filing the application. Among these are a $510 search fee, $210 examination fee and $1,440 issuance fee. *See* USPTO, FY2008 Fee Schedule (available at [http://www.uspto.gov/web/offices/ac/qs/ope/fee2007september30.htm]).

[66]*Id.*

[67]Peter L. Giunta, "Quid Pro Whoa!: An Exponential Fee Structure for Patent Applications," 25 *Cardozo Law Review* (2004), 2317.

[68]John Allison & Mark Lemley, "The Growing Complexity of the United States Patent System," 82 *Boston University Law Review* (2002), 77.

involving the BlackBerry® mobile communications device,[69] the patent proprietor asserted charges of infringement based upon five patents. The first of these patents to issue incorporated 89 claims; the remaining four included 276, 223, 341, and 665 claims respectively.[70] As a general matter, one empirical study has concluded that patents of greater value to their owners tend to have a larger number of claims than average.[71]

The USPTO Claim Rules

Following issuance of notice and a period of public commentary, the USPTO promulgated rules that would impose an obligation upon inventors who file patent applications that have more than five independent claims, or more than 25 total claims (dependent or independent).[72] That obligation consists of the duty to prepare and file an Examination Support Document, or ESD. The ESD contains information about the claimed inventions that may assist the USPTO in conducting its examination tasks. In order to prepare the ESD, the applicant must conduct a search of databases of patents and the scientific literature. The applicant must then provide a detailed explanation of why the submitted claims are patentable over the prior art discovered during the search, as well as provide additional information pertinent to the patentability determination.[73]

The USPTO is concerned that applicants might attempt to file multiple applications directed toward the same or similar inventions in order to avoid the obligation to submit an ESD. The USPTO rules therefore require applicants to disclose all applications that are commonly owned and have at least one inventor in common.[74] If the examiner determines that the applications have "substantially overlapping disclosures," the examiner may presume that the claims are not "patentably distinct" and will apply the 5/25 claim limitation to the total number of claims in the relevant applications. The USPTO further "cautioned" applicants from

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[69]NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1281 (Fed. Cir. 2005). *See* Gerard N. Magliocca, "Blackberries and Barnyards: Patent Trolls and the Perils of Innovation," 82 *Notre Dame Law Review* (2007), 1809.

[70]The five patents asserted in the *NTP v. RIM* litigation were U.S. Patent Nos. 5,436,960; 5,625,670; 5,819,172; 6,067,451; and 6,317,592.

[71]John R. Allison *et al.*, "Valuable Patents," 92 *Georgetown Law Journal* (2004), 435.

[72]USPTO Rules, *supra*, at 46,721.

[73]More specifically, an ESD must include (1) a statement explaining that a prior art search was done; (2) a listing of the search results most closely related to the subject matter of each claim; (3) identification of all the limitations of each claim that are disclosed by the prior art; (4) a detailed explanation particularly pointing out how each of the independent claims is patentable over the prior art; and (5) a showing where each limitation of each of the claims is supported by the patent's specification. *Id.* at 46,741 (discussing Rule 265).

[74]USPTO Rules, *supra*, at 46,721.

attempting to avoid this rule by filing separate applications outside the two-month window.[75]

On the other hand, the USPTO has recognized that applicants may permissibly file continued applications in order to obtain additional claims without the filing of an ESD. As the new continuation rules allow applicants to file two continuation applications and one RCE without special justification, applicants may potentially obtain 15 independent claims, and 75 total claims without the filing of an ESD.[76]

As with the rules with respect to continued applications, the claiming practice rules were to apply to applications filed after November 1, 2007. In addition, the rules were to apply to applications that had been filed at the USPTO prior to November 1, 2007, provided that they had not yet been reviewed by the USPTO.

The USPTO justified these restrictions upon claiming practice on a number of grounds. One rationale was that these reforms would lead to a "better focused and effective examination process" that would allow examiners to concentrate upon a smaller number of claims, or in the alternative be assisted by an ESD.[77] According to the USPTO, the result would be a reduction in "the large and growing backlog of unexamined applications," while "the quality of issued patents" would be maintained or possibly improved.[78]

The USPTO also expressed concerns that, absent rule changes, the public would face difficulty in analyzing numerous claims in issued patents that were directed towards "patentably indistinct inventions."[79] Patents are often complex, technical instruments that may prove difficult to parse.[80] It is not uncommon for jurists who frequently adjudicate disputes concerning patents to disagree on their appropriate construction.[81] The transaction costs and uncertainty surrounding determinations of patent scope may be further exaggerated if the patent includes a large number of claims. These circumstances may not favor the ability of others to innovate themselves, and also to compete in the marketplace.

Although the USPTO rules place no absolute restrictions upon the number of claims that may be incorporated within a particular application, they were subject to negative commentary by many patent professionals. In particular, some observers viewed the filing of an ESD as a costly, time-consuming, and potentially risky endeavor. Patent attorneys John Pegram and Ronald Lundquist opined that preparing

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[75]*Id.* at 46,722.

[76]*Id.* at 46,721.

[77]*Id.* at 46,717.

[78]*Id.*

[79]*Id.* at 46,718.

[80]*See* Allison & Lemley, *supra*.

[81]*See* Andrew B. Dzeguze, "Did *Markman* and *Phillips* Answer the Right Question? A Review of the Fractured State of Claim Construction Law and the Potential Use of Equity to Unify It," 15 *Texas Intellectual Property Law Journal* (2007), 457.

an ESD may require more technical and legal effort than drafting its associated patent application.[82] Submitting an ESD might therefore significantly increase the costs of procuring patent rights in the United States.

In addition, some observers believe that ESDs will commonly incorporate statements and disclosures that might potentially be viewed as admissions. An ESD might therefore limit the scope of protection and enforceability of any patent that resulted from its application.[83] Other observers believed that the claim rules would negatively impact patent rights without meaningfully serving the goals identified by the USPTO. As explained by patent attorneys John R. Harris and Daniel E. Sineway:

> For the USPTO to claim that an ESD will "improve examination quality" seems disingenuous — the improvement in quality will likely result *not* from any greater scrutiny or effort by the patent examiner, but from patent applicants providing the examiner with the ammunition to reject the application. The ESD will give examiners the information and reasoning needed to deny a patent, and/or force the applicant to fill the file history with information that helps infringers avoid liability in later litigation.[84]

As a result, patent attorney Kevin Noonan opined that "an applicant should avoid filing an ESD under any circumstances."[85]

If inventors widely subscribe to this view, then they will be practically limited in the number of claims that they can obtain from the USPTO. This effect may limit the extent of patent protection an inventor may effectively procure, particularly in view of a number of judicial opinions that have stressed that inventors possess the ability to draft claims using words of their own choosing.[86] Courts have further observed that a patent's claims are intended to provide notice to third parties of its owner's proprietary rights.[87] If the claims do not match the accused infringer's product or process literally, then courts may be reluctant to employ equitable principles such as the "doctrine of equivalents" to reach a finding of infringement.[88]

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[82]John B. Pegram & Ronald C. Lundquist, "USPTO Final Rule Changes for Continuations and Claims," (September 6, 2007) (available at [http://www.fr.com/news/2007/Sept/v3%209%206%2007%20Rules%20Webinar.pdf]).

[83]John R. Harris & Daniel E. Sineway, "New USPTO Rules Will Significantly Affect Patent Strategy: Several New Rules Create Sweeping Changes in Patent Office Procedure," (September 27, 2007) (available at [http://www.mmmlaw.com/downloads/clientalerts/NewUSPTORulesMaySignificantlyAffectProsecutionStrategy.pdf]).

[84]Harris & Sineway, *supra*, at 3.

[85]Kevin E. Noonan, "An Analysis of the New Rules: USPTO Releases ESD Guidelines," (September 17, 2007) (available at [http://www.patentdocs.us/patent_docs/2007/09/ an-analysis-o-8.html]).

[86]*See* Sage Products, Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1425 (Fed. Cir. 1997).

[87]*See* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 28-29 (1997).

[88]*See* Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1364 (Fed. Cir. 2007) ("A finding of infringement under the doctrine of equivalents requires a showing that the difference

(continued...)

As the Federal Circuit explained, "as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] forseeable alteration of its claimed [invention]."[89] Some observers believe that the combination of judicial stress upon precise claim drafting and administrative limitations upon claims will make the patent system less attractive, thereby decreasing investment in R&D, diminishing innovation, and encouraging use of trade secret law.[90]

The *Tafas v. Dudas* Litigation

Criticisms over the propriety of the claims and continued application rules led to litigation against the USPTO in federal court. The result was the October 31, 2007 decision of the U.S. District Court for the Eastern District of Virginia in *Tafas v. Dudas.*[91] That decision led to the issuance of a preliminary injunction against the USPTO. As a result of this ruling, the USPTO may not implement its claims and continued application rules until the court makes a final determination.

The *Tafas v. Dudas* ruling arose from lawsuits filed by two separate plaintiffs: (1) individual inventor Triantafyllos Tafas, and (2) the multinational pharmaceutical enterprise organized as Smithkline Beecham Corp. and Glaxo Group Limited (collectively known as "GSK"). The plaintiffs requested a preliminary injunction that would prevent the USPTO from implementing the claims and continued application rules. The District Court consolidated the two cases, although its analysis emphasized the arguments offered by GSK.

In analyzing GSK's assertions, Judge Cacheris considered four factors: (1) the likelihood of GSK's success on the merits, (2) irreparable harm if the injunction is not granted, (3) the balance of hardships between the parties, and (4) the public interest.[92] The District Court determined that each of these four factors favored GSK.

Likelihood of Success on the Merits. The District Court reasoned that there was a "genuine possibility" that the USPTO would lose a full trial on the merits.[93] Judge Cacheris observed that the Patent Act provided the USPTO with authority to engage

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[88](...continued)
between the claimed invention and the accused product was insubstantial.").

[89]Sage Products, *supra*, at 1425.

[90]*See* Letter to the Honorable Jon Dudas, Under Secretary of Commerce and Director of the USPTO, from E. Anthony Figg, Chair, American Bar Association Section of Intellectual Property Law (May 3, 2006) (available at [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/aba-ipl.pdf]).

[91]*See* Tafas v. Dudas, Case No. 1:07cv846 (E.D. Va. 2007); Smithkline Beecham Corp. v. Dudas, Case No. 1:07cv1008 (E.D. Va. 2007).

[92]Tafas v. Dudas, slip op. at 8-9.

[93]*Id.* at 21.

in rulemaking with respect to the "conduct of proceedings before the Office,"[94] but not with respect to substantive matters. Judge Cacheris believed that GSK had raised at least a "colorable question" whether the claims and continuation rules were substantive in nature, and therefore beyond the reach of USPTO authority.[95]

Judge Cacheris further observed that the statutory provisions governing continued applications place no express limitations upon the number of such applications that could be filed.[96] The district court also concluded that the case law of the Federal Circuit "suggests that a decision by the [USPTO] to limit the number of continuing applications would run contrary to the mandate of Section 120."[97] In view of the potential conflict between the statutory language and the USPTO rules, the District Court believed that GSK had raised "serious concerns" over the legality of the claim and continuation rules.[98]

Judge Cacheris next addressed GSK's assertion that the claims and continued application rules were retroactive in effect. Under governing law, an agency's rulemaking cannot be retroactive unless expressly authorized by Congress.[99] Because Congress has not so authorized the USPTO, and because the rules applied to patent applications that had been filed prior to their effective date, Judge Cacheris concluded that GSK had "demonstrated a real likelihood of success" with respect to impermissible retroactivity.[100]

Irreparable Harm. Observing that GSK had filed numerous applications that would be affected by the USPTO rules,[101] Judge Cacheris concluded that the claims and continued application rules would immediately harm GSK's investments and create a disincentive to innovate and file patent applications. He further concluded that "GSK will be unable to recover their losses if the Final Rules are ultimately determined to be invalid."[102] The District Court therefore concluded that GSK would be likely to suffer irreparable harm if the preliminary injunction was not granted.

Balance of Hardships Between the Parties. Judge Cacheris reasoned that GSK would suffer immediate damage to its investments if the claims and continued application rules were implemented. On the other hand, the USPTO would

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[94]35 U.S.C. § 2(b)(2) (2006).

[95]Tafas v. Dudas, slip op. at 21.

[96]The two statutory provisions are section 120 of the Patent Act, which governs continuations and CIPS (continuations-in-part), and section 132(b), relating to RCEs (requests for continued examination).

[97]Tafas v. Dudas, slip op. at 23.

[98]*Id.* at 21.

[99]*Id.* at 27 (citing Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988)).

[100]*Id.* at 29.

[101]*Id.* at 6.

[102]*Id.* at 35.

experience only the costs of maintaining its older claims and continued application rules.[103]

The Public Interest. Judge Cacheris reasoned that the public interest favored the maintenance of a stable, reliable patent system. In this respect, he explained that "[a]llowing the implementation of rules that may or may not remain in effect is likely to cause much greater uncertainty and squelching of innovation than a preliminary injunction giving the Court time to consider the validity of the Final Rules before they go into affect."[104]

Because all four factors favored GSK, the District Court issued a preliminary injunction blocking the USPTO from implementing its claims and continued application rules. Although the ruling in *Tafas v. Dudas* is temporary in nature, its immediate impact is that the USPTO may not implement its rules until the court makes a final determination. These proceedings are underway at the time of the publication of this report.

Reactions to the ruling in *Tafas v. Dudas* have varied. Patent attorney Kevin Noonan described the opinion as "thorough and well-reasoned."[105] In contrast, Arti Rai, a member of the faculty of the Duke University School of Law, concluded that "[t]he court's reasoning about the alleged conflict between the statute and the rules contains several errors of administrative law."[106] In general, Rai believes that the District Court failed to defer sufficiently to the USPTO's interpretation of the Patent Act as required by the judicial opinions of the Supreme Court. As these proceedings continue, parties with diverse views about the legality of the claims and continued application rules will have the opportunity to present them before the court.

IDS Practice Reform

Although patent professionals have focused attention upon the claims and continued application rules, the USPTO has proposed additional reforms as well. One of these reforms relates to the so-called Information Disclosure Statement, or IDS.[107] An IDS is a document submitted to the USPTO that discloses all journal articles, patents, and other "prior art" of which a patent applicant is aware.[108] The USPTO has expressed concerns that applicants too frequently include numerous

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[103]*Id.* at 35-37.

[104]*Id.* at 38.

[105]Kevin E. Noonan, "Tafas v. Dudas; SmithKline Beecham Corp. v. Dudas (E.D. Va. 2007)" (available at [http://www.patentdocs.net/patent_docs/2007/10/tafas-v-dudas-1.html])

[106]Arti K. Rai, "The GSK Case: An Administrative Perspective," *Patently-O Blog Law Journal* (2007) (available at [http://www.patentlyo.com/lawjournal/files/RAIGSK.pdf]).

[107]Department of Commerce, USPTO, "Changes to Information Disclosure Statement Requirements and Other Related Matters," 71 *Federal Register* 38,808 (July 10, 2006) (hereinafter "IDS Notice").

[108]*See Black's Law Dictionary* 795 (Thomson-West, 8th ed. 2004).

"irrelevant or marginally relevant" prior art reference that not only fail to bring the most relevant material to the attention of examiners, but also require them to sort through dozens or hundreds of documents that are not pertinent to the question of patentability.[109]

As a result, the USPTO has proposed rules that would impose additional applicant responsibilities with respect to IDS filings. In particular, the USPTO proposes that if more than 20 documents are disclosed in an IDS, the applicant must provide an explanation of each cited document. That explanation consists of "an identification of a portion of a document that caused it to be cited, and an explanation of how the specific feature, showing, or teaching of the document correlates with language in one or more claims."[110] If an IDS contains fewer than 20 documents, the applicant would be required to provide an explanation only for documents not published in English, or for English-language documents over 25 pages in length.[111]

Critics of the proposed IDS rules assert that "their practical effect will be to dramatically increase the cost of obtaining patent protection" and "make it much more difficult for inventors and innovators to protect their legitimate intellectual property rights . . .."[112] At present time, the USPTO has not taken final action with respect to the proposed IDS rules.

Congressional Issues and Alternatives

Should Congress conclude that the current situation with respect to the USPTO rulemaking is satisfactory, then no action need be taken. If Congress wishes to intervene, however, a number of options present themselves. In the 110th Congress, H.R. 1908 would expressly provide the USPTO with regulatory authority to specify the circumstances under which a patent applicant may file a continued application.[113] That bill passed the House on September 7, 2007, as the "Patent Reform Act of 2007," and was referred to the Senate. No other pending legislation — including S. 1145, the Senate legislation also titled the "Patent Reform Act of 2007" — addresses the subject matter of the claims or continuation rules.

One possibility would be to provide the USPTO with substantive rulemaking authority. In the 110th Congress, an earlier verison of H.R. 1908 would have granted the USPTO Director the authority to "promulgate such rules, regulations, and orders that the Director determines appropriate to carry out the provisions of this title or any

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[109]IDS Notice, 71 *Fed. Reg.* at 38,809.

[110]*Id.* at 38,810.

[111]*Id.*

[112]*See* Letter to the Honorable Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs, Office of Management of Budget, from David E. Boundy, Cantor Fitzgerald L.P. (October 17, 2007), at 2 (available at [http://www.whitehouse.gov/omb/oira/0651/comments/477.pdf]).

[113]H.R. 1908, § 14.

other law applicable to the United States Patent and Trademark Office."[114] This provision was ultimately removed from the bill in favor of a more narrow grant of authority with respect to continued applications.

More specific legislative amendments provide another option. Amendments to the relevant provisions of the Patent Act could confirm that no limitations should be imposed upon the number of claims or continuations that applicants may file. They could also address IDS filing requirements or other aspects of USPTO procedures. Alternatively, amended statutory provisions could impose such limitations, or grant the USPTO the authority to do so.

Patent administration has becoming increasingly difficult as the USPTO faces both a rising number of filings and more technologically complex applications. On the other hand, many patent professionals have viewed both judicial and legislative developments as emphasizing well-crafted applications.[115] Limitations upon claims and continued application practice have been widely viewed as constraining the ability of patent professionals to achieve this goal.[116] Establishing the appropriate balance of rights and responsibilities between applicants and the USPTO forms an important consideration in maintaining a fair and efficient patent system.

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[114]H.R. 1908, § 11 (as originally introduced).

[115]*See, e.g.*, Paul Gillette, "'Maximum Security': Continuation and Reissue as Means of Obtaining Optimum Patent Protection After *Festo*," 27 *Thomas Jefferson Law Review* (2005), 371.

[116]*See, e.g.*, Mary Ann Liebert, "The Comments of the Biotechnology Industry Organization on the United States Patent & Trademark Office Proposed Rules Changes Concerning Continuation Practice and Claim Limitations," 25 *Biotechnology Law Report* (2006), 473.