NOW YOU SEE THEM, NOW YOU DON'T: THE PTO'S RULES ON CLAIMS AND CONTINUATIONS

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I. INTRODUCTION

The number of applications for patents filed at the United States Patent and Trademark Office (PTO) has grown rapidly, rising from 206,276 in 1996 to 443,652 in 2006.[1] Consequently, the backlog of unexamined applications at the PTO grew from 303,720 pending applications in 1996 to 1,003,884 in 2006.[2] The PTO faces a difficult problem: how to manage the increasing backlog of applications while maintaining or improving patent quality.

As part of its efforts in formulating a solution, the PTO published controversial new rules ("the Final Rules") in August 2007 that may significantly change the practice of patent prosecution.[3] The PTO planned to make the rules effective on November 1, 2007,[4] but on the eve of their implementation, the U.S. District Court for the Eastern District of Virginia granted a preliminary injunction preventing the PTO from implementing the changes.[5] The court recently upheld its preliminary decision by granting summary judgment against the PTO.[6] Nevertheless, if the PTO succeeds on appeal or receives explicit authority from Congress, the PTO may ultimately put the rules into practice.

The PTO initially published a set of proposed rules ("the Proposed Rules") in January 2006.[7] After a period of public commentary, the PTO

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1. U.S. PATENT & TRADEMARK OFFICE, PATENT APPLICATIONS FILED (2006), *available at* http://www.uspto.gov/web/offices/com/annual/2006/50302_table2.html.

2. U.S. PATENT & TRADEMARK OFFICE, PATENT APPLICATIONS PENDING PRIOR TO ALLOWANCE (2006), *available at* http://www.uspto.gov/web/offices/com/annual/2006/50303_table3.html.

3. *See* Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716, 46716-46843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) [hereinafter Final Rules].

4. Final Rules, *supra* note 3, at 46716.

5. Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007).

6. Tafas v. Dudas, 2008 U.S. Dist. LEXIS 26086 (E.D. Va. Apr. 1, 2008).

7. Final Rules, *supra* note 3, at 46717.

revised the Proposed Rules to generate the Final Rules.[8] In most aspects, the Final Rules are less drastic than the Proposed Rules.[9]

The Final Rules alter the procedures for prosecuting patent applications in three major ways. First, the rules limit continuation and continuation-in-part applications, as well as requests for continued examination.[10] Second, the rules limit the number of claims in an application.[11] Third, the rules require patent applicants to identify related applications.[12]

The rules, if implemented, will give applicants fewer chances to claim the subject matter within their applications. Consequently, the rules may decrease incentives for innovation, particularly in industries that rely on continuation applications, such as the biotechnology industry. Nevertheless, if the rules are successful in managing the backlog and decreasing the pendency of applications in the PTO, they may increase incentives for innovation in industries that rapidly send inventions to market, such as the software industry.

Part II of this Note briefly describes the current practice of patent prosecution and the rules and practices that the Final Rules may change. Part III discusses the PTO's motivation behind the rules and the major provisions of the Final Rules. Part IV discusses the industry and patent bar responses to the rules, the PTO's authority to promulgate rules, the ongoing litigation regarding the rules, and the future of the rules. Part V argues that the rules are not likely to help the PTO decrease its backlog of unexamined applications.

II. PRACTICE PRIOR TO THE FINAL RULES

Inventors obtain patents for their inventions through a process called patent prosecution.[13] A patent applicant, usually acting through a patent attorney, prepares an application that describes an invention and files it with the PTO.[14] The application includes a specification that describes the invention and one or more "claims" that precisely identify the scope of

8. *Id.* at 46718.

9. For example, the Proposed Rules would have limited applicants to one continuation per application without justification, whereas the Final Rules limit applicants to two continuations per application without justification. *Id.* at 46719.

10. *Id.* at 46716.

11. *Id.*

12. *Id.*

13. *See* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 159-63 (4th ed. 2006).

14. *Id.* at 160.

legal protection that the applicant seeks.[15] A patent examiner at the PTO examines the application to determine whether it meets the statutory requirements of the Patent Act.[16] If the application is deficient, the examiner issues an "office action" setting forth the grounds of rejection.[17] The applicant may then respond and argue against the rejection.[18]

In practice, this process of office action and response often involves successive rounds of negotiations between the applicant and the patent examiner.[19] Typically, the negotiations discuss "prior art,"[20] which describes other patents or publications, filed or published before the filing date of the application (the "priority date") that may render the invention unpatentable. Eventually, the examiner issues either a patent or a final rejection.[21] An applicant who receives a final rejection may appeal the decision to the Board of Patent Appeals and Interferences (BPAI).[22] The applicant may also continue to debate the examiner by filing one of several special types of applications, described in Section II.A, that claim the priority date of the initial application.[23]

The remainder of this Part describes the major patent prosecution rules subject to amendment by the Final Rules: applications that enjoy the priority date of a prior application; the claims of a patent application; and the doctrine of double patenting. Part III will describe how the Final Rules will affect this framework.

A. Applications that Claim the Priority Date of a Prior Application

The first element of the prosecution process affected by the rules changes includes procedural tools that applicants use to: 1) convince the PTO that a patent is warranted and 2) reach an agreement with the PTO to define the scope of that patent. Continuation applications, continuation-in-part (CIP) applications, and divisional applications are all based on earlier applications submitted to the PTO and benefit from the earlier priority dates of those applications. A request for continued examination (RCE) is a request from an applicant to continue prosecution of an application after an examiner issues a final rejection; filing an RCE operates similarly to

15. *Id.*
16. *See id.*
17. *Id.*
18. *Id.*
19. *See id.* at 160-61.
20. *Id.* at 160.
21. *See id.* at 160-61.
22. *Id.* at 161.
23. *Id.*

filing a continuation application.[24] Earlier priority dates are valuable to applicants because they establish what prior art may be used against their applications.

1. Continuation Applications

A continuation application is a second application for the same invention disclosed in an earlier application, usually with different claims.[25] The new claims must be directed to subject matter described in the earlier application.[26] An applicant can file a continuation application at any time before the PTO issues a patent on, or the applicant abandons, the earlier application.[27] An applicant can also file a continuation application based on an earlier continuation application; multiple continuations filed in this manner create a chain of continuation applications that all trace priority to the first filed application. Congress authorized continuation applications in 35 U.S.C. § 120.[28]

Pharmaceutical and biotechnology companies have long used continuation applications to update claims in an initial patent application when research and development that occurs after filing results in new information about the claimed invention.[29] These companies initially file broad application disclosures and then file continuation applications with narrower claims to cover specific uses discovered during research and clinical trials.[30] Companies often know that a new chemical type is important, but do not know which particular instances of a class are most useful as pharmaceuticals. Similarly, independent inventors and small companies use continuations when they need to test the market with new products; they can file broad initial disclosures and, after market studies, pursue narrow claims in continuation applications.[31]

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24. *See id.* at 161 n.34.

25. U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURES § 201.07 (8th ed. rev. 5, 2006) [hereinafter MPEP], *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm.

26. *Id.*

27. *Id.*

28. 35 U.S.C. § 120 (2000).

29. *See, e.g.*, Letter from Danielle Pasqualone, Patent Counsel for Genentech, Inc., to Robert W. Bahr, U.S. PTO (May 1, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/genentech.pdf.

30. Laxman Sahasrabuddhe, Note, *Is the PTO Authorized to Promulgate the Proposed Rule Change to the Continuation Practice?*, 22 BERKELEY TECH. L.J. 193, 201 (2007).

31. *Id.*

Currently, an applicant can file as many continuation applications as desired.[32] Applicants file continuation applications to obtain claims varying in scope, and often desire broad claims to cover as many variations as possible, but narrow enough to improve the odds of surviving a validity challenge during litigation. For example, when the PTO allows narrow claims in an application but rejects broader claims, the applicant can allow the original application to issue as a patent with the narrow claims (and enforce that patent against competitors) and file a continuation application to pursue the broader claims.[33]

2. Continuation-In-Part Applications

A CIP application also enjoys the priority date of an earlier application but adds "new matter" that was not disclosed in the earlier application.[34] The new matter is often a description of an improvement or variation of the original invention, such as an updated component that improves operation of a device described in an earlier application. Claims directed to the new matter are not entitled to the priority date of the earlier application.[35]

3. Divisional Applications

A divisional application, like a continuation application, enjoys the priority date of an earlier application, but only contains claims directed to an independent or distinct invention "carved out" of the earlier application.[36] Applicants often file divisional applications when an examiner issues a restriction requirement,[37] a requirement that an application containing two or more independent and distinct inventions be restricted to one of the inventions.[38] Divisional applications are common in the pharmaceutical and biotechnology fields, where applicants often file applications with a large number of related chemical compounds and examiners issue restriction requirements that force applicants to subdivide their large applications.

32. Tafas v. Dudas, 511 F. Supp. 2d 652, 657 (E.D. Va. 2007).
33. MERGES, *supra* note 13, at 161.
34. MPEP, *supra* note 25, § 201.08.
35. MERGES, *supra* note 13, at 161.
36. MPEP, *supra* note 25, § 201.06.
37. *Id.*
38. 35 U.S.C. § 121 (2000).

4. Requests for Continued Examination

An applicant files an RCE to continue negotiating with an examiner after the examiner has issued a final rejection.[39] After the applicant files the RCE, the examiner withdraws the finality of the rejection, and the applicant presents new claims or arguments to the examiner.[40] Currently, an applicant can file as many RCEs as desired, and need only pay the additional application fees for each RCE.[41] Applicants may file several RCEs where they are trying to develop complex arguments or persuade a recalcitrant examiner.

B. The Claims of a Patent Application

The second element of the prosecution process affected by the rules changes relates to the number of claims permitted in an application. The claims of a patent are a numbered series of sentences that describe precisely what the applicant regards as the invention and establish the "metes and bounds" of the property right established by the patent.[42] Currently, the number claims that an applicant may put into a patent application is unlimited;[43] an applicant need only pay additional fees for additional claims.[44] Claims come in two forms: independent claims, which do not reference any other claims, and dependent claims, which narrow and elaborate on other claims.[45]

Applicants accomplish a variety of goals by describing their inventions with multiple claims. In general, applicants want claims that are as broad (i.e., covering many variations of the invention) as the PTO will allow.[46] Nevertheless, applicants also want narrow claims to fall back on in case the broad claims granted by the PTO are later invalidated in litigation.[47] The examiner is more likely to allow narrower claims than broader ones.[48]

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39. 37 C.F.R. § 1.114 (2006).
40. *Id.*
41. *Id.*
42. *See* 35 U.S.C. § 112 (2000); *see also* ROBERT P. MERGES & JOHN P. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 26 (4th ed. 2007).
43. *See* Final Rules, *supra* note 3, at 46720-21.
44. *See* 37 C.F.R. § 1.16(h),(i).
45. 35 U.S.C. § 112 (2000).
46. MERGES & DUFFY, *supra* note 42, at 27.
47. *Id.* at 31.
48. *Id.*

C. Double Patenting

The third element of the prosecution process likely to be affected by the Final Rules relates to double patenting. Double patenting occurs when an applicant files a later application that claims almost the same subject matter as an earlier application or patent owned by the applicant.[49] In that case, if the PTO granted both the earlier and later patents, the patentee would effectively secure exclusive rights to the claimed subject matter for an extended term.[50] The doctrine of double patenting prevents this extension of the patent term by invalidating the claims of the later patent.[51]

The PTO issues two types of double patenting rejections. The first is statutory double patenting, or "same invention," based on 35 U.S.C. § 101, which states in the singular that an inventor "may obtain a patent."[52] The PTO issues a statutory double patenting rejection when an applicant claims exactly the same subject matter in both an earlier application and a later application.[53] The second type of double patenting rejection is a nonstatutory double patenting, which is based on a judicially created doctrine.[54] Typically, the PTO issues a nonstatutory double patenting rejection when a claim in a later application is obvious when considered against an earlier application by the same applicant.[55]

An applicant may overcome a nonstatutory double patenting rejection by filing a "terminal disclaimer."[56] The terminal disclaimer shortens the term of the later patent, thus preventing extension of the term of the earlier patent.[57] An applicant may not overcome a statutory double patenting rejection by filing a terminal disclaimer.[58] Currently, though, the applicant must only respond *after* an examiner has issued a rejection and need not submit any information *before* a rejection to demonstrate the absence of double patenting.

III. CHANGES TO PRACTICE UNDER THE FINAL RULES

The Final Rules, if implemented, will effect sweeping changes in the practice of patent prosecution. Under the Final Rules, applicants are per-

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49. *See* MPEP, *supra* note 25, § 804.
50. See *id.*
51. See *id.*
52. *Id.*
53. *Id.* § 804(II)(A).
54. *Id.* § 804.
55. *Id.* § 804(II)(B).
56. *Id.* § 804.02(II).
57. *See id.* § 804.02(V).
58. *Id.* § 804.02(I).

mitted for each application to file only two continuation applications and one RCE without justification. Each application is limited to five independent claims and twenty-five total claims unless the applicant conducts a prior art search and submits a report to that effect. Finally, applicants are required to report related applications to help the PTO identify double patenting issues.

The Final Rules also add new terminology to patent prosecution. A "continuing application" is any application that claims priority to an earlier U.S. non-provisional application or Patent Cooperation Treaty (PCT) national phase application.[59] Therefore, continuing applications include continuation applications, CIP applications, and divisional applications. An "application family" is an application and its permitted continuation and CIP applications.[60] A "divisional application family" is a divisional application and its permitted continuation and CIP applications.[61]

This Part first discusses the PTO's motivation for the Final Rules. Second, it discusses restrictions on continuing applications and RCEs. Third, it discusses claim limits and examination support documents. Fourth, it discusses related applications and when the PTO can presume that applications contain patentably indistinct claims.

A. The PTO's Motivation for the Final Rules

The PTO asserts that the Final Rules are a response to "the need for a better focused and effective examination process to reduce the large and growing backlog of unexamined applications while maintaining or improving the quality of issued patents."[62] The PTO has repeatedly stated that it cannot reduce the backlog merely by hiring more examiners.[63] According to PTO projections, the backlog could reach 1.4 million unexamined applications by 2012,[64] and the average total pendency for applications within the PTO could reach 38.6 months.[65]

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59. Final Rules, *supra* note 3, at 46729.

60. U.S. PATENT & TRADEMARK OFFICE, QUESTIONS AND ANSWERS, CLAIMS AND CONTINUATIONS FINAL RULE A5 (2007), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrfaq.pdf [hereinafter FAQ].

61. *Id.*

62. Final Rules, *supra* note 3, at 46717.

63. *See, e.g.*, *id.* at 46817, Response to Comment 278.

64. U.S. PATENT & TRADEMARK OFFICE, USPTO STRATEGIC PLAN 2007-2012 11 (2007), *available at* http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf.

65. Final Rules, *supra* note 3, at 46817, Response to Comment 278.

The PTO also believes that unrestricted continuation applications and RCEs allow applicants to abuse the system.[66] To justify the Final Rules, the PTO relied on a 2004 article by Mark A. Lemley and Kimberly A. Moore titled "Ending Abuse of Patent Continuations."[67] Lemley and Moore argued that continuation practice has a number of harmful consequences for the patent system, most notably, delay and uncertainty.[68] Nevertheless, they acknowledge that a combination of legislation and court decisions have solved the worst abuse of continuation applications, known as "submarine patenting" and "evergreening."[69]

Submarine patenting involved filing chains of continuation applications solely to delay issuance of a patent, with the hope of eventually using those patents to extract huge royalties from a mature industry that evolved around the disclosed technology.[70] Congress changed two rules in the 1990s that largely ended submarine patenting: first, Congress changed the patent term from seventeen years from the date of issuance to twenty years from filing date; and second, Congress required publication of most patent applications eighteen months after filing.[71]

Evergreening is a now defunct tactic that related entirely to pharmaceutical companies that exploited a loophole involving the FDA's "Orange Book."[72] Specifically, an applicant could file multiple continuations covering obvious variants of the same drug and then list those patents with the FDA in the Orange Book.[73] Once those patents were listed, the patent owner could obtain, for each patent, a thirty-month stay preventing a generic drug company from entering the market while litigation was pending, thus gaming the Hatch-Waxman rules for pharmaceutical patents.[74] Congress closed this loophole in 2003 by requiring that patentees obtain no more than one thirty-month stay per product regardless of how many patents are listed in the Orange Book.[75]

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66. *Id.* at 46718-19.

67. *Id.* (citing Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 64 (2004)).

68. Lemley & Moore, *supra* note 67, at 71.

69. *Id.* at 79-94.

70. *Id.* at 79.

71. *Id.* at 80.

72. *Id.* at 81-83. Under the Hatch-Waxman Act, a pharmaceutical patent owner can list patents in the Orange Book, and then sue any generic company who intends to manufacture a listed drug and obtain an automatic thirty-month stay preventing the generic from entering the market. *Id.* at 82.

73. *Id.*

74. *Id.* at 82-83.

75. *Id.* at 83.

Although Congress has curbed the practices of submarine patenting and evergreening, the PTO asserts that the Final Rules are necessary to defeat other improper uses of continuations.[76] Specifically, the PTO is concerned that applicants are not distinctly claiming their inventions in their original applications, thus making those applications more difficult to examine.[77] Furthermore, the PTO believes that applicants are defeating the public notice function of patents by keeping application families open (i.e., subject to broadening claims in continuation applications) for long periods of time.[78]

In addition to the PTO's belief that applicants are abusively filing continuation applications, the PTO avers that applicants file too many claims per application.[79] The PTO asserts that this hampers effective examination because "[a]pplications which contain a large number of claims . . . continue to absorb an inordinate amount of patent examining resources, as they are extremely difficult to properly process and examine."[80]

B. Restrictions on Continuing Applications and RCEs

The Final Rules provide that an applicant may file only two continuation or CIP applications claiming the benefit of an initial application without justification.[81] Furthermore, an applicant can only file one RCE in an application family without justification; the applicant may use the RCE to extend examination of either the initial application or a permitted continuation or CIP application.[82] Applicants can submit an additional continuation application or RCE by filing a petition "showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted."[83] Amendments, arguments, and evidence could have been "previously submitted" during the prosecution of the initial application, two continuation or CIP applications, and one RCE in an application family.[84]

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76. Final Rules, *supra* note 3, at 46719.

77. *Id.* at 46760, Comment 46.

78. *See, e.g., id.* at 46757, Comment 40.

79. *Id.* at 46720-21. If an application contains claims directed to independent and distinct inventions, the PTO can issue a restriction requirement and force the applicant to divide the application. *See supra* Section II.A.3.

80. Final Rules, *supra* note 3, at 46721.

81. FAQ, *supra* note 60, at B1.

82. *Id.*

83. Final Rules, *supra* note 3, at 46716.

84. *See* FAQ, *supra* note 60, at E6 ("If an amendment, argument or evidence could be submitted during the prosecution of the initial application, two continuation or CIP

1. Petitions for Additional Continuation Applications and RCEs

Applicants will find it difficult to make the proper showing to justify submission of additional continuation applications and RCEs. Under no circumstances will the PTO grant a petition automatically; each petition will be considered on a case-by-case basis.[85] The PTO asserts that, when deciding whether to grant a petition for additional continuations or RCEs, it *may* consider:

> Whether the applicant should file an appeal or a petition under 37 CFR 1.181 (e.g., to withdraw the finality of an Office action) rather than a continuing application or RCE;
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> The number of applications filed in parallel or serially with substantially identical disclosures; and
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> Whether the evidence, amendments, or arguments are being submitted with reasonable diligence.[86]

Applicants are "reasonably diligent" under the third factor when they submit applications that are initially in proper form for examination (e.g., free of typographical errors and the like) and they make earnest efforts to overcome outstanding rejections.[87]

The PTO has identified several situations where it will not grant a petition for an additional continuation or RCE. Showing that the examiner made new arguments or a new ground of rejection in a final office action will not be sufficient justification, unless the applicant also shows that it could not have anticipated the new ground of rejection.[88] Similarly, showing that an applicant added new subject matter in a CIP application will not be sufficient justification.[89] The PTO will not grant a petition for an additional application where the applicant has changed patent lawyers, even where the previous patent lawyer made clear errors.[90] Furthermore, an applicant cannot circumvent these requirements by submitting a new set of claims instead of an amendment: the PTO considers a new claim in

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applications, and an RCE in an application family, applicant must present such an amendment, argument or evidence earlier rather than wait to submit it later in an additional continuing application or RCE.").

85. *Id.* at E4.
86. *Id.* at E6.
87. *Id.*
88. *Id.* at E7.
89. *Id.* at E8.
90. Final Rules, *supra* note 3, at 46776.

a continuation application to be "an amendment to the claims of the prior-filed application."[91]

Perhaps most notably, the PTO has indicated that it will likely deny a petition for an additional RCE to submit an Information Disclosure Statement (IDS), which describes relevant prior art that the applicant is aware of, or an amendment necessitated by newly discovered prior art.[92] Consequently, an applicant who discovers new prior art after receiving a notice of allowance will not be able to file an RCE with an IDS. However, the PTO has proposed new IDS rules[93] that would alleviate the harshness of this rule by allowing applicants to submit an IDS without a continuation or RCE in some cases.[94] Furthermore, applicants who receive prior art from a foreign patent office search will be permitted to file an IDS after the close of prosecution in some cases.[95]

The PTO has also identified a few situations where it will likely grant a petition. For example, the PTO has stated it will likely grant a petition if:

> in a continuing application or request for continued examination, the data necessary to support a showing of unexpected results just became available to overcome a new rejection under 35 U.S.C. 103 made in the final Office action, and the data is the result of a lengthy experimentation that was diligently commenced and could not have been completed earlier.[96]

The PTO will also likely grant a petition in the unusual situation where "an interference is declared in a second continuation or continuation-in-part application that contains both claims corresponding to the count and claims not corresponding to the count, and the BPAI suggests that the claims not corresponding to the count be . . . pursued in a separate application."[97]

2. Divisional Application Practice

An applicant may file two continuations and one RCE based on a divisional application without justification and without exhausting the permitted continuations and RCE of the initial application. Thus, a divisional application is permitted its own family of continuations and RCEs, distinct

91. FAQ, *supra* note 60, at E2.
92. Final Rules, *supra* note 3, at 46773, Response to Comment 85.
93. *Id.* at 46764, Response to Comment 58.
94. *Id.*; *see also id.* at 46773, Response to Comment 85.
95. *Id.* at 46773, Response to Comment 85.
96. *Id.*
97. *Id*. at 46776.

from the continuations and RCEs permitted for the initial application.[98] An applicant may file a divisional application only if the PTO issues a restriction requirement.[99] Nevertheless, an applicant may file a Suggested Requirement for Restriction (SRR) if two or more independent and distinct inventions are claimed in an application; the SRR proposes the applicant's desired restriction requirement to the PTO.[100] The applicant must file the SRR before the PTO issues a first office action on the merits or its own restriction requirement.[101]

The Proposed Rules would have limited applicants to filing divisional applications in parallel, but the Final Rules permit applicants to file divisional applications in serial.[102] In other words, the Proposed Rules would have allowed applicants to file divisional applications based on an initial application only while that initial application was still pending, which would have required applicants to file all divisional applications before the initial application issued. The Final Rules allow applicants to file divisional applications that are based on other divisional applications (i.e., divisional applications filed after the initial application). Thus, only one application in the family needs to be pending to permit an applicant to file additional divisional applications. Applicants filing divisional applications in this manner (i.e., serially) create a chain of applications similar to the way that applicants created chains of continuation applications prior to the Final Rules.

C. Claim Limits and Examination Support Documents

The Final Rules require applicants whose applications contain more than five independent claims or more than twenty-five total claims to submit an examination support document (ESD), which is essentially a detailed prior art search report.[103] The five/twenty-five limit includes all of the claims in any other co-pending application having a patentably indistinct claim, including those co-pending applications that the PTO pre-

98. FAQ, *supra* note 60, at C2.
99. *Id.* at C1.
100. *See id.* at H1.
101. *Id.* at H1-H2.
102. Final Rules, *supra* note 3, at 46718.
103. *Id.* at 46721. The PTO believes that ESDs will encourage faster examination. *See id.* at 46718 ("The examination support document will assist the Office in the examination process and the determination of patentability of the invention by providing the most relevant prior art and other useful information.").

sumes contain at least one patentably indistinct claim.[104] An ESD must include:

> (1) A statement that a preexamination search . . . was conducted . . . (2) A listing of the reference or references deemed most closely related to the subject matter of each of the claims . . . (3) For each reference cited, an identification of all the limitations of each of the claims . . . that are disclosed by the reference . . . (4) A detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references; and (5) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. § 112 in the written description of the specification.[105]

The ESD is substantially similar to the Accelerated Examination Support Document that applicants are required to provide in order to use the Accelerated Examination program.[106]

Most applicants will avoid filing ESDs. Writing an ESD will be expensive; the PTO estimates that it could cost up to $13,000 per application for small entities.[107] Additionally, mistakes made during the search required to prepare the ESD will expose the applicant to inequitable conduct charges during litigation.[108] Therefore, most applicants will likely limit claims in their applications to the five/twenty-five limit. Some practitioners have suggested that they will never file ESDs because of the risks involved.[109]

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104. FAQ, *supra* note 60, at F1; *see also infra* Section III.D (discussing when the PTO presumes that co-pending applications have patentably indistinct claims).

105. Final Rules, *supra* note 3, at 46842.

106. *See* U.S. PATENT & TRADEMARK OFFICE, COMPARISON OF ACCELERATED EXAMINATION SUPPORT DOCUMENT AND EXAMINATION SUPPORT DOCUMENT UNDER 37 CFR 1.265 (2007), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcomparison.pdf.

107. ICF INTERNATIONAL, CERTIFICATION ANALYSIS UNDER THE REGULATORY FLEXIBILITY ACT 18 (June 29, 2007), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcertificationanalysis.pdf.

108. Posting of Russ Krajec to Anything Under the Sun Made By Man, Patent Strategies in Light of the New Rules, http://www.krajec.com/index.php?/weblog/patent_strategies_in_light_of_the_new_rules/ (Sept. 4, 2007).

109. *Id.*; *see also* Posting of Peter Zura to 271 Patent Blog, The "5/25 Rule", "Representative Claims", and the USPTO, http://271patent.blogspot.com/2007/08/525-rule-representatitve-claims-and.html (Aug. 27, 2007).

1. Impacts of the Five/Twenty-Five Limit and ESD Requirement

According to the PTO, the Final Rules will not require many applicants to file an ESD or file fewer claims. Less than eight percent of the applications filed in fiscal year 2006 would have required either the cancellation of one or more independent claims or an ESD to comply with the rules.[110] Less than twenty-five percent of the applications filed in fiscal year 2006 would have required either the cancellation of one or more dependent claims or an ESD for compliance.[111]

Nevertheless, the Final Rules may have a disparate impact on patents according to their significance. Specifically, the rules may have more effect on "important" patents, those patents that are more likely to be involved in litigation.[112] According to one report, approximately 4400 of the patents issued between January 1, 2002 and August 1, 2007 have been involved in some type of litigation, and 35% of these "important" patents have more than twenty-five claims.[113] In contrast, the PTO asserted that only about 5% of all applications filed in fiscal year 2006 would have required either the cancellation of claims or an ESD.[114] Additionally, the number of patents affected by the claim limits varies across technology groups. One study found that from 2002-2006, 46% of medical device patents would have been affected, 43% of pharmaceutical patents would have been affected, and 47% of biotechnology patents would have been affected.[115]

2. The Claim Limits in the Finals Rules Differ Substantially from the Limits in the Proposed Rules

The five/twenty-five claim limit is substantially different from the standard the PTO suggested in the Proposed Rules, which would have required applicants to elect ten "representative" claims for initial examination, including all of the independent claims.[116] The proposed approach would have allowed applicants to secure as many as ten independent claims and an unlimited number of dependent claims without an ESD, but

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110. Final Rules, *supra* note 3, at 46718.

111. *Id.*

112. Posting of Dennis Crouch to Patently-O, Patents with More Than 25 Claims, http://www.patentlyo.com/patent/2007/08/patents-with-mo.html (Aug. 23, 2007).

113. *Id.*

114. Final Rules, *supra* note 3, at 46718 ("[B]y prosecuting an initial application and two continuation applications serially, about ninety-five percent of the applications filed in fiscal year 2006 would not have required either the cancellation of any claims or an examination support document.").

115. Zura, *supra* note 109.

116. Final Rules, *supra* note 3, at 46718.

could have protracted the examination process. The PTO asserts that its departure from the Proposed Rules was in response to comments it received during the comment period.[117] This provision is one of few where the Final Rules are stricter than the Proposed Rules.

D. Related Applications and the Rebuttable Presumption of Patentably Indistinct Claims

The Final Rules require applicants to identify certain commonly owned applications and patents and allow the PTO to presume that certain applications contain patentably indistinct claims.[118] The PTO created these provisions to prevent applicants from filing multiple similar applications, which could have allowed applicants to circumvent the ESD requirement and secure claims in excess of the five/twenty-five limit.[119] Although multiple similar applications would be subject to double patenting rejections without these provisions, the PTO asserts that examination will be more efficient when double patenting issues are identified and resolved early in the process with an applicant's assistance.[120]

Under the Final Rules, an applicant must identify other commonly owned pending applications or patents that: (1) have a claimed filing or priority date within two months of the claimed filing or priority date of the application; and (2) name at least one inventor in common with the application.[121] The Final Rules also create a rebuttable presumption that applications filed by the same applicant on the same day, with at least one shared inventor and substantially overlapping disclosures, contain at least one claim pair between the two applications that is not patentably distinct.[122] In this case, the applicant must file a terminal disclaimer or explain how the applications (or application and patent) contain only patentably distinct claims.[123]

Applicants still have a duty to notify examiners of other applications that are "material to patentability," so an applicant cannot easily evade the identification requirement by intentionally filing outside the two-month window.[124] Commonly owned applications containing patentably indistinct claims will be treated as a single application for claim counting purposes; either the total number of claims in all of those applications must be

117. *Id.*
118. *Id.* at 46721-22.
119. *Id*. at 46722.
120. *Id*. at 46780, Response to Comment 112.
121. FAQ, *supra* note 60, at J1.
122. *Id.* at J8.
123. *Id.* at J9.
124. *Id.* at J7.

below the five/twenty-five limit or the common applicant must submit an ESD.[125] The PTO may refer any registered practitioner who repeatedly fails to comply with this rule to the Office of Enrollment and Discipline.[126] Furthermore, failure to comply could expose the patent to charges of inequitable conduct in subsequent litigation.

As a result of the related application disclosure requirement, large technology companies that file thousands or tens of thousands of patent applications in a year will disclose long lists of related applications. For example, many software and computer technology patents recite common language ("boilerplate") that describes generic computers and computing technology, which means that the new disclosure requirement could require them to submit a list of hundreds or even thousands of patents. These long lists will likely be too cumbersome to help examiners find double-patenting situations.

Nevertheless, the provisions of the Final Rules regarding related applications are not as onerous as they appeared when initially published. The Proposed Rules would have required applicants to identify related applications for all pending applications, including applications filed before the November 1, 2007 effective date of the Final Rules. For example, in preparation for enactment of the rules, IBM conducted an initial search and believed that it would be required to disclose approximately 10,000 related applications (of its entire portfolio of over 25,000 pending applications) to the PTO under the Final Rules.[127] In early October, before the Final Rules went into effect but after they had been published for over a month, the PTO effectively withdrew that requirement in a published "clarification" document.[128] Therefore, under the clarification document, IBM did not need to review its entire portfolio of pending applications.

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125. *Id.* at F1.

126. *Id.* at J15.

127. Declaration of David J. Kappos, On Behalf of IBM, In Support of AIPLA Amicus Brief in Matter of GSK Preliminary Injunction Motion to Stay New PTO Rules, ¶¶ 7-8 (Oct. 24, 2007), *available at* http://www.patentlyo.com/patent/Kappos_20Declaration.pdf.

128. U.S. PATENT & TRADEMARK OFFICE, CLARIFICATION OF THE TRANSITIONAL PROVISIONS RELATING TO CONTINUING APPLICATIONS AND APPLICATIONS CONTAINING PATENTABLY INDISTINCT CLAIMS 3-5 (Oct. 10, 2007), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/clmcontclarification.pdf.

IV. INDUSTRY RESPONSE AND THE STATUS OF THE RULES

The Final Rules, controversial since their conception, limit continuation and CIP applications, RCEs, and claims, and they require applicants to disclose certain related applications to help the PTO identify double patenting. This Part discusses the industry and patent bar response to the Final Rules, the PTO's authority to promulgate them, ongoing litigation regarding them, and their future.

A. Response to the Proposed Rules

The PTO initially published the Proposed Rules in January 2006 and received a substantial amount of feedback.[129] Software companies and electronics companies generally supported the Proposed Rules because those companies develop products rapidly and are concerned with reducing application pendency.[130] Biotechnology companies and independent inventors opposed the Proposed Rules because those groups must file patent applications on many inventions before they can determine which variations will be valuable and therefore rely on continuation applications in order to claim the marketable invention.[131]

The relationship between the PTO and the patent bar is changing as patent practitioners develop hostile feelings toward the PTO.[132] Patent

129. Final Rules, *supra* note 3, at 46717-18.

130. *See, e.g.*, Letter from Robert W. Holleyman, II., President and CEO of Business Software Alliance, to Jon Dudas, Dir., U.S. PTO (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/bsa.pdf ("The consequences of a patent system with a million-plus application backlog and 8 year average pendency in art areas relating to the technologies being developed by our members is very troubling and particularly burdensome to the highly innovative technology companies in the software and hardware sectors."); Letter from David Simon, Chief Patent Counsel of Intel Corp., to John Doll, Commissioner for Patents at the PTO (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/intel.pdf.

131. *See, e.g.*, Letter from A. Scott Whitaker, COO of Biotechnology Industry Organization, to Robert W. Bahr, U.S. PTO (May 2, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/bio.pdf; Letter from Ron Rhode, Inventors Alliance, to John Doll, PTO Commissioner for Patents (May 3, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/ia_con.pdf.

132. *See, e.g.*, Posting of Joff Wild to IAM Magazine Blog, Fear and Loathing in the US Capital, http://www.iam-magazine.com/blog/detail.aspx?g=35cea80a-d11d-4823-bbd1-6b904ee9a029 (Oct. 20, 2007) ("[T]he relationship between the USPTO and practitioners is profoundly unhealthy at the moment . . . . There is real venom—sometimes even contempt—in the language I have been hearing from members of the US Patent bar . . . when they speak about the [PTO].").

lawyers voiced negative opinions on the Final Rules, and they have reacted similarly to related rules packages that the PTO is promulgating, including rules for appeals to the BPAI and rules regarding IDSs.[133] One group of patent practitioners went further and sued the Secretary of Commerce for appointing Margaret Peterlin as deputy director of the PTO in May 2007, alleging that Peterlin's appointment was illegal under 35 U.S.C. 3(b), which requires that the deputy director have "a professional background and experience in patent or trademark law."[134] The U.S. District Court for the District of Columbia dismissed that lawsuit.[135]

B. The PTO's Authority to Promulgate the Final Rules

The PTO may not have the authority to limit continuation applications as a matter of administrative law.[136] 35 U.S.C. § 2(b)(2) authorizes the PTO to promulgate rules; however, the PTO is only authorized to promulgate procedural rules, not substantive rules.[137] It is unclear whether the Final Rules are purely procedural or whether they also include substantive aspects.[138]

The PTO previously attempted to limit the number of allowable continuations in *In re Henriksen*.[139] There, the Court of Customs and Patent Appeals rejected the PTO's attempt to restrict the number of continuation applications as a matter of right to three.[140] Nevertheless, in *In re Bogese*,[141] the Federal Circuit affirmed the PTO's authority to reject continuation applications where an applicant fails to advance prosecution of his application for an unreasonably long time.[142] There, the applicant filed a chain of eleven continuation applications without amending the claims

133. *See* Posting of Peter Zura to 271 Patent Blog, Comments Posted on USPTO Regarding New BPAI Rule Changes, http://271patent.blogspot.com/2007/11/comments-posted-on-uspto-on-new-appeal.html (Nov. 8, 2007) ("The comments are in on the PTO's proposed BPAI rule changes—they are not favorable.").

134. Posting of Dennis Crouch to Patently-O, Patently-O TidBits, http://www.patentlyo.com/patent/2007/07/patently-o-ti-1.html (July 24, 2007).

135. Posting of Peter Zura to 271 Patent Blog, Peterlin Lawsuit Dismissed in the DC District Court, http://271patent.blogspot.com/2007/12/peterlin-lawsuit-dismissed-in-dc.html (Dec. 10, 2007).

136. *See* Sahasrabuddhe, *supra* note 30, at 193-94.

137. *Id.* at 194.

138. *See id.* at 195.

139. 399 F.2d 253 (C.C.P.A. 1968).

140. *Id.* at 255.

141. 303 F.3d 1362 (Fed. Cir. 2002).

142. *Id.* at 1363.

or offering any arguments addressing the rejections in any of those applications.[143]

C. The Ongoing Litigation

When the PTO published the Final Rules in August 2007, an individual inventor, Dr. Triantafyllos Tafas, immediately filed a declaratory judgment action in the U.S. District Court for the Eastern District of Virginia, requesting that the court declare the Final Rules in conflict with the Patent Act and therefore invalid.[144] Later, pharmaceutical heavyweight GlaxoSmithKline (GSK) filed another action requesting the court to enjoin the PTO before the effective date of the rules.[145] The court consolidated the two cases.[146]

The court scheduled a hearing to decide a motion for a preliminary injunction on October 31, 2007, the day before the PTO's planned effective date.[147] Patent prosecutors watched anxiously and frantically filed continuation applications and RCEs.[148] On the morning of the 31st, Judge James Cacheris issued a preliminary injunction from the bench.[149] Patent prosecutors rejoiced as the PTO belatedly posted a notice on its website that the Final Rules would not be going into effect.[150]

The court held in favor of GSK on each of the four factors relevant to granting the preliminary injunction.[151] The court considered the following four factors: (1) the likelihood of the plaintiff's success on the merits; (2)

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143. *Id.* at 1364-65.

144. Posting of Dennis Crouch to Patently-O, Dr. Tafas Files Declaratory Judgment Action to Block Implementation of Continuation Rules, http://www.patentlyo.com/patent/2007/08/dr-tafas-files-.html (Aug. 22, 2007).

145. Posting of Dennis Crouch to Patently-O, GlaxoSmithKline vs. Dudas: An Attempt to Stop Implementation of PTO Prosecution Rules, http://www.patentlyo.com/patent/2007/10/glaxosmithkline.html (Oct. 13, 2007).

146. MVS Filewrapper Blawg, Glaxo's preliminary injunction motion to be heard October 31, consolidated with earlier challenge, http://www.filewrapper.com/index.cfm/2007/10/18/Glaxos-preliminary-injunction-motion-to-be-heard-October-31-consolidated-with-earlier-challenge (Oct. 18, 2007).

147. *Id.*

148. *See* Posting of Dennis Crouch to Patently-O, Patent Prosecutors: Don't Wait for the Witching Hour, http://www.patentlyo.com/patent/2007/10/patent-prosecut.html (Oct. 29, 2007).

149. Posting of Gene Quinn to PLI Patent Blog, Glaxo Wins Injunction—Part 2, http://www.pli.edu/patentcenter/blog.asp?view=plink&id=151 (Oct. 31, 2007 12:10 p.m.).

150. Posting of Sherri Oslick to Patent Docs, USPTO Late to Its Own Party, http://www.patentdocs.net/patent_docs/2007/10/uspto-late-to-i.html (Oct. 31, 2007 10:45 a.m.).

151. Tafas v. Dudas (*Tafas I*), 511 F. Supp. 2d 652, 663-71 (E.D. Va. 2007).

irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest.[152]

Regarding likelihood of success, the court discussed six arguments advanced by GSK as to why it was likely to prevail on the merits of the case.[153] The court found that GSK was likely to succeed on four of its arguments, that the PTO was likely to succeed on one, and that neither party could claim likely success on the remaining issue.[154]

In favor of GSK, the court found that GSK "created a colorable question as to whether the Final Rules are truly substantive" and therefore was likely to show that the PTO, which only has authority to promulgate procedural rules, did not have the authority to promulgate the Final Rules.[155] The court also found that GSK would likely prevail on its claim that "Section 120 of Title 35 prohibits the PTO from limiting the number of continuation applications that may be filed."[156] Furthermore, the court found that GSK demonstrated a real likelihood of success in showing that the rules were impermissibly retroactive.[157] Finally, the court found that GSK "raised serious concerns as to whether a reasonably prudent person would be able comply with the ESD requirements," and that therefore GSK was likely to win on its Constitutional vagueness challenge.[158]

In favor of the PTO, the court found that GSK was not likely to prevail in showing that the PTO's rationale, that the rules are justified on grounds of administrative efficiency, was arbitrary and capricious.[159] The court relied on the fact that the PTO considered weaker alternatives and concluded that those alternatives would be inadequate.[160] Furthermore, the court found that neither party could claim a strong likelihood of success on the issue of whether the limits on claims and RCEs are contrary to the Patent Act.[161]

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152. *Id.* at 659 (citing Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1200-01 (Fed. Cir. 2007)).

153. *Tafas I*, 511 F. Supp. 2d at 664-68.

154. *Id.*

155. *Id.* at 664.

156. *Id.* at 664-65.

157. *Id.* at 667.

158. *Id.* at 668.

159. *Id.* at 666.

160. *Id.*

161. *Id.* at 665.

1. The ESD Requirements May Be Unconstitutionally Vague

GSK argued that the pre-examination search rule is vague and does not put applicants on sufficient notice as to how to comply.[162] According to GSK, the rule, which requires searching "U.S. patents and patent application publications, foreign patent documents and non-patent literature," does not provide any boundaries on the scope of the search, such as whether electronic or manual searches are required, which countries' databases must be searched, or which libraries must be searched.[163] Furthermore, GSK argued that the PTO's guidance documents are not regulations and do not cure the vagueness of the ESD requirement.[164]

The PTO responded by arguing that there is no due process interest in patent applications or procedures, and further, that the ESD requirement is clear.[165] The PTO contended that, although the rule itself does not address "every imaginable circumstance that may confront a patent applicant conducting a search," the rule is constitutionally sound because of the guidance from the final Federal Register notice, the Manual of Patent Examining and Procedure (MPEP), and the PTO's extensive public guidance, including the FAQ document posted on the PTO's website.[166]

The court held that GSK had demonstrated a real likelihood of success on this issue, apparently crediting GSK's rebuttal argument that the need for official guidance suggests an admission of vagueness.[167] The court also suggested that any guidance documents generated by the PTO outside of the notice and comment rulemaking process violate the Administrative Procedure Act.[168]

2. A Hobson's Choice?

GSK also argued that the standard for granting petitions for additional continuations forces it and other applicants into a Hobson's choice[169] un-

162. Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction at 26, Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) (Civ. No. 1:07cv1008) [hereinafter GSK Motion].

163. *Id.* at 26-27.

164. *Id.* at 27.

165. Defendants' Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction at 35, Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) (Civ. No. 1:07cv1008 (JCC/TRJ) Consolidated with No. 1:07cv846) [hereinafter PTO Motion].

166. *Id.* at 26-37.

167. Tafas v. Dudas, 511 F. Supp. 2d 652, 668 (E.D. Va. 2007).

168. *Id.*

169. A "Hobson's Choice" is an apparently free choice, but one that is made because there was no real alternative.

der PTO ethical rules that bar a practitioner from knowingly making a false statement of law or fact.[170] According to GSK, the PTO made it clear that the standard—that a petition will be denied unless the applicant "could not have" previously entered the argument or amendment—applies not only to the grant of a petition, but also to the actual filing of the petition.[171] Consequently, according to GSK, if an applicant wants to file a petition for an additional continuation or RCE but knows that it physically could have previously presented the amendment, evidence, or argument, then the applicant is barred from even filing the petition.[172] GSK called this situation a "regulatory trap."[173]

The PTO responded by noting that other procedural options exist that allow applicants to claim all of the subject matter in their applications without using the petition process.[174] In particular, the PTO pointed out that applicants can claim the subject matter in the initial application and any continuation applications, and that applicants can use SRRs and divisional applications to add claims drawn to independent or distinct inventions.[175] Citing these options, the PTO called GSK's concern about violating ethical rules "a red herring."[176]

The court did not rule on that issue or even discuss it. Many practitioners agree with GSK—they would like to be able to file petitions and argue them even if they know that under the strict standard they are not entitled to additional applications. Nevertheless, a relaxed standard would place an additional burden on the PTO by requiring it to review petitions filed by applicants who know they cannot meet the "could not have" standard.

D. The Future of the Final Rules

The court in the GSK litigation recently upheld its preliminary decision and granted summary judgment in favor of GSK and Tafas.[177] The court held that the Final Rules—including the 5/25 claim limits and the limits on RCEs—are substantive in nature.[178] The PTO's rulemaking authority does not extend to substantive rules, so the court found the Final

170. GSK Motion, *supra* note 162, at 19.
171. *Id.*
172. *Id.* at 19-20.
173. *Id.* at 20.
174. PTO Motion, *supra* note 165, at 14-15.
175. *Id.*
176. *Id.* at 15.
177. Tafas v. Dudas (*Tafas II*), 2008 U.S. Dist. LEXIS 26086 (E.D. Va. Apr. 1, 2008).
178. *Id.* at *15, *25-34.

Rules void as unlawful agency action under section 706(2) of the Administrative Procedure Act.[179]

The PTO plans to appeal that decision to the Federal Circuit.[180] Some provisions of the Final Rules may survive, however, even if some are ultimately blocked.

If the Federal Circuit enjoins the PTO from implementing some or all of the Final Rules, Congress may grant the PTO explicit authority to promulgate the rules. The Patent Reform Act of 2007, passed by the House in September 2007 and pending in the Senate as of this writing, amends 35 U.S.C. § 2(c) by adding the following:

> The powers granted under paragraph (2) of subsection (b) include the authority to promulgate regulations to ensure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121 and 365(c) of the filing date of a prior filed application for patent.[181]

The House Report clarifies that this section is intended to "resolve the ambiguity behind the USPTO's rulemaking authority that *In re Henriksen* has caused," and that the PTO "has always had authority to promulgate rules that place limitations or conditions on patent applications, including continuation applications."[182] As of this writing, the Senate is still struggling with the Patent Reform Act, which includes many other provisions.[183]

V. WILL THE FINAL RULES HELP REDUCE THE BACKLOG?

The PTO asserts that the Final Rules will assist it to achieve two primary goals: to reduce the backlog by improving the efficiency of examination, and to improve the quality of issued patents, making them easier to evaluate, enforce, and litigate. Many participants argued during the comment period that the rules will not accomplish these goals.[184] Nevertheless,

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179. *Id.* at *34 (citing 5 U.S.C. § 706(2)).

180. Posting of Dennis Crouch to Patently-O, *Tafas v. Dudas*: Appeal and Legislation, http://www.patentlyo.com/patent/2008/04/tafas-v-dudas-a.html (Apr. 2, 2008).

181. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 14(a) (as passed by House, Sept. 10, 2007).

182. H.R. Rep. No. 110-314, at 87 (2007).

183. Posting of Dennis Crouch to Patently-O, Patent Reform in the Senate, http://www.patentlyo.com/patent/2007/10/patent-reform-i.html (Oct. 29, 2007).

184. *See, e.g.*, Final Rules, *supra* note 3, at 46763, Comment 55.

the PTO remains confident that under the Final Rules, "the exchange between applicant and the examiner will be more efficient because applicant can no longer delay the submissions of amendments, argument, and evidence."[185]

It is unclear whether and to what extent the rules will alleviate the backlog of unexamined applications. The PTO acknowledges that the rules changes alone cannot control the backlog.[186] Nevertheless, the PTO asserts that the Final Rules, as part of a comprehensive effort including hiring new examiners, are crucial to managing the backlog and assuring timely examination.[187]

This Part analyzes whether the rules are likely to reduce the backlog and concludes that any reduction due to the rules will be small relative to the overall size of the backlog for several reasons, which are discussed in the following Sections. First, the Final Rules will not significantly decrease the number of continuing applications. Second, appeals to the BPAI will increase as a result of the Final Rules and will thus delay examination. Third, additional examination burdens will offset improvements to examination speed attributable to fewer claims. Fourth, the rules do not address the root of the problem: the PTO's lack of resources to hire and retain examiners.

A. The Number of Continuing Applications Will Probably Not Significantly Decrease

The PTO asserts that one reason the backlog is so severe is that applicants file too many continuing applications.[188] According to the PTO, the volume of continuing applications "is having a crippling effect on the Office's ability to examine 'new' (*i.e.*, non-continuing) applications."[189] In particular, the PTO points out that the volume of continuation application filings (including RCEs but not divisional applications) as a percentage of overall filings has increased steadily from about 11.4 percent in fiscal year 1980 to 29.4 percent in fiscal year 2006.[190] However, some commentators believe that the PTO's statistics are misleading and that continuation applications as a percentage of overall filings have not grown over a longer

185. *Id.* at 46764.

186. *Id.* at 46756 ("The [PTO] does not expect that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications.").

187. *Id.* at 46764.

188. *See id.* at 46718.

189. *Id*

190. *Id.*

time period.[191] Indeed, these commentators establish that the actual percentage of second continuation applications filed per total applications filed *decreased* from 2002-2005.[192]

One reason for the popularity of continuations and RCEs is that the examiner production system, which measures examiners' productivity and is used to monitor and reward examiners, encourages examiners to draw out the examination process.[193] Patent examiners receive credit, called "counts," for issuing first office actions and for disposing of applications by finally rejecting or allowing them.[194] Examiners are assigned production goals on the basis of the number of counts they are expected to earn in a two-week period.[195] Examiners consider a count earned by examining a continuation application or an RCE to be an "easy" count if they examined the initial application and are already familiar with subject matter.[196] This encourages examiners to issue final rejections as quickly as possible so that they can get easy counts by examining RCEs and continuations; this in turn causes applicants to file RCEs and continuations to placate examiners.[197]

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191. Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 566-67 (2006) ("[W]ith the exception of the anomaly in the mid 1990's due to enactment of the 20 year patent term from date of filing, the percentage of continuations has stayed statistically the same (about 27%) since 1975.").

192. *Id.* at 564. Furthermore, the Final Rules, unlike the Proposed Rules, only impede third continuation applications, not second continuation applications. *See supra* Section III.B.

193. *See* Harold C. Wegner, Testimony on the New Rules (Mar. 14, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/wegner.pdf. Wegner asserts that examiners trying to boost their production figures is "[o]ne of the greatest abuses that has spawned the proliferation of continuing applications" and that "[t]he proof of the pudding lies in the greatly increased number of continuing application filings." *Id.*

194. UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 7 (Sept. 2007), *available at* http://www.gao.gov/new.items/d071102.pdf [hereinafter GAO REPORT].

195. GAO REPORT, *supra* note 194, at 7.

196. Posting to Just a Patent Examiner, Hard Counts, Easy Counts, and the New Rules, http://just-n-examiner.livejournal.com/24329.html (Oct. 20, 2007 17:08:00); *but see* Lemley & Moore, *supra* note 53, at 74 (arguing that continuations "wear down" examiners and cause them to grant patents because they are sick of them, but not acknowledging the extra credit examiners get to continue examination). Commentators have criticized Lemley and Moore's argument that continuations "wear down" examiners. *See, e.g.*, Schreiner & Doody, *supra* note 178, at 563.

197. *See* Final Rules, *supra* note 3, at 46817, Comment 279.

The Final Rules do nothing to address the examiner production system[198] and instead focus on preventing applicants from extending chains of continuation applications. However, the PTO's own statistics suggest that the rules will only block a small number of applications: the Final Rules would have affected only 2.7 percent of the filings in fiscal year 2006.[199] Eliminating only 2.7 percent of filings will not greatly reduce the backlog. Many commentators believed that even the Proposed Rules, which would have allowed only one continuation application without justification and potentially cut 6.5 percent of filings, would not have helped.[200]

Furthermore, applicants are likely to file divisional applications where previously they would have filed continuation applications. For example, an applicant who files a large application containing many distinct inventions might have previously pursued claims to each invention in separate continuation applications.[201] Under the Final Rules, that applicant can file an SRR with the large application and pursue claims to each invention in separate divisional applications.[202] In this case, the Final Rules reduce the number of continuation applications, but they do not decrease the total number of applications that the PTO must examine.

In GSK's litigation regarding the preliminary injunction, GSK argued that the PTO's backlog rationale for the Final Rules is arbitrary and capricious, relying primarily on the PTO's concession that less than 2.7% of applications involved a third or subsequent continuation or a second or subsequent RCE.[203] GSK contended that the PTO cannot meaningfully hope to reduce its backlog by revising the continuing application process, and that the backlog rationale is a "red herring."[204]

The PTO responded by asserting that, according to its models, the changes in the Final Rules will have an "appreciable" impact on the back-

198. According to the PTO, the examiner production system is outside the scope of the Final Rules. *Id.* at 46805, Response to Comment 243. Nevertheless, the PTO asserts that changes to examiner production goals, appraisal plans, and award systems alone will not be sufficient to address the backlog. *Id.* at 46818, Response to Comment 279.

199. *Id.* at 46755.

200. *See, e.g.*, Schreiner & Doody, *supra* note 191, at 563 (asserting that the Proposed Rules would "barely mak[e] a dent in the purported problem").

201. The PTO explicitly states that these "voluntary divisionals," which are not the result of a restriction requirement, will be counted as continuation applications. Final Rules, *supra* note 3, at 46720.

202. *See supra* Section II.B.2.

203. GSK Motion, *supra* note 162, at 23-24.

204. *Id.*

log.[205] The PTO averred that the Final Rules are part of an "integrated scheme" to reduce the backlog.[206] More convincingly, the PTO noted that the 2.7% figure represents approximately 11,000 continuation applications and requests for continued examination.[207] The PTO believes it would take 275 new patent examiners one year to examine that many applications.[208]

Preventing examination of 11,000 applications sounds like a huge accomplishment; however, that number of applications is small, relative to the enormous backlog and the growing number of applications being filed each year. The backlog is currently over one million applications,[209] and the PTO's projections show that the backlog could reach 1.4 million unexamined applications by 2012.[210] Although the limits on continuation applications and RCEs would slightly reduce the number of filed applications, those limits seem unlikely to significantly alleviate the backlog. Moreover, the PTO cannot have it both ways. The PTO must reckon with the consequences that the Final Rules significantly reduce continuation applications and thus risk harming incentives for innovation in certain industries, or that the Final Rules do not affect enough applications to significantly reduce the backlog.[211]

B. Appeals to the BPAI Will Greatly Increase and Thus Delay Applications

Currently, applicants who receive a final rejection may file a continuation application or an RCE, or appeal to the BPAI. Under the Final Rules, prudent applicants will probably hold their one RCE and two continuation applications in reserve until they are needed, for example, after losing an appeal to the BPAI.[212] Consequently, applicants will appeal adverse decisions and follow through with the appeals process to a final decision much more frequently. If applicants appeal to the BPAI (instead of abandoning the appeal and filing an RCE) just one or two more times per examiner than currently, the BPAI will have to decide two or three times the number appeals that it currently does.[213]

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205. PTO Motion, *supra* note 165, at 32.
206. *Id.*
207. *Id.* at 30 n.22.
208. *Id.*
209. PATENT APPLICATIONS PENDING PRIOR TO ALLOWANCE, *supra* note 2.
210. STRATEGIC PLAN, *supra* note 64, at 10.
211. *See supra* Section IV.A.
212. See Email from Hal Wegner, Continuation Rules: Board of Patent Appeals and Interferences Backlog under the New Rules, Sept. 18, 2007 (on file with author).
213. *Id.*

The PTO believes that the pendency of an appeal[214] is relatively short and that the BPAI is ready for the increase in appeals.[215] The PTO justifies its belief by noting that it recently reduced the inventory of pending appeals and implemented new procedures to streamline the appeals process.[216] In particular, the PTO points to an appeal conference program to review the rejections in applications in which an applicant has filed an appeal brief, and to a pre-appeal brief conference program that allows an applicant to have a rejection reviewed by a panel of examiners.[217]

According to the PTO, the current (as of the end of the second quarter of fiscal year 2007) pendency of a decided appeal is 5.6 months.[218] Professor Dennis Crouch's analysis reveals a different picture.[219] In his study of thirty recent BPAI decisions, applicants waited about eighteen months from filing an appeal brief until the BPAI reached a decision.[220] Most of the delay was attributable to the time to complete briefing (about eleven months on average), which involves an applicant's brief, an examiner's answer, and a reply brief.[221] Thus, although the delay is not directly attributable to the BPAI, it still takes twice as long as the PTO asserts to get a decision from the appeal process. Many commentators are skeptical of the BPAI's ability to handle the increase in the number of appeals.[222]

Many also predict that the changes in the Final Rules will force applicants to appeal applications that are not in condition for appeal.[223] When an examiner issues a final rejection, the applicant can petition to submit an after-final amendment to change the application in response to the examiner's arguments and prepare the application for appeal.[224] However, examiners often refuse to enter the after-final amendments,[225] hoping that the applicants will file RCEs and give them easy counts.[226] Thus, practitioners have long used continuations and RCEs to "place the application in better

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214. The pendency of an appeal is the period between the assignment of an appeal number and the mailing date of the decision. Final Rules, *supra* note 3, at 46763, Response to Comment 54.

215. *Id.* at 46720.

216. *Id.*

217. *Id.*

218. *Id.* at 46763, Response to Comment 54.

219. Posting of Dennis Crouch to Patently-O, How long does a BPAI appeal take?, http://www.patentlyo.com/patent/2007/09/how-long-does-a.html (Sept. 17, 2007).

220. *Id.*

221. *Id.*

222. *See, e.g.*, Final Rules, *supra* note 3, at 46763, Comment 54.

223. See, e.g., id.

224. *Id.* at 46763, Response to Comment 53.

225. *See id.* at 46763, Comment 54.

226. *See supra* Section IV.A (discussing the examiner production system).

condition for appeal because most examiners refuse to enter the after-final amendments."[227] Under the Final Rules, though, applicants will not want to use their single RCE to further an essentially procedural purpose, necessary only due to the PTO's misguided production system for its employees. Thus, applicants' extensive use of RCEs is not solely an abuse of the system, but rather at least partially a result of the PTO's own policies. The PTO responded to these comments by noting that applicants "should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and one request for continued examination in an application family."[228]

The Final Rules, by re-routing examination disputes to the appeals board, will arguably give examiners more time to work on new applications and in that respect, reduce the backlog. Nevertheless, this will only decrease the pendency of applications until the first office action; it will not help decrease the total pendency of applications if many applications are subjected to lengthy appeals. Moreover, the PTO's separate improvements to the appeals process will likely re-route some disputes to the BPAI even without the Final Rules,[229] so not all of the appeals-related backlog reduction can be attributed to the Final Rules.

C. Examiners Will Not Be Able to Examine Faster

Examiners should be able to examine applications with fewer claims at greater speed, and that should help reduce the backlog. The five/twenty-five limit on claims will force at least some applicants to file applications with fewer claims.[230]

Nevertheless, additional examination burdens will offset improvements to examination speed attributable to fewer claims. Applicants "will be forced to front-load responses to every Office action with interviews, declarations and other evidence when the attorney's argument alone otherwise might have been sufficient."[231] It is likely that applicants will begin to argue more over dependent claims to prepare for appeals, request interviews to avoid appeals and filing RCEs, and make every possible argument in responses to office actions. These tactics will force examiners to

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227. Final Rules, *supra* note 3, at 46763, Comment 54.

228. *Id.* at 46763, Response to Comment 54.

229. *Id.* at 46763, Comment 54 ("[O]nce applicants appreciate the appeal process changes, more applicants w[ill] file appeals rather than continuing applications and requests for continued examination.").

230. About eight percent of the applications filed in fiscal year 2006 had more than five independent claims, and about twenty-five percent of the applications filed in fiscal year 2006 had more than twenty dependent claims. *See id.* at 46718.

231. *Id.* at 46764, Comment 57.

spend more time on applications and will erase improvements to examination speed caused by claim limits.

The Final Rules also introduce a lot of new documents for the PTO to process: petitions for additional continuations and RCEs, long lists of related applications, additional terminal disclaimers to rebut the presumption of patentably indistinct claims, and SRRs. Although petitions may not be decided by examiners, and the PTO asserts that it will "make every effort to decide the petitions in a timely manner,"[232] the petition process will at some level divert PTO resources that could otherwise be devoted to examining new applications or supporting the examination of new applications.

D. Hiring and Retaining Examiners Is the Root of the Problem

Hiring and retaining examiners appears to be the key to controlling the backlog. The PTO has recognized this and plans to hire 9,000 new examiners between 2005 and 2012.[233] The PTO projects that with aggressive hiring, the average time of patent pendency will only rise to about forty months by 2012, as opposed to fifty-five months without such a plan.[234]

The rapid growth of the backlog occurred because staffing levels for examiners did not keep pace with application growth.[235] For example, from 1990 to 2002, applications increased by 79 percent, whereas the number of examiners increased only 73 percent.[236] Similarly, from 2002 to 2004, applications increased seven percent while examiners increased by only four percent.[237] The PTO is a fee-funded agency, but it still receives annual appropriations before it can spend its fee revenues, and Congress limited the PTO's access to its fees beginning in 1992.[238] Between fiscal

232. *Id.* at 46752.

233. STRATEGIC PLAN, *supra* note 64, at 11.

234. *Id.*

235. NATIONAL ACADEMY OF PUBLIC ADMINISTRATION, US PATENT AND TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY 13 (Aug. 2005) [hereinafter NAPA REPORT]; *see also* Letter from Michael Kirk, Executive Dir. American Intellectual Property Law Association, to Jon Dudas, Dir., U.S. PTO (Apr. 24, 2006), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/aipla.pdf ("Congress essentially starved the PTO of the resources it needed to keep pace with the increase in patent application filings from roughly FY 1992 through FY 2003, diverting nearly $800 million in fees generated by [a fee] increase. Hundreds of examiners, who would be fully trained and experienced today, were not hired.").

236. NAPA REPORT, *supra* note 235, at 13.

237. *Id.*

238. *Id.* at 40.

years 1992-2004, Congress kept $573 million in patent funding from the PTO.[239]

A study by the National Academy of Public Administration shows that if the PTO had used those funds for examiner hiring, the current backlog would be much smaller.[240] The study used the Patent Production Model, which is maintained by the Office of Financial Management under the Commissioner for Patents.[241] According to the study, if the PTO had used the $543 million of unavailable funding entirely for examiner hiring, total application pendency would have averaged 21.2 months in 2004, instead of the actual 2004 pendency of 27.6 months.[242] If the PTO had used only $503 million for examiner hiring, total application pendency would have averaged 22.6 months.[243] If the PTO had spent $680 million on examiner hiring, which would have required diversion of some of the unavailable trademark funds to patent work, the total application pendency would have averaged 20.8 months and never exceeded level for fiscal year 1996.[244] The study stressed that consistent hiring, which was used in the simulations, is key to reducing pendency.[245] The study criticized the intermittent "emergency" hiring that actually occurred (citing fiscal years 1998, 1999, and 2002) as not as efficient or effective as consistent hiring.[246]

The PTO asserts that hiring alone will not reduce the backlog of pending applications in the near future.[247] The PTO's assertion is misdirected: hiring alone will not suffice because the PTO lacks the institutional capacity to hire enough examiners,[248] not because no possible number of examiners could do the job. Furthermore, part of the reason that the PTO lacks the institutional capacity to hire enough examiners is that examiner attri-

239. *Id.* Recent appropriations permit the PTO to retain all of the fees collected to process patent applications. *Id.* at 48.

240. *Id.* at 41-49.

241. *Id.* at 41.

242. *Id.* at 43.

243. *Id.* at 44.

244. *Id.* at 42.

245. *Id.* at 45.

246. *Id.*

247. Final Rules, *supra* note 3, at 46817, Response to Comment 278.

248. GAO REPORT, *supra* note 194, at 5 ("Over the last 5 years the [PTO] has moved away from its prior strategy because it realized that it did not have the institutional capacity to train and supervise the relatively large number of new patent examiners it would need to hire annually to keep pace with the increasing number of incoming patent applications expected each year.").

tion significantly offsets hiring.[249] If the PTO could hire and retain enough examiners, it could successfully manage the backlog without implementing new restrictions on the application process.

Therefore, the backlog is primarily a result of insufficient examiner hiring and retention to keep pace with the rising number of applications. Pursuing efforts that expand the PTO's hiring capacity and examiner retention should be the most effective way to address the backlog. For example, the PTO is planning to explore options such as allowing examiners to work from home and establishing regional PTO offices.[250] Limiting continuation applications and RCEs will not solve the underlying problem causing the backlog.

VI. CONCLUSION

The growing backlog of unexamined patent applications challenges the PTO's ability to process applications in a timely manner. The PTO has responded admirably by securing all of its fees collected for patent examination and setting out an aggressive plan to hire enough examiners to keep up with the growing number of applications.

Nevertheless, the Final Rules, if implemented, would almost certainly negatively affect patent prosecution practice and would ultimately reduce incentives to innovate, particularly in biotechnological and pharmaceutical fields. Moreover, the Final Rules are unlikely to significantly reduce the backlog due to the low percentage of applications affected and the unintended consequence of increased appeals and increased examination burdens. Thus, the PTO should reconsider whether the Final Rules are an appropriate part of the scheme to manage the backlog.

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249. *Id.* at 6 ("Although [the PTO] is hiring as many new patent examiners as it has the annual capacity to supervise and train, for nearly every two patent examiners it has hired over the last 5 years at least one has left the agency."). The reason that examiners leave so frequently is not clear. *See id.* The PTO management asserts that personal reasons drive examiners to leave, whereas examiners blame the examiner production system. *Id.*; *see also supra* Section V.A (discussing the examiner production system).

250. STRATEGIC PLAN, *supra* note 64, at 16.