IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED, d/b/a GLAXOSMITHKLINE,	:	
Plaintiffs,	:	
v.	:	**Civil Action No. 1:07cv1008**
JON W. DUDAS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and	:	
UNITED STATES PATENT AND TRADEMARK OFFICE,	:	
Defendants.	:	

DECLARATION OF HARRY F. MANBECK, JR.

I, Harry F. Manbeck, Jr., hereby declare under penalty of perjury that:

1. I am an attorney and, from 1990 to 1992, served as the Commissioner of Patents and Trademarks of the United States and Assistant Secretary of Commerce. I am presently a member of the law firm of Rothwell, Figg, Ernst and Manbeck, with offices at 1425 K Street, N.W., Washington, D.C. 20005. Prior to my government service, I practiced patent law for over 35 years. At the time of my appointment by the President of the United States as Commissioner and Assistant Secretary, I was General Patent Counsel of the General Electric Company.

2. I have been retained by counsel for the Plaintiffs SmithKline Beecham plc; SmithKline Beecham Corporation, doing business as GlaxoSmithKline; and Glaxo Group Limited, doing business as GlaxoSmithKline (collectively referred to as "GSK") in the above-captioned action. The law firm that employs me bills my time in this matter at my standard fee rate of $700.00 per hour for time spent on this matter, with reimbursement for actual expenses. No part of my compensation depends on the outcome of this litigation. Attached to this report as exhibits are my curriculum vitae (Exhibit A); a list of publications that I have authored or co-authored (Exhibit B); and a list of the intellectual property cases in which I have testified in court or in deposition as an expert in the last four years (Exhibit C).

3. I am familiar with the PTO's Rules of Practice and Procedure, 37 C.F.R. pt. 1, as they are presently constituted. I am also familiar with the PTO's regulations entitled "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46716, 46716-843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) ("the Final Rules"). The PTO has indicated that it will implement the Final Rules on November 1, 2007.

4. The Final Rules revise the rules of practice in the PTO relating to, among other things, continuing applications, requests for continued examination, and for the examination of claims in patent applications.

5. More specifically, the Final Rules amend, among other sections, 37 C.F.R. §§ 1.75, 1.78, and 1.114, and add 37 C.F.R. § 1.265. The changes to § 1.75 and addition of § 1.265 apply to any nonprovisional application pending on or after November 1, 2007 that has yet to receive a first Office Action on the merits. 72 Fed. Reg. at 46716. The changes to § 1.78, except for those changes to §§ 1.78(a) and 1.78(d)(1), apply to any nonprovisional application pending

on November 1, 2007. *Id.* at 46717. The changes to § 1.114 apply to any application in which a request is made after November 1, 2007. *Id.* Thus, the changes affect GSK patent applications that have already been filed and are pending in the PTO. *Id.* at 46717.

I. The PTO Has Limited Rulemaking Authority

6. The PTO's rulemaking authority, which derives from 35 U.S.C. § 2, is limited to non-substantive rulemaking. Section 2(b)(2) grants the PTO the authority to:

> establish regulations, not inconsistent with law, which—
>
> (A) shall govern the conduct of proceedings in the Office;
>
> (B) shall be made in accordance with section 553 of title 5;
>
> (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 [35 U.S.C. § 122] relating to the confidential status of applications; . . . .

7. The Patent Act confines the PTO's powers to regulating internal procedures in practice before the agency. Section 2(b)(2) does not confer upon the PTO general rulemaking power to interpret the Patent Act.

8. Absent from the precise enumeration of proper subjects for rulemaking in the six sub-provisions of Section 2(b)(2)(A) through (F) is the conferral of any type of power to limit any substantive provisions of the Patent Act. For this reason, the Federal Circuit has held that the broadest rulemaking power the PTO possesses is Section 2(b)(2)(A), which allows the PTO merely to issue rules governing "the conduct of proceedings in the Office." Thus, overall, the Patent Act does not confer upon the PTO any power to decide questions that extend beyond matters of internal proceedings at the PTO.

9. The Federal Circuit has long highlighted, and recently reaffirmed, that Section 2(b)(2) does not confer on the PTO the power to issue substantive rulemakings. *See Merck &*

Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) ("As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a) [now 35 U.S.C. § 2(b)(2)(A)]—authorizes the Commissioner to promulgate regulations *directed only to* the conduct of proceedings in the PTO; it does NOT grant the Commissioner the authority to issue substantive rules." (citations omitted) (emphasis in original)); *see also Eli Lilly & Co. v. Board of Regents of University of Washington*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003) (reaffirming continued agreement with the *Merck* holding).

10. In 1999, Congress added Section 2(b)(2)(C), empowering the PTO to issue regulations that would "facilitate and expedite the processing of patent applications." *See* Fiscal Year 2000 Consolidated Appropriations Act, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-573 (1999). But, when Congress added that provision, it did not express any intent to overrule *Merck* and its progeny in the Federal Circuit. Thus, the addition of Section 2(b)(2)(C), as a subsidiary heading of power, did not expand the PTO's rulemaking authorities.

11. Since 1999, Congress has twice proposed, but failed to pass into law, legislation that would have expanded the PTO's rulemaking authority. On June 8, 2005, the House of Representatives introduced the Patent Reform Act of 2005, H.R. 2795, which would have granted the Director the power to promulgate regulations concerning continuation practice. *See* H.R. 2795 § 8. More broadly, the Patent Reform Act of 2006, S. 3818, introduced on August 3, 2006 in the United States Senate, contained a provision that would have allowed the PTO the authority to issue rulemakings to "carry out" the Patent Act. *See* S. 3818 § 6(e).

12. On September 7, 2007, the House of Representatives passed H.R. 1908. Section 14 of H.R. 1908 amends Title 35 to add § 2(c)(6), which grants the PTO "authority to promulgate regulations to insure 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 prior filed application for patent." Section 14 of H.R. 1908 further states that any regulations passed under Section 2(c)(6) can not take effect before the end of sixty days after the Director submits to each House of Congress a copy of the regulation. If a joint resolution of disapproval is passed, the regulation shall not become effective. The Senate is considering S. 1145, which unlike H.R. 1908, does not include a grant of similar rulemaking authority to the PTO. Based on this legislative action, it is clear that: (i) While the House of Representatives couches the provision as a clarification of existing law, Congress has not yet granted the PTO the authority to make rules of practice that restrict continuing applications—if Congress had already given the PTO such authority in 35 U.S.C. § 2, then Section 14 of H.R. 1908 would be redundant and meaningless; (ii) The House of Representatives takes the position that the PTO should not promulgate such rules until Congress has been given 60 days to consider and perhaps disapprove them; (iii) The Senate has yet to, and may not, follow the House of Representatives in approving a bill that grants the PTO this rulemaking authority; and (iv) The issue of PTO rulemaking authority is still subject to significant congressional debate, has not been agreed upon, and, indeed, may never be agreed to in the future. Notably, when Congress last revised Section 120 in 1999 (in the Fiscal Year 2000 Consolidated Appropriations Act), it did not restrict the number of continuing applications and may never decide to do so.

II. Background On Patent Applications And Continuations

13. Under the patent laws, an inventor is entitled to a patent unless the invention that is the subject of the application for the patent is not new or is obvious. 35 U.S.C. §§ 102-03.

14. To obtain a patent, an inventor must file a written application that contains a specification, an oath and "one or more" claims. 35 U.S.C. §§ 111-12. An application's filing

date is critical because the applicant's entitlement to a patent, e.g., novelty under 35 U.S.C. § 102 and non-obviousness under 35 U.S.C. § 103, will be judged from the earliest filing date to which the application is entitled. By obtaining the earliest possible filing date, an applicant may establish that its patent application was filed before a similar application filed by someone else.

15. The universe of "prior art" will also be determined based on the application's filing date, or its earliest priority date. In other words, the application's filing date allows an applicant to demonstrate that its application was filed before the date of publication of information. In such a case, the information is not "prior art" that an examiner may consider in evaluating patentability.

16. A continuation patent application is a patent application that stems from, and claims the benefit of the filing date of, an earlier-filed patent application. A continuation application contains the same disclosure as the original application.

17. The first application is called the "parent" application. The subsequently filed applications are known as "continuation" applications. In the lexicon of patent practitioners, an application that directly follows a "continuation" application is known as "child"; and the next application in line is the "grandchild"; and so on.

18. Continuation applications are statutorily authorized under 35 U.S.C. § 120, which provides that a patent application filed by an inventor for an invention previously disclosed in a pending patent application "shall have the same effect, as though filed on the date of the prior application," if, among other things, it contains a specific reference to the prior application. Section 120 allows inventors to file chains of patent applications that relate back to a first filed application and entitle the later applications to the benefit of the filing date of the first filed application for each application in the chain.

19. The priority filing date is critical. If the priority filing date is lost so that an applicant cannot claim the benefit of it in a later-filed application, the later-filed application will only be entitled to its actual filing date, and the later-filed application will be analyzed against prior art (before the PTO and in later litigation) that became available between the earlier-filed application and the later-filed application. In such situations, in view of the fact that patent applications are usually published eighteen months after they are filed, 35 U.S.C. § 122, the originally-filed application may itself constitute prior art against the later-filed application.

III. Historical Background Of Continuation Application Laws

20. As early as 1863, the Patent Act was understood to allow an applicant to file continuation patent applications. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863) (in interpreting the act of 1839, the Supreme Court recognized that "if a party choose to withdraw his application for a patent . . . intending at the time of such withdrawal to file a new petition, and he accordingly do so, the two petitions are to be considered as parts of the same transaction, and both as constituting one continuous application . . . .").

21. Subsequently, the law did not limit the number of continuing applications that may be filed. In discussing continuation applications, William Robinson's 1890 patent treatise noted that "[i]t is immaterial how many of these substituted applications may be filed, or for how long a period such efforts to obtain a patent may be continued." 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 581, at 204 (reprinted, 1972); *see also* 1 Walter F. Rogers, *The Law of Patents* 21 (1914) ("[N]o number of successive applications indicates an intention to abandon, . . . in reference to the question of abandonment, all such may be regarded as one application, the ones subsequent to the first being known as 'continuing' applications.").

A. The Patent Act Of 1952

22. Congress codified the existing case law regarding continuations when it enacted 35 U.S.C. § 120 in the Patent Act of 1952. According to the legislative history, Section 120 represented "present law not expressed in the statute, except for the added requirement that the first application must be specifically mentioned in the second." Senate Report No. 1979, June 27, 1952 (accompanying H.R. 7794), at 2413.

23. 35 U.S.C. § 120, as enacted in 1952, stated that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Act of July 19, 1952, Pub. L. 593, ch. 950, § 120, 66 Stat. 800, *reprinted in* 1952 U.S.C.C.A.N. 761.

24. The 1952 enacted version of Section 120 stated that an application "shall" be entitled to the benefit of the filing date of an earlier application, as long as four conditions are met: (1) the application is for an invention disclosed in an application previously filed in the United States; (2) the application is filed by the inventor named in the previously filed application; (3) the application is filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application; and, (4) if it contains or is amended to contain a specific reference to the earlier filed application.

B. Judicial Interpretations Of 35 U.S.C. § 120 Under The 1952 Act

25. After 35 U.S.C. § 120 was enacted, the Court of Customs and Patent Appeals—the predecessor to the United States Court of Appeals for the Federal Circuit— stated that the PTO could not limit the number of continuing applications that an applicant could file. *See In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968). More specifically, the court held that a patent examiner had "no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of co-pendency may be traced to obtain the benefit of the filing date of the earliest of a chain of co-pending applications, provided applicant meets all the other conditions of the [§120] statute." *Id.*

26. The PTO, itself, recognized that under *Henriksen* it lacked the authority to limit the number of continuation applications that an applicant was permitted to file, stating that *Henriksen* "established that the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved." *Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975).

27. The Court of Customs and Patent Appeals also indicated that limiting the number of continuation applications is the province of Congress. Specifically, the court stated that, "it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction [on continuation practice] . . . is to be imposed." *In re Henriksen*, 399 F.2d at 262. In 1977, the Court of Customs and Patent Appeals reiterated that limiting "continuing applications is a matter of policy for the Congress . . . ." *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977).

28. Since *Henriksen*, courts have continued to interpret Section 120 very broadly. *See In re Bauman*, 683 F.2d 405, 406-407 (C.C.P.A. 1982) (denying the PTO's ability to "require

recognition of a nonstatutory exception to the clear language of § 120"); *Transco Products Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556-557 (Fed. Cir. 1994) (not requiring a patent applicant update its "best mode" disclosure when filing a continuation application, because it was not required under § 120's "plain and unambiguous meaning").

C. Congressional Amendments To Section 120

29. The original language of Section 120 has changed only slightly since its original enactment in 1952. In 1975, Congress amended Section 120 to reference applications filed under Section 363 pursuant to the Patent Cooperation Treaty. *See* Pub. L. No. 94-131, ch. 37, sec. 9, § 120, 89 Stat. 685 (1975).

30. Congress amended Section 120 again in 1984 by deleting "'by the same inventor' and inserting in lieu thereof 'which is filed by an inventor or inventors named in the previously filed application.'" Patent Law Amendments Act of 1984, Pub. L. No. 98-622, sec. 104(b), § 120, 98 Stat. 3383 (1984).

31. In 1999, Congress contemplated and altered the scope of the PTO Director's discretion under 35 U.S.C. §120 to deny an application the benefit of a priority. *See* Fiscal Year 2000 Consolidated Appropriations Act, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-563 to 1501A-564 (1999). Specifically, Congress added the following paragraph to Section 120:

> No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director ***may consider*** the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director ***may establish procedures***, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Id. (emphasis added). In amending Section 120 in this manner, Congress explicitly granted the PTO limited powers to "empower the Director to: (1) establish a time by which the priority of an

earlier filed United States application must be claimed; (2) consider the failure to meet that time limit to be a waiver of the right to claim such priority; and (3) accept an unintentionally late claim of priority subject to the payment of a surcharge." 145 Cong. Rec. S14,719 (daily ed. Nov. 17, 1999). Congress did not grant the Director or the PTO any other discretionary powers.

IV. Patent Claims Under Section 112

32. The quid pro quo for the Patent Act's grant of exclusivity to use of the invention is that the applicant must disclose its invention in the manner provided in 35 U.S.C. § 112 so that the public benefits from the applicant's scientific advance and, using that foundation, can further develop the technology. The application must contain, among other things, a specification containing a written description that enables one of ordinary skill in the art to make and use the invention, the best mode of practicing the invention, and "one or more claims." 35 U.S.C. § 112, ¶¶ 1-2.

33. Moreover, the claims must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." *Id.* As a matter of form, a "claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form." 35 U.S.C. § 112, ¶ 3. Further requirements for specifying claims in dependent form and in multiple dependent form are provided. *See id.* § 112, ¶¶ 4-5. Nothing in these provisions suggest that Congress envisioned any restrictions on the number of claims an applicant could submit.

V. Requests For Continued Examination Under Section 132

34. Section 132(b) of Title 35 requires the Director and the PTO to continue examination of applications when an applicant so requests. Section 132(b) provides that "[t]he Director ***shall*** prescribe regulations to provide for the continued examination of applications for patent ***at the request of the applicant.***" (emphasis added).

35. To promote efficiency in the examination process and to avoid needless appeals of claim rejections by Examiners at the PTO, Congress amended 35 U.S.C. § 132(b) to allow for requests for continued examination ("RCEs") of an application. *See* Fiscal Year 2000 Consolidated Appropriations Act, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-560 (1999). Congress has not authorized the PTO to limit the number of RCEs that an applicant may file, as Section 132(a) states that the PTO "shall" continue examination upon request. *See* 35 U.S.C. § 132(a) ("if after receiving such notice [of rejection or objection], the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined."). Section 132(b) provides that the "Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." Section 132(b), particularly when read in conjunction with Section 132(a), does not authorize the Director to restrict continued examinations.

VI. GATT Implementing Legislation Reduces The Incentives For "Submarine" Patenting

36. Some comments to the proposed rules appeared to support the PTO's restrictions on continuing applications out of concern about "submarine patents." A "submarine patent" is one that is filed and remains unpublished for a lengthy period of time. Congress, however, largely eliminated the submarine patent abuse when it changed the exclusivity period from 17 years running from the date of issuance to 20 years from the filing date of the first application to which the patent claims priority. Also, the publication of applications eighteen months after they are filed informs interested parties of the inventions on which patents are being sought.

VII. The Final Rules

A. The Final Rules Substantively Change Continuing Application Practice

37. The Final Rules relating to continuing applications differ from those that the PTO initially proposed in January 2006, which would have limited an applicant to only a single application before triggering the petition and showing requirement. Instead, the Final Rules limit an applicant to two nonprovisional continuing applications. An applicant who seeks to file an additional continuing application must submit a petition showing that the amendment, arguments, or evidence could not have been presented during the prosecution of the prior-filed application. *See* 72 Fed. Reg. at 46839. An application that cannot satisfy the "could not have been submitted" showing, loses the benefit of priority it was otherwise entitled to under 35 U.S.C. §§ 120, 121, or 365(c).

38. There are a number of valid reasons an applicant may file a continuation application, including:

- To differentiate the claimed invention from the prior art, which may occur after the patent examiner at the PTO rejects the claims over prior art or indicates that he or she is not persuaded by arguments that an applicant made earlier.

- To present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. In a recent opinion, the Federal Circuit recognized this as a valid reason for filing continuing applications. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005).

- To add new claims directed to subject matter that is disclosed in the application, but which was not claimed in an earlier application for which examination has closed on the merits.

- To disclose new prior art, often times, as a result of the receipt of a "Search Report" from a foreign patent office during the examination of a related foreign patent application. If an applicant failed to do so, it would almost certainly face a charge of inequitable conduct in later litigation. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995) (finding inequitable conduct based on failure to submit references cited in a search report from the European Patent Office).

39. Remarkably, in its responses to comments that accompanied the Final Rules, the PTO specifically indicated that these reasons would be insufficient to carry the applicant's burden of showing that the argument or evidence "could not have been" submitted earlier under the Final Rules. 72 Fed. Reg. at 46772-77.

40. Further, the PTO has indicated that the following reasons for filing continuation applications, which were all normal, customary, sanctioned and accepted reasons for filing continuations prior to the Final Rules, are no longer adequate to support a petition:

- The applicant attempts to submit "newly discovered prior art" (Response to Comment 85).
- The examiner's interpretation of the claims is unusual and only recently understood by the applicant or the examiner changes his or her interpretation of claim language (Response to Comment 87).
- The applicants have recently discovered a commercially viable product, financial resources, useful subject matter, a competing product, or similar or parallel technology on the market (Response to Comment 91).
- The applicant becomes disabled for a lengthy time during the pendency of the application (Response to Comment 100). *Id.* at 46773-77.

The PTO has made these pronouncements despite the fact that the Federal Circuit has stated that an applicant "may [] refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive." *See Symbol Techs.*, 422 F.3d at 1385.

41. The doctrine of prosecution laches is a judicially created doctrine meant to be applied in extreme cases of an applicant's unreasonable and unexplained delay. *See id.* at 1384-85. The Federal Circuit has cautioned that the doctrine should be applied sparingly: "There are legitimate grounds for refiling a patent application that should not normally be grounds for a holding of laches, and the doctrine should be used sparingly lest statutory provisions be unjustifiably vitiated. The doctrine should be applied only in egregious cases of misuse of the

statutory patent system." *Id.* at 1385. Thus, the doctrine does not authorize the PTO to impose bright-line restrictions on continuing applications.

42. The Final Rules apply the provisions of newly amended 37 C.F.R. § 1.78(d), aside from (d)(1), retroactively. *Id.* at 46717. As to newly amended subsection (d)(1), the Final Rules apply to any application filed on or after November 1, 2007, which includes a continuing application claiming the benefit of an application filed before November 1, 2007. *Id.* at 46716-17.

43. Further, the newly amended subsection (d)(1) applies the petition requirement retroactively to second or subsequent continuing applications that claim the benefit under 35 U.S.C. §§ 120, 121, or 365(c) of nonprovisional applications or international applications filed before August 21, 2007, if there is no other application filed on or after August 21, 2007 that also claims the benefit under 35 U.S.C. §§ 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications. The Final Rules purport to "provide applicants with 'one more' continuation application or continuation-in-part application of a second or subsequent continuing application (continuation application or continuation-in-part application) that was filed prior to the publication date of this final rule in the Federal Register without a petition under § 1.78(d)(1)(iv)." 72 Fed. Reg. at 46736-37. The "one more" grace application is not provided for in new Section 1.78.

44. On October 10, 2007, the PTO released a "Clarification of the Transitional Provisions Relating to Continuing Applications and Applications Containing Patentably Indistinct Claims." That clarification revises, in an *ad hoc* manner, the "one more" application by allowing one additional continuing application after November 1, 2007 without the filing of a petition and showing if the application claims priority to a divisional application (1.78(d)(1)(ii))

or a continuation of a divisional application (1.78(d)(1)(iii)). Patent application families that do not claim priority to a divisional application are not affected by this clarification. Accordingly, those patent application families do not have "one more" grace application.

B. The Difficult Choice The Final Rules Pose For Patent Applicants

45. Under the current rule, i.e., those in place before November 1, 2007, an applicant could file more than two continuation applications as needed and obtain the benefit of the priority date of a parent application so long as the applicant complied with the formal requirements of Section 120. Under the soon-to-be-implemented Final Rules, an applicant can only do so by submitting a petition showing that it "could not have" submitted the information or claims earlier.

46. In explaining the requirement in response to comments, the PTO has made clear that the "could not have" evidentiary burden in almost all cases precludes not just the grant of a petition, but also the actual filing of a petition itself. *See id.* at 46767-79. For example, the "could not have" standard creates a conflict for applicants and their counsel under 37 C.F.R. § 10.85(a)(5) in the PTO's rules of professional conduct, which bars a practitioner from knowingly making a false statement of law or fact. The PTO apparently construes the term "could not have" in its ordinary sense of meaning, i.e., that one could not have physically presented the amendment, evidence or argument, and, as a result, the attorneys for an applicant like GSK would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition.

47. This conflict renders compliance with the PTO's new petition requirement extremely difficult, if not impossible, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations as well as the "could not have" standard. As a result, the PTO's petition and showing requirement represents a difficult, if not false, choice.

C. The Final Rules Impose Barriers That Restrict The Number Of Claims An Applicant May Present In An Application

48. In the Final Rules, the Director and PTO restrict the number of claims an applicant may file before being required to file an examination support document ("ESD"). *See* 72 Fed. Reg. at 46836-37 (proposed § 1.75(b)). The Final Rules allow an applicant five independent claims and/or twenty-five total claims in a single application before requiring the applicant to submit an ESD in compliance with newly added Section 1.265. 72 Fed. Reg. at 46836.

49. The Final Rules purport to apply the changes to 37 C.F.R. § 1.75 retroactively. Specifically, the Final Rules state that the changes to Section 1.75 apply "to any nonprovisional application filed under 35 U.S.C. 111(a) on or after November 1, 2007, and to any . . . nonprovisional application filed before November 1, 2007, in which a first Office action on the merits was not mailed before November 1, 2007." 72 Fed. Reg. at 46716.

D. The Final Rules Are Vague And, In Important Respects, Provide Applicants Almost No Direction As To How To Comply

50. The Final Rules are vague and do not put GSK on sufficient notice of what it must do to comply. Newly created § 1.265 sets forth the requirements of an ESD, one of which, § 1.265(a)(1), requires that the applicant perform a preexamination search. *Id.* at 46842. Rule 1.265(b) sets forth requirements of a preexamination search as including the searching of "U.S. patents and patent application publications, foreign patent documents and non-patent literature." *Id.*

51. Newly added § 1.265(b), however, does not provide boundaries on the scope of the search and, as a result, GSK will be unable to know how to comply with this regulation. For instance, the rule does not indicate whether the applicant must conduct electronic searches,

manual searches, or both; in which countries' databases the applicant must search; or which libraries it must search.

E. The Final Rules Substantively Change RCE Practice

52. The Director and the PTO made significant changes to the PTO's practice relating to RCEs. Specifically, under newly amended § 1.114, an applicant is permitted only a single RCE in a patent family before being required to file a petition and "showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application . . . ." 72 Fed. Reg. at 46841. The changes to § 1.114 in the Final Rules are more extensive than those proposed by the PTO in January 2006.

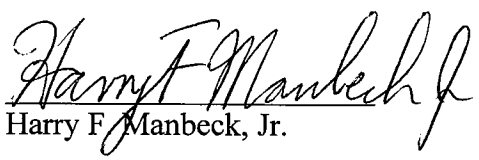
53. The Final Rules apply newly amended 37 C.F.R. § 1.114 retroactively by requiring a petition and showing if an applicant files an RCE after November 1, 2007 but had previously filed an RCE in an application chain. 72 Fed. Reg. at 46717.

VIII. Conclusion

In view of the foregoing, it is my opinion that the Director and the PTO have exceeded their statutory authority in promulgating the Final Rules, that the Final Rules exceed the plain language of the Patent Act, and that the Final Rules' ESD requirement hopelessly lacks guidance.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on this 15th day of October, 2007.



Harry F. Manbeck, Jr.