

EXHIBIT 5

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

TRIANTAFYLLOS TAFAS,	:	
	:	
Plaintiff,	:	
	:	
v.	:	1:07cv846 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

CONSOLIDATED WITH

SMITHKLINE BEECHAM	:	
CORPORATION,	:	
d/b/a GLAXOSMITHKLINE, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	1:07cv1008 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

DECLARATION OF HARRY F. MANBECK, JR., IN SUPPORT OF
GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT

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. As Commissioner, I exercised general supervision over the entire work of the United States Patent and Trademark Office ("PTO"), including the activities of all personnel involved in the granting and issuing of patents and the registration of trademarks; and decided various questions brought before me by petition. I was directly involved in the PTO rulemaking process while I was Commissioner, and certain rules dealing with the duty of disclosure and compliance with it were revised and reissued during my tenure.

2. I graduated with Highest Honors from Lehigh University in 1949 with a B.S. in Electrical Engineering. I received my law degree with Honors from the University of Louisville in 1954. Prior to my studies at Lehigh, I served in the U.S. Army Signal Corps.

3. After graduating from Lehigh, I joined the General Electric Company as a test engineer. At the General Electric Company, I advanced to become General Patent Counsel in 1970, a position I held until becoming Commissioner. While at the General Electric Company, I prosecuted patent applications for a number of years and, as General Patent Counsel, I was responsible for overseeing the activities of people involved in the prosecution of patents and patent applications in the United States and abroad. I practiced patent law for over thirty-five years before becoming Commissioner.

4. I am presently a member of the law firm of Rothwell, Figg, Ernst and Manbeck, P.C. with offices at 1425 K Street, N.W., Washington, D.C. 20005.

5. I am a member of the District of Columbia, Connecticut, Indiana, Kentucky, and Massachusetts Bars. I am admitted to practice before the United States Court of Appeals for the Federal Circuit. I am also registered to practice before the PTO.

6. I have served as Chairman of the Patent, Trademark and Copyright Section of the American Bar Association; President of the Association of Corporate Patent Counsel; a Director of the Intellectual Property Owners Association; and a Director of the Federal Circuit Bar Association. I am also a member of the American Intellectual Property Law Association.

7. Since September 2003, I have testified, either at deposition or at trial, in over fifty cases as an expert witness. My testimony has in many instances related to the practices and procedures before the PTO.

8. 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.

9. When I was Commissioner of Patents and Trademarks, my associates and I understood that the PTO did not have substantive rulemaking authority. I am unaware of Congress delegating any such authority after my tenure.

10. 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 published 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. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (“the Final Rules”).

A. Patent Background

11. 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 under sections 102 and 103 of the patent laws or does not meet certain other statutory requirements.

12. To obtain a patent, an inventor must file a written application that contains a specification, an oath, and “one or more” claims as required by sections 111 and 112 of the patent laws. The specification contains a written description that illustrates the invention, often with figures, formulae, and test data, so that one of ordinary skill in the art can make and use the claimed invention. The claims are the numbered paragraphs at the end of the patent or patent application that define the metes and bounds of the inventions.

13. Once the applicant has filed his patent application, the PTO reviews the application, and a back-and-forth exchange between the applicant and the PTO begins. The PTO employees charged with examining applications are called “examiners.” The back-and-forth exchange between an examiner and a patent applicant is called “prosecution” of the application and addresses whether the application should issue as a patent. Prosecution primarily involves an analysis of whether the claimed invention meets the statutory requirements of novelty under section 102, non-obviousness under section 103, and the written description, best mode, and enablement requirements of section 112.

14. When the application is filed and is complete, the application is afforded a filing date. An application’s filing date is critical because the applicant’s entitlement to a patent, *e.g.*, novelty under section 102 and non-obviousness under section 103, will be judged from the

earliest filing date to which the application is entitled. The earliest possible filing date to which an application is entitled is called the “priority date.” An early priority date is desirable because it may allow an applicant to establish that it has “priority” over another applicant, *i.e.*, that his application has an earlier filing date than another’s patent application disclosing related subject matter.

15. The priority date is also used to define the universe of “prior art.” Prior art is information regarding earlier activities or technology that may preclude an applicant from obtaining a patent or that may require an applicant to narrow the scope of his claimed invention. If the applicant’s priority date is before the date of publication of information, then that information is not prior art that an examiner may consider in evaluating patentability.

16. The first application is called the “parent” application. Subsequent applications that claim the priority date of the parent application are known as “continuing” applications. In the lexicon of patent practitioners, an application that directly follows a parent application is known as the “child”; the next application in line is the “grandchild”; and so on.

17. The subsequent applications are entitled to the priority date of the parent application if certain requirements are satisfied. Any new matter added to the subsequent applications is not entitled to the priority date of the parent application. Thus, the claims filed in the subsequent applications must have support in the parent application’s written description to be afforded the priority date.

18. The priority date is critical. If the priority date is lost, an applicant cannot claim the benefit of the earliest possible filing date. This means that the later-filed application will only be entitled to its actual filing date. As a result, the later-filed application will be analyzed against an even larger universe of prior art because that universe now includes the prior art that

became available during the time between the filing of the parent application and the filing of the later application.

19. In the United States, most applications are now published eighteen months after they are filed. If a subsequent application is not entitled to the filing date of an earlier application, then the earlier application itself may in certain circumstances constitute prior art against the later-filed application. Thus, if the later-filed application claims subject matter disclosed in or made obvious by the parent application, the examiner will reject the claims of the later-filed application as not new and/or obvious in view of the prior art. In short, an applicant's earlier application may bar the patenting of a later-filed application if the later-filed application is not entitled to the earlier application's priority date.

20. As discussed herein, in light of the Final Rules changing the settled expectations of patent applicants and running contrary to statutory rights and long-established case law, the Final Rules are clearly "substantive" in nature.

21. In my experience and understanding of the law, patent applications have indicia of constitutionally protected property. Patent applications are transferable and assignable; patent applications can form the *res* of a trust; patent applications can pass to the trustee in bankruptcy; patent applications are taxable property; and patent applications provide provisional rights to collect damages for infringement.

B. The Patenting Process

22. In my experience, a development project may result in several interrelated patentable inventions. In such scenarios, an applicant will often file a single patent application with the PTO disclosing separately patentable inventions, *i.e.*, "patentably distinct" inventions, in a single application. One reason for doing this is that the interrelated nature of some patentably

distinct inventions may require disclosure in a single application to comply with section 112's requirement that the application enable one of ordinary skill in the art to make and use the invention. In other words, if one aspect of the interrelated inventions is omitted, an application may not teach one of ordinary skill in the art how to make and use the invention(s) that involved that aspect. In such a case, the applicant must disclose the patentably distinct inventions in a single patent application.

23. If the examiner finds that a claim is anticipated under section 102, obvious under section 103, or that the application does not comply with section 112, then the examiner will reject the application and issue an "Office Action" detailing the examiner's reasons for rejecting the application. The examiner's first action on the merits of an application is called a First Office Action or a "non-final" Office Action. In some instances, the examiner may allow some claims or the entire application in the First Office Action.

24. In response to a non-final Office Action, the applicant has several options. In my experience, the two most prevalent responses to a non-final Office Action are to (1) amend the claims to differentiate the claims from the prior art or to comply with section 112 and/or (2) present arguments as to why the examiner's rejection of the claims is incorrect. In some instances, the applicant may present evidence demonstrating why the claims are patentable, *e.g.*, by submitting a declaration describing test results that demonstrate that the claimed invention is an advance over the prior art.

25. In view of the applicant's response, the examiner may allow some claims or the entire application. If the examiner wishes to reject some claims of the application, then the examiner will issue another Office Action. This second Office Action is often issued as a "Final" Office Action and closes prosecution on the merits with respect to that application.

26. In response to a Final Office Action, an applicant may not amend the claims as a matter of right. However, the applicant still has several courses of action he may follow. The primary options for an applicant are to file a request for continued examination ("RCE") (detailed below); file a response attempting to persuade the examiner that his rejection is incorrect; file an appeal of the examiner's rejection to the PTO's Board of Patent Appeals and Interferences, which can take several years; or file a continuing application (detailed below). The applicant will often conduct an interview to try to reach agreement with the examiner before taking any of these options.

C. Requests for Continued Examination

27. In response to a Final Office Action, an applicant may file an RCE under section 132. An RCE reopens prosecution on the merits of a finally rejected application and allows an applicant to amend the claims, present additional evidence, present additional arguments as to why the applicant believes the examiner's rejection is incorrect, or perform a combination of some or all of those responses. An applicant may also file an RCE to comply with his duty of disclosure under PTO Rule 56. The RCE is a relatively new procedure at the PTO having been implemented pursuant to section 132, which Congress passed in 1999. In my practice, I have seen these types of RCEs and would characterize them as normal practice.

28. In my experience, an applicant is entitled to file any number of RCEs. Since Congress enacted the RCE, I have not seen any limit on the number of RCEs an applicant may file, and I am not aware of any. The ability to file any number of RCEs drives certain prosecution choices made at the time of drafting and filing patent applications.

29. Changing the RCE rules for already-filed applications retroactively changes those settled expectations.

D. Continuing Applications

30. An applicant may also file a continuation application under section 120 in response to a Final Office Action. In addition, an applicant may file a continuation at any time so long as the application to which the continuation is claiming direct priority is still pending. 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.

31. Continuation applications are statutorily authorized under section 120 of the patent laws, 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 entitles each later application to the benefit of the filing date of the first-filed application.

32. There are many reasons why an applicant may file a continuation application. In my experience, examples include amending the claims to overcome a prior art rejection; submitting additional evidence on patentability; submitting additional arguments as to why the claims are patentable over the prior art; and adding new claims to cover inventions disclosed in the original specification but not yet claimed. An applicant may also file a continuation application to comply with his duty of disclosure under Rule 56 of the PTO’s rules. For example, an applicant may file a continuation to disclose, and have considered by the examiner, newly discovered prior art, including prior art that was provided to an applicant during litigation of a related patent or prior art cited by a foreign patent office during prosecution of a related

patent. In my years of practice, I have seen all of these types of continuations and I would characterize them as normal practice considered to be acceptable by the PTO. I also know that the PTO has recognized these reasons as valid reasons for filing a continuation application.

33. In my experience, an applicant may file an initial patent application without knowing exactly what aspects of the disclosure will be commercialized or will become strategically important for the applicant's company or business. In such instances, an applicant may use continuation applications to continue prosecution of varying aspects of his invention. The applicant maintains a pending application at the PTO so that, when it becomes clear what aspects of the invention are important, the applicant will be able to protect the important aspects of the application. Based on my experience, this is normal practice heretofore acceptable to the PTO and the courts.

34. Sometimes when the examiner has allowed some claims, but rejected others, an applicant will cancel the rejected claims in the parent application so that the parent application will issue as a patent while also filing a continuation application under section 120 containing the rejected claims to continue prosecuting the rejected claims. Again, based on my experience, this is normal practice heretofore acceptable to the PTO and the courts.

35. In my experience, when an applicant files an application containing more than one patentably distinct invention, the applicant will also initially submit claims directed with particularity to the different patentably distinct inventions. In such a situation, the applicant may file a divisional application or applications, either voluntarily or as a result of the examiner issuing a restriction requirement so that each invention is claimed in a separate application. A "restriction requirement" is an Office Action in which the PTO requires the applicant to select one invention from multiple patentably distinct claimed inventions for prosecution. "Divisional

applications” are continuing applications just like continuations in that they are entitled to the priority dates of their parent applications. Division practice is well-recognized and accepted by the PTO and the courts.

36. In my experience, as a result of continued developmental efforts, an applicant may discover a patentable enhancement to the parent application after initial filing. In such a situation, the applicant may file a continuation-in-part (“CIP”) application. A CIP is a type of continuing application that contains some or all of the written description of a parent application but also adds new information not disclosed in the parent application. Some of the claims of the CIP application may be directed only to subject matter of the parent application. In such a case, those claims would be entitled to the benefit of the filing date of the parent application under section 120. Conversely, if a claim encompasses new subject matter added in the CIP, then those claims are not entitled to the benefit of the parent application’s filing date under section 120; rather, such claims are only entitled to the benefit of the filing date of the CIP.

37. An applicant can file a continuation, divisional, or CIP at any time. In other words, an applicant does not need to wait until it receives a Final Office Action. These three types of applications are referred to as “continuing” applications.

38. In my experience, an applicant is entitled to file any number of continuing applications. Based on my many years in this field, I can say that patent practitioners have come to understand that there is no limit to the number of continuing applications an applicant may file (except if prosecution laches applies), and practitioners draft patent applications with these settled expectations in mind. The ability to file any number of continuations drives certain prosecution choices made at the time of drafting and filing applications.

39. Changing the continuing application rules for already filed applications retroactively changes those settled expectations.

E. The Difficult Choice That The Final Rules Pose For Patent Applicants

40. Under the current rule, *i.e.*, those in place before November 1, 2007, an applicant could file more than two continuing 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. Similarly, an applicant could file more than one RCE per family under section 132. Under the Final Rules, an applicant may only do so by submitting a petition showing that he “could not have” submitted the arguments, information, or claims earlier.

41. In explaining the petition and showing requirement in response to public 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* 72 Fed. Reg. at 46,767-79. 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.

42. 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.

F. Claims

43. Each claim is a separate statement of a patented invention under section 282 of the patent laws. 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.

44. 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. A patent claim may be "independent" or "dependent." An independent claim is one that stands on its own and includes only the elements of the invention recited in the independent claim. A dependent claim refers to a prior claim, includes all of the limitations of the prior claim to which it refers, and sets forth at least one more element of the invention. Further requirements for specifying claims are provided in section 112, paragraphs 4-6. These are the basic statutory restrictions on claim presentation.

45. When filing a patent application, an applicant will often include many claims of varying scope. An applicant will often include a claim that describes the invention very broadly and will include successively narrower claims to cover the entire spectrum of the invention. There are a number of reasons for claiming an invention in this manner. For instance, an applicant often does not know the entire universe of prior art. Though the applicant may obtain a

patent, when it comes time to enforce the patent, an infringer or potential licensee may identify previously unknown prior art. The prior art may render the broader claims invalid, but not the narrower claims. By including claims with a varied range of scope, the applicant (now patentee) has increased the chances that one or more of his patent claims will survive a validity challenge.

46. In my experience, companies (both large and small), sole inventors, patent practitioners, and the PTO have recognized that an applicant may file any number of claims that an applicant deems necessary to protect his invention. Over my many years in this field, I have seen no established limit to the number of claims an applicant may pursue, and I know from my experience that patent practitioners rely upon these settled expectations when they draft and file their patent applications. The ability to file any number of claims drives certain prosecution choices made at the time of drafting and filing patent applications.

47. Changing the claims rules for already-filed applications retroactively changes those settled expectations.

G. Examination Support Document

48. Under Final Rule 75, if a patent application contains, or is amended to contain, more than five independent claims or twenty-five total claims, then the applicant would be required to file an Examination Support Document (“ESD”) in compliance with Final Rule 265. Final Rule 265 sets forth the ESD requirements, including one mandating that an applicant perform a preexamination search. The preexamination search requires an applicant to search “U.S. patents and patent application publications, foreign patent documents and non-patent literature.”

49. Final Rule 265 does not indicate what steps an applicant must take to comply with the preexamination search requirement. Final Rule 265 does not indicate whether the applicant

must conduct electronic searches, manual searches, or both; in which countries' databases the applicant must search; or in which libraries the applicant must search. Certainly, the cost of searching could be quite large, and the rule does not set forth an expense cap or limitation. A practitioner would question whether he would be required to conduct electronic or manual searches, or both; what databases he would be required to search; what libraries he would be required to search; and in which countries' databases and libraries he would be required to search. The fact that the preexamination search requirement of Final Rule 265 does not contain a cost cap means that the practitioner would not know when he could end his searching and still comply with the preexamination search.

50. It is my understanding that the PTO has relied on its Manual of Patent Examining Procedure ("MPEP") in an effort to help explain the preexamination search required by the proposed Final Rule 265. The MPEP is not subject to notice and comment rulemaking and does not have the force of law. Instead, it is a guide to the PTO's examiners and patent practitioners as to the PTO's internal procedures. Further, the MPEP does not answer the questions raised by the preexamination search requirement's vagueness.

51. It is my understanding that the PTO has also issued guidance documents explaining the proposed Final Rules, including Final Rule 265. However, the guidance documents were not subject to notice and comment. Moreover, the guidance documents do not answer the questions raised by the vagueness of the preexamination search requirement.

52. Requiring that applicants submit ESDs for already-filed applications retroactively changes settled expectations.

H. Bargained-For Exchange

53. In my experience, when an invention is developed, the applicant sometimes must choose between protecting the invention as a trade secret or seeking patent protection by filing a patent application. When the applicant opts to file a patent application, he loses trade secret protection in exchange for the opportunity to seek patent rights covering the full scope of the inventions. That opportunity includes the understood ability under the current system to file any number of continuing applications, RCEs, and claims as the applicant deems appropriate. In applying the proposed limits of the Final Rules to already-filed patent applications, the PTO is retroactively altering that bargained-for exchange on which applicants relied. Under the Final Rules, GSK, and others like it, would no longer have the right to seek the appropriate spectrum of patent protection, nor would they be able to reclaim the trade secrets disclosed in patent applications already filed and published. The Final Rules would therefore effectively eliminate investments applicants made in reliance on the existing system.

I. Lack of Factual Support for Rule Changes

54. It is my understanding that the PTO relies on a single document (A05641-721) to show that the Final Rules will have an appreciable impact on the backlog of pending patent applications. Specifically, the PTO relies on page A05645 of the Administrative Record.

55. To my understanding, page A05645 does not adequately explain the PTO's conclusions or its analysis. Under the heading of "Efficiency Gains," there is one line that indicates that "Calims [sic], Continuations & IDS (Examiner Bonus Structure)" will have a one percent effect in fiscal year 2008 and then a two percent effect in fiscal years 2009 through 2013. The base on which the effect is realized is not stated. Nor does the document explain upon what

the PTO bases its assumptions, where the efficiency gains come from, or how they were broken down between the three (or possibly four) sources of such gains.

56. The data page A05645 appears to assume hard limits on the number of continuing applications and claims that the PTO will allow. The data does not appear to account for the additional burden that the new filings (*i.e.*, petitions and ESDs) will impose on the PTO. For example, in determining its assumed efficiency gains, the PTO does not appear to have taken into account that some applicants will file ESDs to exceed Final Rule 78's limit on the number of claims an applicant may file. In that event, any efficiency gains will be offset by the additional administrative burdens of analyzing the filed ESDs. The PTO likely does not account for the additional burdens that ESDs will impose because it likely expects that most applicants will opt to abide by the limit on the number of claims rather than file an onerous ESD. This modeling assumes linear workload reductions based on the proposed limit on claims in Final Rule 78. There is no dynamic modeling that accounts for the multiple variables that impact efficiency.

57. Further, the IDS rule is a separate proposed rule that has not yet been promulgated in final form. Nothing explains what the reference to Examiner Bonus Structure means. Indeed, the publication of the Final Rules themselves contains only two, albeit inconsistent, references to bonuses and their potential to help reduce the PTO's backlog: (1) an indication that the PTO was looking into future reforms in bonus structures and (2) a response to a comment, one page later, suggesting that better bonuses were not needed. Lastly, nothing explains how the Final Rules' restrictions on continuing applications, RCEs, and claims affect the PTO's analysis.

J. Logical Outgrowth

58. Proposed rule 75 would have limited an applicant to ten representative claims before requiring that an applicant file an ESD. The selected representative claims could be a

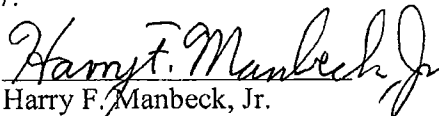
combination of independent and dependent claims. The proposed rule, however, would have required that all independent claims be designated as representative, which would have effectively limited an applicant to ten independent claims before requiring that the applicant submit an ESD. The proposed rule did not restrict the total number of claims an applicant could seek.

59. Final Rule 75, however, limits applicants to only five independent claims before requiring that an applicant submit an ESD. Further, Final Rule 75 limits the total number of claims an applicant could seek before requiring that an applicant submit an ESD.

60. Interested parties could not have expected the PTO to so drastically change the limit on the number of claims it would allow before requiring an ESD. From the proposed rule to Final Rule 75, the PTO cut by fifty percent the number of independent claims an applicant could submit and, for the first time, imposed a cap on the total number of claims an applicant could submit. That cap was twenty-five claims. According to the PTO, the proposed rule would have affected only 1.2% of applications while Final Rule 75 would impact 23.7% of applications. That is an increase of over 1800%. I believe that interested parties could not have anticipated such a drastic change in the claims rule.

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

Executed on this 20th day of December, 2007.


Harry F. Manbeck, Jr.