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

TRIANTAFYLLOS TAFAS, Plaintiff,)))
v.)) Civil Action No. 1:07cv846(JCC/TRJ))
JON W. DUDAS,)
Defendant)))
CONSOLIE	DATED WITH
SMITHKLINE BEECHUM CORPORATION, d/b/a GLAXOSMITHKLINE,))))
Plaintiff, v.)) Civil Action No. 1:07cv1008(JCC/TRJ))
JON W. DUDAS,)
Defendant))

BRIEF FOR AMICUS CURIAE BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT AND MOTION FOR PERMANENT INJUNCTION AGAINST UNITED STATES PATENT OFFICE FINAL RULES

TABLE OF CONTENTS

I.	INTRODUCTION1
II.	THE INTEREST OF AMICUS CURIAE
	THE FINAL RULES WERE ISSUED DESPITE THE EXISTENCE OF LESS EROUS ALTERNATIVES
	THE FINAL RULES ARE INCONSISTENT WITH BOTH THE PATENT ACT AND NG-STANDING PATENT PROSECUTION PRACTICES
A.	The Patent Act Does Not Authorize the Final Rules' Limitation on the Filing of Continuations
B.	The Continuation Rules Contradict Real-World Patent Prosecution Practice
C.	The Retroactive Effect of the Final Rules Would Deprive Patent Applicants of Existing Rights in Their Inventions. 8 1. The Final Rules Will Deprive Patent Applicants the Right to Patent Protection on 8 1. The Final Rules Will Deprive Patent Applicants the Right to Patent Protection on 8 2. The Final Rules Affect Applicants' Substantive Rights in Their Pending 9
D.	The RCE Rules are Based on an Unrealistic View of Patent Applicants and their Resources
E.	The Final Rules will Effectively Prohibit the Long-Standing, Established Practice of Filing Multiple Applications From Common Disclosures
F.	The Claims Rules Also Are Inconsistent With Real-World Patent Prosecution Practices
	1. The ESD Requirement Imposes a De Facto Limit on the Number of Claims Applicants Can File
V.	CONCLUSION

TABLE OF AUTHORITIES

Cases

Chamber of Commerce of United States v. S.E.C., 443 F.3d 890, 908 (D.C. 2006)	4
In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002)	5, 9
Johnson & Johnston Assoc., Inc. v. R.E. Service Co., Inc., 285 F.3d 1046 (Fed. Cir. 2002)	
Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co., 144 U.S. 248 (1892)	12, 13
Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 277 F.3d 1361 (Fed. Cir.	
2002)	5, 9

Statutes

3
1
9
5
3
4
L

Rules

Other Authorities

· · · · · · · · · · · · · · · · · · ·	
Order On Microsoft's Motions For Judgment As A Matter Of Law And New Trial And Lucen	t's
Motion To Alter Or Amend The Judgment Regarding U.S. Patent Nos. 5,341,457 And Re	
39,080, U.S. District Court for the Southern District of California, Case 3:02-cv-02060-B-	
CAB Document 1975 (2007)	12
Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals, 7	72
Fed. Reg. 41472 (2007)	11
Transcript of Address of Giles S. Rich on The Patent Act of 1952, publication of the New York	ζ
Patent Law Association (1952)	5
U.S. Const. Art. I, § 8	7

I. INTRODUCTION

The Patent, Trademark & Copyright Section of the Bar Association of the District of Columbia ("BADC") respectfully submits this brief as *amicus curiae* in support of the motions of plaintiffs Triantafyllos Tafas ("Dr. Tafas") and Glaxosmithkline ("GSK") for summary judgment of invalidity of the Final Rules of the United States Patent and Trademark Office ("PTO") 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, et seq. (Aug. 21, 2007) ("Final Rules"). As discussed below, the Final Rules are contrary to the patent laws and patent practice, and would significantly impair the ability of inventors to protect their inventions with patents.

II. THE INTEREST OF AMICUS CURIAE

The Patent, Trademark & Copyright Section of the BADC is one of the senior-most intellectual property bar associations in the United States, drawing its membership from government, industry and private practice, including both representing the interests of patentees and those seeking to avoid patents. The BADC and its members have a substantial interest in the adjudication of issues defining our patent laws, and only submit *amicus curiae* briefs when issues of significant magnitude arise. The interest of the BADC is entirely *pro bono*, to advance and create a fair and predictable system of patent law and procedure to promote the advancement of science and the useful arts.

Counsel for plaintiffs Dr. Tafas and GSK have consented to the filing of this *amicus curiae* brief. Counsel for the PTO has indicated that the PTO will take no position regarding the filing of this *amicus curie* brief. No counsel for a party has authored any part of this brief, nor has anyone other than the BADC made any monetary contribution to the preparation and submission thereof. Counsel for the BADC prepared this brief on a *pro bono* basis.

III. THE FINAL RULES WERE ISSUED DESPITE THE EXISTENCE OF LESS ONEROUS ALTERNATIVES

In January 2006, the United States Patent and Trademark Office ("PTO") published a set of proposed rule changes ("Proposed Rules") affecting the rules of practice governing the ability of patent applicants to file continuing applications and the ability of patent applicants to obtain examination on the claims filed in any one application.¹

The Proposed Rules would have severely limited the ability of patent applicants to obtain patent protection on their inventions, and in many cases would have foreclosed that ability entirely. The BADC submitted comments regarding the Proposed Rules, as did many other members of the patent community, including the American Intellectual Property Law Association (AIPLA), American Bar Association Intellectual Property Law Section, and the National Association of Patent Practitioners. Comments also were submitted by companies with significant experience with the patent process and who file and prosecute hundreds of patent applications a year, including Caterpillar, Inc.; Eastman Kodak Company; and E.I. du Pont Nemours and Company. These comments from the public regarding the Proposed Rules were almost uniformly negative, criticizing the Proposed Rules as being unnecessarily restrictive and beyond the rulemaking power of the PTO.

The Final Rules were published on August 21, 2007. "*Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims,* and *Examination of Claims in Patent Applications*, 72 Fed. Reg. 161 at p. 46716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) The PTO's stated purposes in issuing the Final Rules were to ease the backlog of unexamined applications, promote efficiency, and assist the PTO in issuing

¹ See Changes to Practice for Continuing Applications, Requests for Continued Examination, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (January 3, 2006) and Changes to Practice For the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (January 3, 2006).

higher-quality patents. However, as noted by the BADC and many other parties submitting comments to the Proposed Rules, there are less onerous alternatives that also would achieve these goals without violating the Patent Act, 35 U.S.C. § 101 et seq.

For example, the PTO could significantly raise the filing fees for "excess" claims and continuation applications. This would discourage the filing of large numbers of claims and continuation applications. It could also provide funding for the PTO to hire and retain the personnel needed to examine such applications and improve examination quality. The PTO could also hire additional administrative law judges (ALJs) to alleviate the backlog of appeals from rejected patent applications pending at the PTO. The lack of a timely appeal procedure has made the appeal process a route of last resort for many practioners because of the time it takes to get through the process, and has thus encouraged additional continuation filings as part of the effort to obtain the understanding and approval of the application by the patent Examiner.

It is unclear why the PTO has not pursued these or other alternatives that do not conflict with the Patent Act. Instead, the PTO has insisted on going forward with rules that limit the ability of inventors to pursue protection of their inventions by effectively limiting the number of continuations that may be filed and the number of claims that may be presented, despite the lack of any such limits in the Patent Act.

IV. THE FINAL RULES ARE INCONSISTENT WITH BOTH THE PATENT ACT AND LONG-STANDING PATENT PROSECUTION PRACTICES

The Final Rules published on August 21, 2007 remain flawed. As noted by the plaintiffs, the provisions of the Final Rules regarding the filing and examination of claims ("Claims Rules") are very different from the Proposed Rules, and in fact so different that a new notice and comment period under the Administrative Procedures Act was required. *See* 5 U.S.C. § 553(c). Indeed, the issuance of the Claims Rules without such a new notice and comment period renders

them invalid. 5 U.S.C. § 706(2)(d); *see also Chamber of Commerce of United States v. S.E.C.*, 443 F.3d 890, 908 (D.C. 2006) ("APA provides that the court shall 'hold unlawful and set aside agency action, findings, and conclusions found to be ... without observance of procedure required by law,' . . . with 'due account ... taken of the rule of prejudicial error'").

Nevertheless, the Rules are invalid for at least the following reasons. *First*, the limits on continuations and claims set forth in the Final Rules are inconsistent with the Patent Act, which places no limit on the number of continuations or the number of claims an applicant may file. *Second*, the Final Rules are inconsistent with established procedures and practices that have been relied upon by patent practitioners and patent applicants over the years, practices and procedures that have been both permitted and encouraged by the patent laws and judicial and historic agency interpretation of those laws. *Third*, the retroactive effect of the Final Rules deprives applicants of the full scope of their already disclosed inventions. *Fourth*, as with the deeply-flawed Continuations Rules, the Final Rules will severely curtail previously available Requests for Continued Examination ("RCE"), divisional applications, and the number of claims an applicant may prosecute.

As discussed below, the Final Rules will significantly impair the ability of inventors to obtain full patent protection on their inventions and so may remove many incentives for inventors to innovate or disclose their innovations so that the public may benefit.

A. The Patent Act Does Not Authorize the Final Rules' Limitation on the Filing of Continuations

The Final Rules include provisions that will effectively limit a patent applicant to only two continuation or continuation-in-part applications in an application family. Final Rule 37 C.F.R. § 1.78(d). The PTO has cited instances in which it argues patent applicants have utilized continuations to extend the life of a patent or write claims on new products while claiming the benefit of a parent application's earlier filing date. *Defendant's Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction* at pp. 25-26 (citing to *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.,* 277 F.3d 1361 (Fed. Cir. 2002) and *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002)). The argument does not justify contravention of the existing law of continuation applications, articulated in 35 U.S.C. § 120, which allows an inventor to file a continuation application that "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...." There is no limit on the number of such continuing applications, as recognized by recently amended 35 U.S.C. § 154, which refers to an earlier filed application "or applications under section 120. . . ." Section 154 further constrains the patent term of all continuation applications to expiration at 20 years from the filing date of the earliest application in a series, which prevents any extension of a patent term through the filing of continuation applications.

As noted by future Federal Circuit Judge Giles S. Rich in his 1952 commentary regarding Section 120 of the newly passed Patent Act:

Section 120 gives co-pending applications the benefit of the filing date of a parent case, but only if there is in the later application a specific reference to the earlier one. Some people have questioned whether this would apply to more than one succession, one application in succession to one parent; I think that, on careful reading, you will agree that *the number of generations of the lineage is unlimited*. (emphasis added)

Transcript of Address of Giles S. Rich on The Patent Act of 1952, publication of the New York Patent Law Association (1952). Judge Rich was a member of the 1952 Drafting Committee which played a large part in drafting the 1952 Act, and his comments regarding Section 120 provide strong evidence of the legislative intent regarding Section 120 not to impose any limit on the number of continuations an applicant can file. Patent prosecution practice and PTO examination has relied upon this interpretation for over fifty years.

B. The Continuation Rules Contradict Real-World Patent Prosecution Practice

The Continuation Rules would prevent patent applicants from engaging in the following well-established practices to protect the full scope of the inventions embodied in applicants' inventions, all of which are authorized and accounted for by codified at, *inter alia*, 35 U.S.C. §§ 120, 154.

1. Applicants Often File Continuations to Prosecute Non-Allowed Claims after Some Claims in an Application Are Allowed

Applicants often file continuation applications in cases where an Office Action issued by the PTO indicates that some, but not all, claims in an application are allowed. In such a case, a patent applicant may choose to obtain a patent on the allowed claims immediately, so that those claims can be enforced, licensed, or otherwise used in the applicant's business. Such a strategy allows applicants to begin to recoup the investment in the invention and thus benefit financially from their innovation, while pursuing additional prosecution of the rejected claims in a continuation application through claim amendments and/or argument on patentability. This approach is also expressly authorized by statute. *See* 35 U.S.C. § 120 (authorizing continuation applications) and § 132 (stating an application "shall be reexamined," with or without amendment by applicant, when applicant persists in his claim for a patent),

Comments by the PTO regarding the Continuation Rules, however, indicate that filing a third continuation application in this case would likely not be permitted and thus would not be reexamined, contrary to 35 U.S.C. § 132. For example, in the PTO Response to Comments 86 and 87 at 72 Fed. Reg. 46774, the PTO indicates that the Examiner's maintenance of a rejection

would "likely not be sufficient" grounds under § 1.78(d)(1)(vi) to permit the filing of a third continuation.

Thus, at the intersection of the second and third continuation application, applicants would have two options (1) continue the dialogue with the Patent Office to seek allowance of *all* the claims in the application, thereby delaying enforcement of any of the allowed claims (2) cancel the non-allowed claims and be foreclosed from seeking the full scope of the invention. However, the Final Rules also preclude an applicant from filing a second Request for Continued Examination (RCE) in an application if an RCE has been filed in *any application* in the application family, thus greatly limiting the applicant's ability to engage in such a dialogue with the Patent Office. The Final Rules consequently fail to accord with either the protections of the Patent Act (as discussed above) or with the patent clause of the Constitution (Art. I, § 8, "The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

2. Applicants Often File Continuations to Pursue Disclosed Subject Matter as Resources Permit

Applicants also often file continuation applications when a patent application discloses more subject matter than initially claimed. This can occur for many reasons. Patent applicants, especially small entities or individual inventors, often have limited resources. For such applicants, the cost of filing and prosecuting more than the 3 independent and 20 total claims permitted for the basic filing fee is prohibitive. For example, PTO fees for filing more than "3 and 20" claims, \$210 for each such "excess" independent claim and \$50 for each "excess" claim, can quickly add up. 37 C.F.R. § 1.16. In addition to these initial out-of-pocket filing fee costs, an applicant must pay for his attorneys' time, which in complex applications can be significant. Moreover, the experience of BADC members is that applications with fewer claims often are taken up by Examiners sooner and are prosecuted to allowance in less time, creating an even greater incentive for applicants to limit the number of claims in an application to basic application's "3 and 20."

For all of these reasons, applicants often have strong incentives to spread out their claims, either over a number of different applications filed simultaneously or over a number of applications filed as continuation applications in series. However, as noted below, the Claims Rules will significantly impair patent applicants' ability to file multiple concurrent applications, while the Continuation Rules may foreclose their ability to file sequential ones. Thus, under the Final Rules, a patent applicant would run the significant risk of being unable to claim all of the inventions or aspects of an invention disclosed in an application. However, any inventions disclosed in a patent application but not claimed are "dedicated to the public." *See e.g., Johnson & Johnston Assoc., Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002). Many companies, particularly small entities, may well therefore choose not to disclose their inventions at all but keep them as trade secrets, thus depriving the public of the benefits of such companies' innovation.

C. The Retroactive Effect of the Final Rules Would Deprive Patent Applicants of Existing Rights in Their Inventions

The Final Rules are also troubling in their retroactive effect on existing applications, including applications filed long before the Continuation or Claims Rules were proposed.

1. The Final Rules Will Deprive Patent Applicants the Right to Patent Protection on Inventions Disclosed in Existing Applications

The Continuation Rules will affect applications that were filed and prosecuted in reliance on the patent laws and existing rules and procedures that did not place arbitrary restrictions on the number of applications or continuations that could be filed.² Many of these applications are part of issued patent and patent application families having more than two continuation applications. Although the PTO will permit applicants in such a case to file "one more" continuing application without the need for a petition and showing, as discussed above and as detailed by GSK in its preliminary injunction briefing, it is highly unlikely that a petition for any further continuations will be granted. Thus, as noted above, any subject matter not yet covered by the claims of any application in the family will be dedicated to the public, to the detriment of inventors who have elected to file for patent protection rather than keep their inventions as a trade secret.

2. The Final Rules Affect Applicants' Substantive Rights in Their Pending Applications

Relying on old case law, the PTO has argued that patent applicants do not have any rights in their patent applications, and that the Final Rules therefore do not affect any substantive rights. *See Defendant's Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction* at pp 33-34.

However, due to a change in the patent laws in 2000 providing for publication of pending patent applications, this is no longer true. Although applicants cannot enforce any patent rights until a patent actually issues, under 35 U.S.C. § 154, applicants now have at least provisional rights in their patent applications. This statutory provision gives patentees the right to pursue damages beginning on the date of an application's publication if the claims of the issued patent are substantially the same as the claims as published.

² Although *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.,* 277 F.3d 1361 (Fed. Cir. 2002) and *In re Bogese*, 303 F.3d 1368 (Fed. Cir. 2002) both discussed the limits that can be placed on applicants who file excessive continuations in an attempt to improperly extend the patent monopoly, as extensively discussed by plaintiffs in their preliminary injunction briefing, the Federal Circuit has cautioned that the circumstances involved in these cases are exceptional, and should be very sparingly applied to other cases.

The Final Rules can adversely affect these substantive rights of patent applicants in their published applications in several ways. One noteworthy example stems from the interaction of the Final Rules to prevent an applicant from pursuing all of the claims in a published application if the application has more than "5/25" claims and is part of a family that already has more than two continuations. See Final Rule 37 C.F.R. §§ 1.75(b)(1) and 1.78(d). Although the PTO Claims Rules purport to permit an applicant to file as many as 15 independent claims and 75 total claims in sequential applications, the reality is that the Continuation Rules will in fact often make such sequential applications impossible to obtain if two continuation applications have already been filed. Thus, it may very well be the case that if a published application that is the second continuation in a patent family has more than 5/25 claims, the patent applicant will have to cancel the published claims over the 5/25 limit but will be unable to pursue the cancelled claims in a continuation application. As noted above, the subject matter of those cancelled claims that an applicant cannot pursue under the Rules will, under Federal Circuit case law, be dedicated to the public. In that case, the applicant will suffer a real, significant loss of rights in his invention.

D. The RCE Rules are Based on an Unrealistic View of Patent Applicants and their Resources

The Continuation Rules also limit an applicant to only one Request for Continued Examination ("RCE") – not just in any one application, but in an entire patent application family. Final Rule 37 C.F.R. § 1.114. As noted above, an application family can include several applications filed and prosecuted long before the Continuation Rules were proposed, and in which it is highly likely that an RCE has been filed. Unlike the "one more" continuation permitted without a petition and a showing, the Continuation Rules do not permit an applicant to

file any such "one more" RCE. This is contrary to 25 U.S.C. § 120 and § 132, authorizing continuation applications and requiring the PTO to examine them.

The PTO asserts that the rules limiting an applicant to only one RCE per application family represent no real impediment to an applicant's ability to prosecute their claims before the PTO because of the availability of appeal to the Board of Patent Appeals and Interferences ("Board").

However, the PTO does not tell the whole story. On July 30, 2007, just days after the Final Rules were approved by the General Accounting Office, the PTO published proposed changes to the rules of practice in appeals before the Board. *Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals*, 72 Fed. Reg. 41472 (2007) ("Proposed Appeals Rules"). The BADC, among many others, submitted comments regarding the Proposed Appeals Rules. As noted by the BADC and others, the Proposed Appeals Rules will impose significant new burdens, both substantive and procedural, on applicants seeking to appeal an Examiner's rejection of their patent claims. These burdens will significantly increase the costs of an appeal, as applicants will be required to prepare a Federal Circuit-like appendix consisting of a detailed explanation of the claims, drawings, and prior art. More importantly, the estoppel effect of statements made as part of this appendix will likely create significant disincentives to applicants to pursue any appeal.

In addition, RCEs usually are filed by applicants in order to obtain consideration of an amendment to the claims filed after a final rejection. Under current PTO practice, this final rejection is usually the second Office Action on the merits received during prosecution. What the restriction on RCEs effectively means is that applicants will have only *one* opportunity to amend their claims, i.e., after the first Office Action on the merits, since under 37 C.F.R. 1.116,

amendments after a final Office Action are strictly limited in type and scope. The PTO has suggested that the need to amend the claims is due in part to applicants' fault in preparing and filing their applications. However, that view simply fails to accord with the realities of how an application is prosecuted. For example, it is well-known among practitioners (and examiners) that different art is routinely cited in a second office action. The applicant, however, would be precluded from meaningfully responding to a multi-faceted prior art reference under the new RCE rules. Thus, as noted above, the Final Rules impose such onerous obstacles that applicants may simply choose to forego patent protection altogether and keep their inventions as trade secrets. This would result in a loss to the public, since these inventions would no longer be disclosed and would no longer be available for public use.

E. The Final Rules will Effectively Prohibit the Long-Standing, Established Practice of Filing Multiple Applications From Common Disclosures

Other provisions of the Final Rules will effectively prohibit the filing of "voluntary divisional" applications, i.e., multiple applications having the same specification and different claim sets. As with filing more than 5/25 claims in any one application, this patent application strategy is permitted by the patent laws and is pursued by applicants for many reasons.

Under *Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co.*, 144 U.S. 248, 252 (1892), a patentee cannot split up ownership of an existing patent by assigning separate claims to different parties.³ Thus, although a patent may have multiple owners, for example if there are joint inventors who are affiliated with different entities, each of those multiple owners is an owner of the entire patent, not of specific claims. In these and other cases, it may be desirable for

³ See Order On Microsoft's Motions For Judgment As A Matter Of Law And New Trial And Lucent's Motion To Alter Or Amend The Judgment Regarding U.S. Patent Nos. 5,341,457 And Re 39,080, U.S. District Court for the Southern District of California, Case 3:02-cv-02060-B-CAB Document 1975 (2007) citing *Pope*.

ownership and licensing considerations to split a single patent application up into multiple patent applications with different claims according to ownership. The current rules severely limit the ability of applicants to file such logical "voluntary" divisions.

Moreover, some applicants wish to limit the number claims they have in each application or allocate them in particular ways among several applications in view of *Pope Manufacturing* for business reasons in order to permit flexibility with respect to ownership and licensing of aspects of an invention. For example, applicants may wish to file separate applications and obtain separate patents on aspects of the same invention to be licensed, sold or enforced against different entities. For example, it has long been established practice to file one application directed to one or more apparatus disclosed in the specification, one application directed to the disclosed methods, one directed to a disclosed system and potentially another directed to underlying software. As noted above, excess claim fees involved in filing one applications since it can sometimes be significantly cheaper to do so. Also as noted above, it is widely believed among patent practitioners that Examiners prefer to examine applications with fewer claims, and consequently applicants may well prefer to file several smaller applications rather than one larger application.

However, the "overlapping applications" rules present significant obstacles to an applicant's ability to fully obtain patent protection on the inventions disclosed in these multiple applications. Under this aspect of the Final Rules, the claims of multiple applications containing overlapping subject matter will be treated as being in each such application for the purpose of determining whether each application has more than 5/25 claims unless the applicant can justify – to the satisfaction of the PTO – that such multiple applications are "patentably distinct" and

should be maintained. If the explanation is not deemed sufficient – and the Rules do not provide any guidance as to what would constitute a sufficient explanation – all claims of each application will be aggregated, and each application will be deemed to contain all claims of all applications for the purpose of determining whether any one application contains more than 5 and 25 claims.

F. The Claims Rules Also Are Inconsistent With Real-World Patent Prosecution Practices

The Claims Rules will in fact have a significant impact on patent applicants' ability to seek and obtain full patent protection on their inventions. Final Rule 35 C.F.R. § 1.75(b)(1). The Claims Rules present patent applicants with a Hobson's choice: Give up patent protection by filing no more than 5/25 claims or canceling claims to be within that limit, file a Suggested Restriction Requirement that may not be accepted, or file an Examination Support Document ("ESD"). None of these choices presents a realistic alternative for patent applicants seeking to obtain full protection on their inventions. Instead, they present a *de facto* limit on the number of claims, in violation of the patent statute, which places no such limit.

1. The ESD Requirement Imposes a De Facto Limit on the Number of Claims Applicants Can File

The PTO attempts to characterize its Claims Rules as permitting an applicant to file as many claims as desired, so long as the applicant "assists the PTO" in its examination by preparing and filing an Examination Support Document. However, as the PTO itself has acknowledged, the ESD requirements are so onerous that even the PTO expects that "no one will want to do that." *See Plaintiff Triantayllos Tafas' Memorandum in Opposition To Defendants' Motion for Issuance of Expedited Briefing Schedule in Lieu of a Standard Initial Scheduling Order* at p. 14. In fact, many of the BADC's members believe that there are significant

negatives associated with filing an ESD and trying to comply with its vague and potentially unattainable standards, so that it may be better not to file an ESD under any circumstances.

As GSK argued to this court, the ESD requirements are so extensive and so vague that it will be nearly impossible for applicants to fully comply or comply with any certainty that the PTO will be satisfied. *See Memorandum Opinion* dated October 31, 2007 at pp. 29-31.

2. The Real Cost of an ESD is the Lowered Value of the Resulting Patent

Moreover, the real cost of an ESD may not be the out-of-pocket cost involved in preparing and filing such a document. Instead, it may well be the substantial diminution in the value of any patent resulting from an application in which an ESD is filed which can result from the file history estoppel effects of statements made in characterizing the prior art and the substantial potential for charges of inequitable conduct. The latter risk is particularly important given the vagueness of the ESD requirements, the substantial undertaking required, and the inherent challenge of locating the "most closely related" prior art. If statements are found to be inaccurate, incomplete, or otherwise "misleading," any patent on any such an application is fair game for a charge of inequitable conduct that will make the patent unenforceable and potentially subject the prosecuting attorney to disciplinary action. Thus, the ESD rule, if implemented, will have a significant spillover effect on litigation and licensing of any patent in which an ESD was filed.

3. The Final Rules May Deprive Applicants of Substantive Patent Coverage if Applications Are Amended to Contain More Than 5/25 Claims

Under established, long-standing patent practice, Applicants often file or amend an application so that it contains more than 5 independent claims or more than 25 total claims. Nothing in the Patent Act prohibits applicants from doing so. Under the Claims Rules, this practice will effectively be unavailable due to the ESD requirements.

More significantly, applicants often amend their applications so that they contain more than 5/25 claims in response to Office Actions from the PTO. Under the Rules, any such amendments will trigger the requirement to file an ESD. Thus, because of the desire to avoid filing an ESD for the reasons noted above, an applicant may settle for less patent coverage than he would otherwise be entitled to in order to avoid filing an ESD. An exemplary scenario is set forth below.

An application is filed with 25 claims, 5 independent claims and 20 dependent claims (and thus not needing an ESD). Neither the Examiner nor the applicant suggests restriction of these claims. In a first Office Action on the merits, all of the independent claims are rejected over the prior art, but the dependent claims are all found to be allowable.⁴ Under long-standing, established practice, the applicant would be entitled to 20 independent claims if each of the allowable dependent claims were written into independent form.

However, under the Claims Rules, the applicant cannot amend the dependent claims into 20 independent claims without the need to file an ESD, which, as noted above, is highly undesirable to do. Therefore, in order to avoid the need to file an ESD, the applicant could amend only 5 of the allowable dependent claims into independent form and would be required to cancel the remaining claims. As noted above, if the applicant has previously filed two continuation applications, those claims could not be pursued in any further continuations, and thus would be lost to the applicant.

Alternatively, the applicant could combine the independent claims with the dependent claims so as to result in only 5 independent claims. However, this would result in limiting the scope of the allowable claims to more than is required by the prior art. For example, if each of

⁴ Such an Office Action is not uncommon.

the independent claims were amended to include the allowable limitations of one of their respective dependent claims so as to make them allowable independent claims, the other original claims dependent on those independent claims would automatically be narrowed to include the features of the dependent claims now in the independent claims - even though those limitations are not required by the prior art. Again, this would result in a substantive loss of patent rights to the applicant.

V. CONCLUSION

Thus, as discussed above, the Final Rules are inconsistent with, and will significantly impair, the ability of patent applicants to pursue full, meaningful patent protection on their inventions in the manner authorized by the Patent Act. The Final Rules therefore are inconsistent with the Patent Act which places no such limitations on the ability of patent applicants to file as many continuation applications or claims as may be needed to fully protect their disclosed inventions. Furthermore, the Final Rules are inconsistent with the realities of how patents are prosecuted. That the Rules are retroactive further compels the conclusion that these Final Results must not be implemented.

The BADC therefore respectfully requests that this Court permanently enjoin the Final Rules.

Respectfully submitted,

_/s/

Robert C. Bertin Virginia Bar No. 41,278 Attorney for *amicus curiae* Bar Assn. of the District of Columbia BINGHAM MCCUTCHEN LLP 2020 K Street NW Washington, DC 20006-1806 Telephone: 202-373-6672 Fax: 202-318-0534 email: r.bertin@bingham.com President, BADC PTC Section

Of Counsel Joslyn Barritt POWELL GOLDSTEIN LLP 901 New York Avenue NW Washington DC 20001

Co-Chair Patent Committee, BADC PTC Section

Vandana Koelsch HOWREY LLP 1299 Pennsylvania Ave., N.W. Washington, DC 20004

Chair *Amicus Curiae* Committee, BADC PTC Section

Dan Salehi, Esq. SNELL & WILMER LLP 600 Anton Blvd., Suite 1400 Costa Mesa, CA 92626

Co-Chair Patent Committee, BADC PTC Section

Attorneys for *Amicus Curie* Bar Association of the District of Columbia Patent, Trademark, & Copyright Section

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, the foregoing pleading was filed electronically using the CM/ECF system, which will send notification by electronic means to the following counsel of record:

Joseph D. Wilson Kelley Drye & Warren LLP 3050 K Street, NW, Suite 400 Washington, DC 20007-5108 email: jwilson@kelleydrye.com

Attorney for Plaintiff in CA. No. 1: 07cv846

Elizabeth M. Locke Kirkland & Ellis LLP 655 15th Street, NW - Suite 1200 Washington, DC 20005 email: <u>elocke@kirkland.com</u>

and

Craig C. Reilly Richard McGettigan Reilly & West PC 1725 Duke Street - Suite 600 Alexandria, VA 22314 email: <u>craig.reilly@rmrwlaw.com</u>

Attorneys for Plaintiffs in CA. No. 1: 07ev1008 (JCC/TRI)

Chuck Rosenberg United States Attorney Lauren A. Wetzler R. Joseph Sher Andrew Price Assistant United States Attorneys United States Attorney's Office 2100 Jamison Ave. Alexandria, VA 22314 email: <u>lauren.wetzler@usdoj.gov</u>

Attorneys for Defendants in CA. Nos. 1: 07cv846 and 1: 07cv1008

Rebecca Malkin Carr Pillsbury Winthrop Shaw Pittman LLP 2300 N Street, NW Washington, DC 20037 email: <u>rebecca.carr@pillsburylaw.com</u>

and

Scott J. Pivnick Pillsbury Winthrop Shaw Pittman LLP 1650 Tysons Boulevard McLean, VA 22102-4856 email: scott.pivnick@pillsburylaw.com

Attorneys for Amicus Elan Pharmaceuticals, Inc.

James Murphy Dowd Wilmer Cutler Pickering Hale & Dorr, LLP 1455 Pennsylvania Avenue, NW Washington, DC 20004 email: james.dowd@wilmerhale.com

Attorney for Amicus Pharmaceutical Research and Manufacturers of America

Dawn-Marie Bey Kirkpatrick Stockton LLP 700 13th Street, NW Suite 800 Washington, DC 20005 email: <u>dbey@kslaw.com</u>

Attorney for Amici Hexas, LLC The Roskamp Institute, and Tikvah Therapeutics, Inc.

Randall Karl Miller Arnold & Porter, LLP 1600 Tysons Boulevard Suite 900 McLean, VA 22102 email: randall_miller@aporter.com

Attorney for Amicus Biotechnology Industry Organization and Amicus Monsanto Company Charles Gorenstin Birch, Stewart, Kolasch and Birch, LLP 8110 Gatehouse Road Suite 100 East Falls Church, VA 22042 email: cg@bskb.com

Attorney for Amicus Intellectual Property Institute Williams Mitchell College of Law

Thomas J. O'Brien Morgan Lewis & Bockius LLP 1111 Pennsylvania Avenue, N.W. Washington D.C. 20004 email: to'brien@morganlewis.com

Attorneys for Amicus Curiae American Intellectual Property Law Association

R. Danny Huntington Bingham & McCutchen LLP 2020 K Street NW Washington, DC 20006 email: danny.huntington@bingham.com

Attorneys for Amicus Curie Féderation Internationale Des Conseils En Propriété Industrielle

Matthew Schruers Computer & Communications Industry Association 900 17th Street NW, Suite 1100 Washington, DC 20006 email: mschruers@ccianet.org

Attorneys for Amici Curie Public Patent Foundation, Computer & Communications Industry Association, AARP, Consumer Federation of America, Essential Action, Foundation for Taxpayer and Consumer Rights, Initiative for Medicines, Access & Knowledge, Knowledge Ecology International Prescription Access Litigation, Public Knowledge, Research on Innovation, and Software Freedom Law Center <u>/s/</u>

Robert C. Bertin Virginia Bar No. 41,278 Attorney for *amicus curiae* Bar Assn. of the District of Columbia BINGHAM MCCUTCHEN LLP 2020 K Street NW Washington, DC 20006-1806 Telephone: 202-373-6672 Fax: 202-318-0534 email: r.bertin@bingham.com