

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

TRIANAFYLLOS TAFAS

Plaintiff,

v.

JON W. DUDAS, et al.,

Defendants.

Case No. 1:07cv846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM
CORPORATION, et al.,

Plaintiff,

v.

JON W. DUDAS, et al.,

Defendants.

Case No. 1:07cv1008 (JCC/TRJ)

**BRIEF OF *AMICUS CURIAE* FÉDÉRATION INTERNATIONALE DES CONSEILS EN
PROPRIÉTÉ INDUSTRIELLE IN SUPPORT OF THE PLAINTIFFS' ANTICIPATED
MOTIONS FOR SUMMARY JUDGMENT**

R. Danny Huntington (VSB 16407)
BINGHAM MCCUTCHEN LLP
2020 K Street NW
Washington, DC 20006-1806
(202) 373-6000

Of Counsel
Maxim H. Waldbaum
Julie Busch
Henry L. Mann
SCHIFF HARDIN LLP
900 Third Avenue
New York, NY 10022
(212) 753-5000

Counsel for Amicus Curiae
Fédération Internationale des Conseils
en Propriété Industrielle

I. INTEREST OF THE AMICUS CURIAE

Established in 1906, FICPI is a Switzerland-based international and non-political association of approximately 4,000 intellectual property attorneys from over eighty countries (including the United States). FICPI's members represent individual inventors as well as large, medium and small companies. One of the members' major roles is to advise inventors in intellectual property matters and secure protection for industrial innovation. FICPI supports predictable, balanced global protection of patents, the global harmonization of substantive patent law, and the interests of inventors and the U.S. Patent and Trademark Office (the "PTO") for recognizing a fair scope of patent protection consistent with the claimed invention. FICPI's interest in a fair, non-arbitrary set of PTO procedures is made dramatically clear from the large and increasing patent filings from outside the United States, which account for approximately 45% of all patent filings and maintained patents. *See* USPTO Performance and Accountability Report: Fiscal Year 2007, Nov. 15, 2007 (the "2007 Annual Report") at 109-120, *available at* <http://www.uspto.gov/web/offices/com/annual/2007/2007annualreport.pdf>.

FICPI is one of only two major world organizations that advise the World Intellectual Property Organization ("WIPO"), an intergovernmental organization dedicated to promoting and protecting intellectual property rights worldwide, on all intellectual property matters. In this capacity, FICPI members have attended most Diplomatic Conferences concerning international intellectual property treaties and practices. WIPO's 180 member states (including the United States) comprise almost ninety percent of the world's countries. *See About WIPO*, at <http://www.wipo.int/about-wipo/en/>. As one of the sixteen specialized agencies of the United Nations system of organizations, WIPO administers intellectual property matters recognized by the U.N.'s member states and twenty-three international treaties concerning

intellectual property, including the Paris Convention for the Protection of Industrial Property. *Id.* The United States is a member of the WIPO Standing Committee on the Law of Patents (“SCP”) and works with WIPO in efforts to harmonize substantive patent law worldwide, including pursuant to a Substantive Patent Law Treaty, which currently is in draft form. *See* Substantive Patent Law Harmonization, at <http://www.wipo.int/patent/law/en/harmonization.htm>.

As FICPI is largely comprised of patent practitioners representing foreign inventors and corporate entities, FICPI is poised to give the court the perspective of the international patent community. Because the instant case may potentially significantly affect the way foreign companies operate vis-à-vis their patent filing strategies, FICPI would like to voice concerns regarding the threats posed by the PTO’s “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 “Final Rules”), and, in particular, Final Rule 1.78 regarding voluntary (not restricted by Examiner decision) and involuntary divisional practice.¹ In November 2007, in direct response to such Final Rules, FICPI, assembled at its Executive

¹ Under Final Rule 1.78, “a divisional can be filed for non-examined claims that are subject to a restriction requirement in the parent.

1. Without justification: 2 continuations of the divisional and 1 RCE of the divisional are permitted.
2. With justification: an unlimited number of continuations of the divisional and RCEs of the divisional are permitted.
3. Note restrictions on the claim of priority in the continuation of the divisional.
4. No continuations-in-part of the divisional are permitted”.

Committee in Seville, Spain, adopted a Resolution regarding Divisional Patent Applications and protection relating to those PTO rules. FICPI EXCO/ES07/RES/003 (Nov. 2007) (attached as Exh. A). FICPI is of the opinion that the PTO's Final Rules, particularly Rule 1.78, are contrary to well-established law.

II. THE PTO FINAL RULES ARE INCONSISTENT WITH LAW AND OTHERWISE UNSUPPORTABLE

The PTO's authority to regulate patent applications is granted by Congress and is subject to several limitations. First and foremost, 35 U.S.C. § 2(b)(2) empowers the PTO to "establish regulations not inconsistent with law". Thus, by implication, and as a matter of common sense, the PTO may not promulgate rules that violate any law.

A. The Paris Convention Limits The PTO'S Authority To Restrict Divisional Patent Applications

The Paris Convention for the Protection of Industrial Property, as amended, has been ratified by 172 Contracting Parties, including the United States. 21 U.S.T. 1583, 828 U.N.T.S. 306. Article VI, Clause 2 of the United States Constitution provides that treaties, along with the Constitution and Federal laws, are the "supreme Law of the Land". Thus, the Paris Convention constitutes binding authority which the Final Rules may not contravene. Article 4G of the Paris Convention provides that:

- (1) If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.

(2) The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized.

In accordance with both subsections of Article 4G, an applicant shall be entitled to divide a patent application to preserve the benefit of the priority date of the initial filing, either based on an examiner's finding or the applicant's own initiative. With respect to subsection (2), while the Convention permits signatory nations to "determine the conditions under which such division shall be authorized", it confers no express authority allowing signatories to restrict the number of such divisional applications that an applicant may seek to file. *Cf.* Board of Appeals of the European Patent Office case number J 0011/91, at para. 3.1.1 (Aug. 1992) (attached as Exh. B) (holding that an EPC rule placing an arbitrary time limit on when a divisional patent application could be voluntarily filed violated Article 4G of the Convention).

B. The Patent Act Does Not Confer Substantive Rulemaking Authority Upon The PTO

The Patent Act limits the PTO's authority regarding the nature and the scope of action it is authorized to take. According to the Patent Act, the PTO is entitled to establish regulations in order to "govern the conduct of proceedings in the Office", with the goal to "facilitate and expedite the processing of patent applications". 35 U.S.C. § 2(b)(2). The Patent Act did not vest any general rulemaking power to PTO. A review of recent Congressional proposals makes it clear that any change to the way claims are prosecuted by the PTO are

substantive and will not be allowed without Congressional approval. *See* Decl. of Harry F. Manbeck, Jr. of October 15, 2007 (“Manbeck Decl.”), at paras. 9 - 12.

The Final Rules that PTO wishes to implement, are consequently *ultra vires*, as substantive changes which severely impact the processing system. Indeed, the significant changes in rights proposed by PTO amount to a modification of the substantive law. While referring to the processing of patent applications, the changes operated by the Final Rules limit the number of continuing patent applications, divisional patent applications, independent and dependent claims, all inventor/invention limiting without any studied justification. *See, e.g.* Board of Appeals of the European Patent Office case number J 0011/91, Exh. B at para. 2.3.4 (Aug. 1992) (holding that the imposition of a cutoff time for the filing of divisional applications to be “a substantial limitation” of an “essential right of the applicant which . . . is not justified”). The consequence of such changes leads to a limited protection which an inventor’s *quid pro quo* of giving up effective trade secret protection is vastly compromised. *See* 35 U.S.C. § 122(a).

Additionally, some previous unsuccessful attempts by Congress to enlarge the PTO’s rulemaking power evidence the reality of the PTO’s current limited scope of authority. Indeed, as Mr. Manbeck mentioned in his declaration:

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.

Manbeck Decl. at paras. 11-12. Similarly, the Final Rules place improper restrictions on requests for continued examination (“RCEs”). 35 U.S.C. § 132 provides that applicants may request a reexamination of any patent claim rejected or subjected to an objection or requirement by the PTO. As is the case with continuation and divisional applications, the statute makes no provision for the PTO to limit a patentee’s right to do so, merely providing in subsection (b) that the PTO may “prescribe regulations to *provide* for the continued examination of applications at the request of the applicant.” 35 U.S.C. § 132(b) (emphasis added). This language is consistent with the notion that the PTO may determine the procedural rules and determine the appropriate fee to be charged for RCEs, so long as the rules “provide for”, rather than restrict the procedure.

RCEs serve an important role in the patent prosecution process, representing a form of finality with clarity: dialogue between examiner and applicant to determine the proper scope of claims. If the PTO places restrictions on the Applicant that curtail the examination process, the PTO should provide for alternative procedures to preserve this dialogue, such as additional interviews, informal submissions of proposed claims for review, etc. By simply restricting RCE practice, the PTO impermissibly closes an important communications channel that will adversely affect the quality of patents and create results directly contrary to the intent of the Final Rules.

The rigidity and capriciousness of the limitations that the Final Rules bring into the processing system have extreme consequences and unfairly affect major research industries at the university and corporate levels. Mere procedural changes could not accomplish this. The Final Rules clearly detract from inventors’ legal rights to define their inventions.

C. The PTO Is Without Authority To Make The Final Rules Retroactively Applicable

FICPI shares plaintiffs' position that the PTO's Final Rules are to be considered retroactive. Indeed, the Final Rules would apply to patent applications filed even before the date of the Final Rules' entry into force. As stated in the Memorandum In Support of Plaintiffs' Motion For A Temporary Restraining Order And Preliminary Injunction (the "GSK Memorandum") (dkt. no. 14), the Final Rules "retroactively change the legal consequences of already filed continuing applications and patent prosecutions strategies."

A modification of the processing system should not be imposed on applications already filed, in particular when this modification implies more duties to fulfill by the applicant, who, at the time of the application, was unaware of such duties. Indeed, the requirement of filing a petition and showing to justify more than two continuing applications qualifies as an imposition of new duties with respect to already filed, *i.e.* pending, applications. The retroactive impact of the Final Rules would cause significant injury (without noticeable benefit) to patent application owners, as discussed in the GSK Memorandum.

As this Court correctly noted in its Memorandum Opinion, "because retroactivity is not favored in the law", it is very unlikely that Congress intended to grant the PTO the power to promulgate retroactive rules without stating such intention explicitly. (dkt. no. 64, at 27). The Patent Act, however, does not give mention of the PTO's authority to make rules retroactively applicable. Accordingly, the PTO was not vested with any right to promulgate retroactive rules. Courts should be particularly wary of inferring retroactivity where the negative impact is of such profound magnitude, as is the case here with respect to the Final Rules.

D. The PTO Final Rules Place Arbitrary and Capricious Limitations On The Number Of Continuations, Divisionals, And RCEs

As further discussed in the Court's Memorandum Opinion, the PTO refers to organizational problems as a justification to amend its former rules, "on the ground that the growing number of continuing applications and increasing number and complexity of claims in applications had crippled the PTO's ability to examine newly-filed applications". *Id.* at 4. This is not supportable.

First of all, the statement directly contradicts the language of the recently released Annual Report, which parades the PTO's latest outstanding results. Indeed, the message presented therein by defendant Dudas is that the PTO achieved "another record-breaking year in performance". Annual Report at 3. Detailing the PTO's outstanding performance, Mr. Dudas affirmed that "last year, Patents achieved its highest examination compliance rate in a quarter of a century, at 96.5 percent. This year, Patents matched that with 96.5 percent compliance again." *Id.* Mr. Dudas also added that "beyond achieving higher compliance and in-process review rates, [the PTO's] patent examiners' decisions are also increasingly being affirmed by our Board of Patent Appeals and Interferences. This is the first time in recent history that the Board approved outright the majority of decisions." *Id.* at 4. Accordingly, it is clear that even from the PTO's own perspective, the system is not broken.

Given that the PTO's own public statements regarding its ability to perform its delegated functions without the Final Rules are at such great odds with what it has alleged in this suit, the Court should disregard such a claim as meritless. If there is some other unstated purpose such as making the PTO's workload easier to handle, the PTO should be required to evidence the necessary positive impact of the Final Rules.

In addition to the obvious inconsistencies of the PTO's stated reasons for modifying the current rules, the issue of organizational problems does not provide sufficient grounds to amend well accepted and implemented rules. The balance of hardships between the protection offered to patent applicants and administrative simplicity without study favors the former. In an article recently published in the Federal Circuit Bar Journal, it has been established that the limitation placed on continuing applications are taking up only 30% of the PTO's patent examining resources, but that only 20% of all continuations are second or more continuations. Ayal Sharon and Yifan Liu, *Improving Patent Examination Efficiency and Quality: An Operations Research Analysis of the USPTO, Using Queuing Theory*, 17 Fed. Cir. Bar J. 2, (2007). Thus, the net result of the initially proposed reform eliminates a mere 6% of pending applications. *Id.* Thus, the justifications above for dramatic limitations in claims coverage are belied by the PTO's own statistics which show only 6% of all patent applications would be affected by Final Rules. As the authors state, "the rationale behind this reform does not make sense." *Id.*

Another concern voiced by the PTO to justify the Final Rules is the issue of submarine patents. However, as discussed by Mr. Manbeck, Congress has already acted to curtail this form of abuse by changing the exclusivity period from 17 years from the date of issuance to 20 years from the filing date from which the patent claims priority. Manbeck Decl. at para. 36.

Finally, an analysis of the proposed changes made by the PTO reveals that such modifications would lead to an additional administrative burden on both sides. Indeed, the evidentiary justification requirement stated, for example, under Final Rule 1.78(G) imposes additional and heavy burdens to the applicant who submits a divisional, with substantial

additional paperwork while adding administrative work on the side of the PTO in charge of its review, assuming the PTO does its job.

E. The Exception Of Final Rule 1.78 Is Illusory

Under the previous rules of the PTO, an applicant could file more than two divisional applications as of right, *i.e.* as many 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. In order for an applicant to file more than two divisional applications, the Final Rules add a justification requirement under Rule 1.78(G), requiring the applicant “to justify why the amendment, argument, or evidence sought to be entered could not have been previously submitted.” (emphasis added). This is a standard which requires a proving of the negative, already shown to be a heavy burden for patentees in prosecution history estoppel situations under the *Festo* criteria. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*, 344 F. 3d 1359 (2003). The suggested layering of the Final Rules on patentees’ rights is not healthy for the patent system.

In fact, it appears by the Rules the PTO is attempting to address a problem not mentioned by them for justification, that is, not examiner overload but the abuse and misuse of the PTO proceedings by applicants who wish to delay or submarine the proceedings for later economic advantage. But law already exists to take care of those miscreants: prosecution history laches, as created by the Federal Circuit in *Symbol Technologies, Inc. v. Lemelson Medical, Education and Research Foundation*. 277 F.3d 1361 (2002). There is certainly no study or support to extend those solutions by use of the proposed Final Rules.

The proposed system of requiring a petition with supporting evidence is extremely vague and problematic to put into practice, not to mention expensive in both time and cost to the applicant. How is an applicant supposed to show by proofs that he could not have submitted his applications earlier? The PTO itself seemed to face issues explaining the concrete application of the exception presented by the Final Rules. Indeed, as Mr. Manbeck's Declaration pointed out:

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: (1) the applicant attempts to submit newly discovered prior art; (2) 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; (3) 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; (4) the applicant becomes disabled for a lengthy time during the pendency of the application.

Manbeck Decl. at para. 40 (internal citations omitted). Given the ambiguity as to how an applicant can successfully justify additional filings and the broad discretion of the PTO, this proposed "exception" is illusory in nature and does not alter the unnecessary rigidity of PTO's Final Rules.

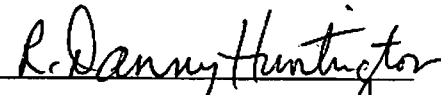
III. CONCLUSION

For the foregoing reasons, this Court should grant plaintiffs' motions for summary judgment and end the attempt to unilaterally implement the Final Rules without proper studied support and Congressional action.

Dated: January 2, 2007

Respectfully Submitted,

**Fédération Internationale Des Conseils
En Propriété Industrielle**

By: 
R. Danny Huntington (VA Bar # 16407)
Bingham McCutchen LLP
2020 K Street NW
Washington, DC 20006-1806
(202) 373-6000

Counsel for Amicus Curiae

Of Counsel:
Maxim H. Waldbaum
Julie Busch
Henry L. Mann
Schiff Hardin LLP
900 Third Ave 23rd Floor
New York, NY 10022
(212) 753-5000

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of January 2008, I filed the foregoing BRIEF OF *AMICUS CURIAE* FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE IN SUPPORT OF THE PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT with the Clerk of the Court and served a true and correct copy to the following by email:

Elizabeth M. Locke
Kirkland & Ellis LLP
655 15th Street, NW Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

and

Craig C. Reilly
Richard McGettigan Reilly & West PC
1725 Duke Street Suite 600
Alexandria, VA 22314
Email: craig.reilly@rmrwlaw.com

Counsel for GSK Plaintiffs

Joseph Dale Wilson, III
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street NW Suite 400
Washington, DC 20007
Email: jwilson@kelleydrye.com

Counsel for Plaintiffs Tafas

Lauren A. Wetzler
United States Attorney's Office
2100 Jamison Ave.
Alexandria, VA 22314
Email: lauren.wetzler@usdoj.gov

Counsel for the Defendants

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave., NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton, LLP
700 13th Street, NW, Suite 800
Washington, DC 20005
Email: dbey@kslaw.com

Counsel for Amicus Hexas, LLC, The Roskamp Institute, Tikvah Therapeutics, Inc.

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

Counsel for Amicus Pharmaceutical Research and Manufactures of America

Rebecca Malkin Carr
Pillsbury Winthrop Shaw Pittman LLP
2300 N St NW
Washington, DC 20037
Email: rebecca.carr@pillsburylaw.com

and

Scott Jeffrey Pivnick
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Blvd, Suite 400
McLean, VA 22102
Email: scott.pivnick@pillsburylaw.com

Counsel for Amicus Elan Pharmaceuticals, Inc.

Randal Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd., Suite 900
McLean, VA 22102
Email: randall_miller@aporter.com

Counsel for Amicus Monsanto Company

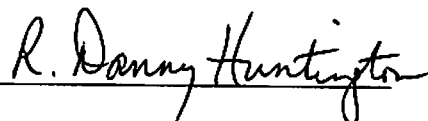
Charles Gorenstein
Michael K. Mutter
Birch, Stewart, Kolasch and Birch, LLP
8110 Gatehouse Rd., Suite 100 East
Falls Church, Virginia 22042
Email: cg@bskb.com

Counsel for Amicus Intellectual Property Institute of the William Mitchell College of Law

Robert E. Scully, Jr.
Stites & Harbison PLLC
1199 North Fairfax Street, Suite 900
Alexandria, Virginia 22314
Email: rscully@stites.com

Counsel for Amicus Human Genome Sciences, Inc.

**Fédération Internationale Des Conseils En
Propriété Industrielle**

By: 

R. Danny Huntington (VA Bar # 16407)
Bingham McCutchen LLP
2020 K Street NW
Washington, DC 20006-1806
(202) 373-6000

Counsel for Amicus Curiae