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, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	1:07cv1008 (JCC/TRJ)
	)	
JON W. DUDAS, et al.	)	
	)	
Defendants.	)	
	)	

BRIEF FOR *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF THE "GSK" PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. RETROACTIVITY OF THE NEW RULES PUNISHES APPLICANTS WHO MADE DECISIONS BASED ON, AND COMPLIED WITH, ESTABLISHED LAW.

A. Introduction and Background

The American Intellectual Property Law Association ("AIPLA") is a national association of more than 17,000 members interested in all areas of intellectual property law. AIPLA members include attorneys and patent agents employed in private practice and by corporations, universities, and government. AIPLA members represent both owners and users of intellectual property across the entire business spectrum from very large corporations to individual inventors and in essentially all areas of technology.

AIPLA presents this brief in support of a pending motion for a temporary restraining order and preliminary injunction enjoining the United States Patent and Trademark Office ("PTO") from implementing 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 "new Rules").

AIPLA focuses here on the related issues of irreparable harm and the public interest. It particularly addresses the irreparable harm caused by the retroactive impact of applying the new Rules to pending patent applications. Those applications were filed, and substantial resources committed, in reliance on fundamental principles of patent law that have applied for more than a century. As explained more fully below, the retroactive impact of the new Rules will cause irreparable injury not only to the GSK Plaintiffs, but to numerous patent application owners (whether business entities, universities, or individual inventors) throughout the country and over

a wide spectrum of technologies.[1] A delay in implementing the new Rules pending resolution on the merits, by contrast, should not adversely impact PTO operations or policy. For these reasons, AIPLA urges the Court to grant the temporary restraining order and preliminary injunction sought by the GSK Plaintiffs.

B. IP Owners Invested in Patent Protection: The Trade Secret/Patent Tradeoff

In 1974, the United States Supreme Court reaffirmed that state trade secret protection is not pre-empted by operation of the federal patent laws. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 473 (1974). Owners of patentable subject matter may elect to maintain their inventions as trade secrets, subject to independent creation or reverse engineering, or seek patent protection, which in theory "forbid[s] any use of the invention for whatever purpose for a significant length of time." *Id.* at 490.

Filing of a patent application does not immediately cause the loss of the trade secret aspects of the subject matter of the application. Applications initially must be kept in confidence by the PTO. 35 U.S.C. § 122(a). However, except in certain limited circumstances, applications must be published "promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title." 35 U.S.C. § 122(b)(1)(emphasis added). As a general rule, once a patent application is published trade secrecy is lost and the application's owner must rely exclusively on the issuance of patents for protection. *See generally* 4 Chisum on Patents § 11.06[3][b][vi].

Owners of intellectual property thus make a series of decisions over time. First, should they commit the resources to file a patent application or instead rely solely on trade secrecy for protection? The public, of course, has a strong interest in obtaining disclosure of the technology.

[1] While AIPLA focuses solely on the retroactive aspects of the new Rules, there may well be other issues not addressed here that would further tip the balance of hardships and likelihood of success.

See, e.g., Graham v. John Deere Co., 383 U.S. 1, 9 (1966) ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.") Second, do they allow their applications to be published 18 months after the filing of the first in a series of continuing patent applications or instead abandon the applications and rely on trade secrecy? Often, this decision is made before the owners have any feedback from the PTO about the scope, if any, of patent protection that may be afforded to their inventions.

But IP owners (*viz.* patent applicants) do not make their decisions in a vacuum. Rather, they are guided by longstanding law guaranteeing a full and fair opportunity to seek a spectrum of patent protection adequate to protect their investments during research and development, product commercialization, and in the patenting process itself. This full and fair opportunity resides in the competency of the PTO examiners, in the defined internal and judicial appeal processes, and in the general right to file continuing patent applications without arbitrary limitations. *See, e.g.,* 35 U.S.C. §§ 6, 134 (Board of Patent Appeals and Interferences); 35 U.S.C. § 141 (appeal to the Court of Appeals for the Federal Circuit); 35 U.S.C. § 145 (appeal to the United States District Court for the District of Columbia); 35 U.S.C. § 120 (continuation practice); *Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863); *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968); *Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975).[2]

As discussed in the GSK Plaintiffs' Memorandum at 9-11, the new Rules restrict the ability of patent application owners to file continuation applications to seek adequate protection for the inventions they elected to protect through the patent system, rather than relying on trade

[2] The GSK Plaintiffs discuss the only limitation on continuation practice, that of "prosecution laches," at pages 20-23 of their Memorandum. AIPLA will not burden the record with a definition of "continuation practice". There is a wealth of written material in the public record, and the Manbeck Declaration provides a fair summary.

secrecy. In this brief, AIPLA focuses on the irreparable harm flowing from the retroactive application of the new Rules' restriction on claiming and continuation practice. Implementing the new Rules will, as a practical matter, compel IP owners to (1) abandon pending patent claims, (2) abandon entire patent applications, and (3) surrender currently existing claim scope without adequate opportunity for consideration by the PTO.

While the new Rules purport to provide patent applicants with options for mitigating the harsh new restrictions, for the reasons discussed below, those options are largely illusory. Indeed, they punish owners of patent applications who have relied on existing law to secure protection for all of the inventions disclosed (but not necessarily claimed) in their patent applications. This reality applies across the spectrum of technologies. The new Rules strip owners of the right to pursue additional applications, substituting options that are discretionary to the PTO as well as expensive and often impractical. Moreover, the new Rules will require many owners to blindly elect which of their disclosed inventions to protect without the benefit of the further developments on which they had planned to base their decisions.[3] These impacts of retroactivity will be immediate, widespread and irreparable.

C. The New Rules Implicate Virtually All Areas of Technology

Innovators from virtually all industry segments have been relying on the existing standards to guide their decision making, and will suffer irreparable harm if the new Rules, with their retroactive requirements, become effective on November 1, 2007. That is the message AIPLA has loudly received from its members.[4] In a slightly different context the National

[3] Those disclosed inventions not protected by patent claims become available to the public.

[4] As an example of the overarching concern created by the new Rules, AIPLA recently held its Annual Meeting in Washington, D.C. During a luncheon presentation, the incoming president of the organization made some remarks to over 800 people in attendance. One of the loudest rounds of applause he received came in response to his comments regarding the harm to IP owners from the new Rules. AIPLA tenders herewith the declarations of

Association of Manufacturers has observed that the "American future hinges on optimizing innovation. U.S. investors are willing to take risks on new ideas; consumers welcome new products and this country protects and rewards research and innovation through intellectual property rights."[5] Retroactive application of the new Rules will cause severe and irreparable harm to innovators across the spectrum of technologies; thus the public interest would be served by delaying their imminent implementation.

II. THE RULES WILL CAUSE IRREPARABLE HARM GENERALLY AND ARE CONTRARY TO THE PUBLIC INTEREST.

A. Irreparable Harm Resulting from Lost Patent Rights

If the new Rules are allowed to take effect as planned on November 1, 2007, it will be impossible to return to the status quo – and important intellectual property rights will be permanently lost. These rights include specific claims as well as entire patent applications. Moreover, in the absence of relief from this Court, as of November 1, 2007 patent applicants will be required to make premature decisions involving surrender of patent rights that cannot be undone after trial, even if trial were expedited. By contrast, delaying implementation of the new Rules until the Court has finally ruled on the merits will not cause material harm to the PTO.

The PTO has provided several procedures to address concerns caused by retroactive application of the new Rules and the resultant loss of rights. However, as discussed below, these procedures do not mitigate the irreparable harm.

The kind of loss that patent applicants will face is significant, and the loss will be impossible to reverse. For many years, patent applicants have frequently elected to protect their intellectual property by including a number of patentably distinct inventions in a single

Samson Helfgott, Joseph F. Hetz, David J. Kappos, and Burt Magen as exemplars from various industries that will experience the profound impact of retroactivity of the new Rules.

[5] *See, e.g.,* http://www.nam.org/s_nam/bin.asp?TrackID=&SID=1&DID=237701&CID=202612&VID=2.

application, for purposes of efficiency and flexibility. *See, e.g., In re Berg*, 140 F.3d 1428, 1435-36 (Fed. Cir. 1998) ("If a potential applicant is unsure whether it has more than one patentably distinct set of claims, the PTO advises that it file all of the claims as one application."); Janice M. Mueller, An Introduction to Patent Law at 172-73 (2003); Landis on Mechanics of Patent Claim Drafting, §§ 2.10, 7.1, 10.1 (1999 ed.); Jeffrey G. Sheldon, *How to Write a Patent Application*, § 6.5.18, Practicing Law Institute (2004). This approach, for example, is particularly useful to new companies formed to develop and commercialize emerging technology. Such applications almost inevitably have more pending claims than will be permitted by the new Rules (five independent claims and 25 total claims).

Applicants who have adopted this approach will be allowed to seek relief from the retroactive impact of the unexpected limitation of the number of claims using one of the two procedures alluded to above: by filing a "Suggested Requirement for Restriction"[6] or by filing an "Examination Support Document."[7] By using the first option (the "SRR"), patent application owners can request that the PTO carve out separate applications and allow them to be prosecuted in parallel. However, the PTO is not obligated to accept such requests. Thus, the PTO would

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[6] If an application contains two or more independent and distinct claims, the applicant may submit a suggested requirement for restriction ("SRR") before the earlier of a first Office action on the merits or a requirement for restriction in the application by the Office. An SRR must also include (a) an election of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and (b) an identification of the claims to the elected invention. The Office suggests that an SRR include an explanation for the suggested restriction.

[7] An applicant may present more than five independent claims or more than twenty-five total claims in an application, if the applicant files an ESD in compliance with new Rule 37 CFR 1.265 before the first Office action on the merits of the application. An ESD must include: (1) a preexamination search statement in compliance with new Rule 37 CFR 1.265(b); (2) a listing of the reference(s) deemed most closely related to the subject matter of each claim in compliance with new Rule 37 CFR 1.265(c); (3) identification of all the limitations of each claim (independent and dependent) that are disclosed by the reference(s); (4) a detailed explanation particularly pointing out how each of the independent claims is patentable over the cited reference(s); and (5) a showing where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification.

have the right to block from substantive consideration future claims to previously-disclosed inventions that application owners have up until now been entitled to present and have reviewed.

That change, as applied to existing applications, is profoundly unfair and will cause irreparable harm to owners of patent applications. If an examiner chooses not to permit the filing of separate applications, the applicant's intellectual property – unprotectable by secrecy if the application has been published – will be effectively destroyed. The forfeiture will come in the form of a reduced number of claims for each of the inventions disclosed in the application or no claims at all to one or more of such inventions. *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (en banc) (subject matter disclosed in a patent application but not claimed is dedicated to the public).

The new Rules nominally allow applicants to seek relief from the limitations on the number of claims by the second option of filing an ESD. The unfortunate reality however, is that the financial and other burdens imposed by the ESD make this an impractical option for many application owners. *See* 72 Fed. Register 161 at 46798 (comment 219). Indeed, the PTO has raised its estimate of the average cost per application under the ESD process once already, from $2,500 to $2,563-$13,121, but practitioners estimate the cost to be much higher.[8]

An ESD, in addition to being expensive to prepare, will create a high risk of inadvertent misstatements of fact about the prior art, the claims, or both, increasing the likelihood of allegations of inequitable conduct during future litigation and thereby diminishing the value of the issued patent. *Id.* at 46801 (comment 233). Furthermore, the required statements made by

[8] *See* Response to Comment 219, See 72 Fed. Register 161 at 46798. *Cf.* Letter dated October 17, 2007 from David E. Bounty, Vice President, Intellectual Property, Cantor Fitzgerald L.P. to Honorable Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs, OMB, Exhibit A (letter of Philip Steiner dated October 8, 2007, estimating the cost of new IDS rules, for 21 references, to be $27,000).

counsel in an ESD are at variance with counsel's role as an advocate.[9] If, upon advice of counsel, the client instead elects to reduce the number of claims to conform to the new Rules, the client may thereby be abandoning valuable IP rights. This presents a Hobson's Choice: either create a record potentially damaging to the patent property or abandon one's rights altogether.

The new Rules even punish applicants for previously having made purely procedural decisions fully authorized under then-existing law. For example, the new Rules cut off an applicant's ability to obtain patent protection by further restricting continuing practice, simply because the applicant had filed a "divisional" application before filing a "continuation" application. *See* Questions and Answers Claims and Continuations Final Rule C12 (September 27, 2007).[10] This formerly innocuous decision, having nothing to do with the substance of the invention, now will result in the loss of two continuation applications under the new Rules, a punishing sanction against the owner that cannot be justified.

Another common practice of applicants is to file multiple patentably indistinct embodiments of an invention in a single application. *See, e.g.,* Landis on Mechanics of Patent

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9 This is because counsel will be required to make concessions of the type normally reserved for litigation, where budgets allow lawyers the luxury of more careful consideration.

10 For example, if, prior to publication of the new Rules, an applicant filed an initial application claiming inventions "A" and "B," received a Restriction Requirement between inventions "A" and "B," prosecuted claims for invention "A" to issuance, filed a divisional to the non-elected claims for invention "B," and subsequently determined the need for filing a continuation directed to unclaimed embodiments related to invention "A," the applicant will be limited to only one continuation directed to invention "A" and one continuation directed to invention "B." This scenario was proposed to the PTO in Questions and Answers Claims and Continuations Final Rule C12: "If applicant received a restriction requirement in the initial application and elected invention 'A' in the initial application, and then applicant filed a divisional application that contains the claims to the non-elected invention 'B' that has not been examined, can applicant file two continuation or CIP applications to present claims to the elected invention 'A' claiming the benefit to the divisional application and the initial application?" In response, the PTO said "No . . . applicant may file a single continuation application for invention "A" . . . [but] . . . may not file the second continuation application for invention 'A' . . . . Furthermore, applicant may only file one continuation application for invention 'B'." The PTO went on to state that "In comparison, if applicant files the continuation applications directly claiming the benefit of the initial application, applicant may file two continuation or CIP applications of the initial application to present claims to the elected invention 'A'. . . [and] . . . applicant may file two continuation applications of the divisional application to present claims to the non-elected invention 'B'." Thus, if applicant already made the decision to file the divisional application before the continuation application months or years before the new Rules were even proposed, applicant loses one continuation for invention "A" and one continuation for invention "B."

Claim Drafting § 10.1. The GSK Plaintiffs are merely one of countless examples of businesses which have adopted this respected strategy. But under the new Rules applicants who have chosen this approach will have at most the right to protect only five of these embodiments per application and a maximum of fifteen embodiments over time – with only five independent claims per application and one independent claim per embodiment.[11] Because those applicants will not be allowed to devote additional independent claims to any other embodiment, all other embodiments, which ordinarily would be covered by new claims filed in additional continuing applications, will become unprotectable. *Johnson & Johnston Assoc., supra.* Whatever can be said about the wisdom of imposing such restrictions prospectively, their retroactive application to those who have unknowingly set themselves up for loss of rights is unconscionable.

Another irretrievable consequence of retroactivity derives from the fact that many patent applicants made decisions a year or more ago to best protect their inventions by simultaneously filing multiple applications based on the same (or similar) specifications, in order to provide a spectrum of protection for a set of inventive concepts. Mueller, *supra*. Under the new Rules, all the claims from all those existing applications will be counted as though they are contained in each application unless the applicants commit the time and resources to justify having parallel applications or combine the sets of claims into one application and abandon all other applications and limit claims to the total amount allowed. Moreover, requiring applicants to engage in this type of analysis (explaining why the claims are "patentably distinct") is not only expensive, but invites assertion of new invalidity arguments, not to mention inequitable conduct claims, as described above.

[11] While an ESD could be filed to allow more claims, as discussed above, an ESD is impractical.

In a related context, retroactive application of the new Rules will even result in applicants having to abandon patent applications containing allowable subject matter or face additional charges of inequitable conduct. This situation will arise, for example, when references come to light in foreign prosecution occurring years after the original United States application was filed. In the interim, if the applicant has exhausted its right to file continuing applications (even its "one more" application)[12] and receives a notice of allowance, the applicant has no right to amend the claims to overcome the reference. The applicant, however, has an obligation to provide this invalidating art to the PTO; but the PTO has no obligation to read it, let alone reopen prosecution. The applicant must then choose between permitting issuance of potentially invalid claims and abandoning the application altogether (or filing a petition which is discretionary with the PTO).

AIPLA recognizes that the new Rules permit applicants to petition for additional continuations. However, in the comments to the new Rules, the PTO has indicated that there are very few reasons why a petition to file another continuation would be granted. The following, for example, are indicated as not, or not likely to be, sufficient: submitting newly discovered prior art (Response to Comment 85 at p. 46773); amending claims as a result of newly discovered prior art (Response to Comment 85 at p. 46773); discovering that the Examiner is under a misunderstanding (Response to Comment 86 at p. 46774); the Examiner's changing his or her interpretation of the claims (Response to Comment 86 at p. 46774); realizing that a limitation in an allowed claim is unduly limiting to protect a different embodiment or species of the invention (Response to Comment 90 at p. 46774-75); tailoring claims to better define the

[12] Applicants may file, without a petition and showing, two continuation or continuation-in-part (CIP) applications; and one request for continued examination (RCE) in an application family, wherein an "application" family includes the initial application and its continuation or CIP applications. Applicants may also file, without a petition and showing, one more continuation if they have exhausted the allowed number of continuations prior to November 1, 2007.

invention with respect to an applicant's product recently discovered to have become commercially viable (Response to Comment 91 at p. 46775); tailoring claims to better define the invention after discovering a competing product (Response to Comment 91 at p. 46775);[13] acquiring the necessary financial resources (Response to Comment 91 at p. 46775); a court's determination that the format of a patented claim is improper (Response to Comment 91 at p. 46775); reassignment by the PTO of the Examiner for the application (Response to Comment 96 at p. 46776); finding errors detrimental to applicant made by a practitioner (Response to Comment 97 at p. 46776); and physical disability of the applicant for a lengthy time during pendency of the application (Response to Comment 100 at p. 46777).

Allowing retroactive implementation of the new Rules would result in loss of patent claims, and even entire applications, by individuals, universities, and companies who have relied on existing law when they formulated and implemented their patent application strategies. That loss constitutes irreparable harm, for the reasons already explained by the GSK Plaintiffs in their brief. That irreparable loss certainly would be contrary to the public interest since the American public counts on the patent system as a reliable source of innovative new products. "Yankee ingenuity has always been America's strength and it has generated the productivity that has accounted for half of the GDP growth over the past 50 years."[14]

B. Irreparable Harm Associated with Compliance Costs

Retroactive application of the new Rules also creates new and additional obligations on applicants, including but not limited to application identification requirements, which

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13 *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874, 9 U.S.P.Q.2d. (BNA) 1384, 1390 (Fed. Cir. 1988) (''Nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.''). Thus, the new Rules would prohibit such continuation practice in direct conflict with Federal Circuit authority that approves it.

14 *See* http://www.nam.org/s_nam/bin.asp?TrackID=&SID=1&DID=237701&CID=202612&VID=2.

collectively will require applicants to devote extraordinary amounts of time and incur unjustifiably excessive costs for compliance. Irreparable harm will result from the hundreds of millions of dollars (as a conservative estimate) of unrecoverable compliance costs that American industry will face in the absence of relief from this Court. Many owners of patent applications already have begun the burdensome effort to comply with the new Rules.[15] The only way to prevent imposition of most of those costs is to delay implementation of the new Rules presently planned for November 1, 2007.

III. CONCLUSION

In view of the foregoing, and on behalf of its more than 17,000 members, *amicus curiae* American Intellectual Property Law Association respectfully requests that the Court grant the GSK Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction. Only by doing so will the Court, pending its full adjudication on the merits of the instant lawsuit, prevent the irreparable loss of rights that is the necessary consequence of retroactive application of the new Rules. Granting relief would maintain the status quo, protecting the investment-backed expectations of a broad array of industries, to the ultimate benefit ofthe general public.

Respectfully submitted,

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[15] The GSK Plaintiffs have submitted evidence to the Court of the costs they are incurring. Additional evidence from the declarations of Messrs. Magen, Hetz, and Kappos, submitted herewith as exemplars, is offered for the obvious proposition that costs of compliance expected to be incurred in other technology segments in the immediate future will be as much or even greater.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of October 2007, I electronically filed in Case No. 1:07cv1008 (JCC/TRJ) the foregoing Brief For *Amicus Curiae* American Intellectual Property Law Association In Support Of The "GSK" Plaintiffs' Motion For A Temporary Restraining Order And Preliminary Injunction using the CM/ECF system and that service was thereby accomplished on:

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