

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

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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 has been granted leave to file an amicus brief in this consolidated case. (Dkt. # 109). AIPLA’s brief explains why the retroactive application of the PTO’s “Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications” (the “new Rules”) is inappropriate.¹

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

A. IP Owners Surrender Trade Secret Property For Patent Protection

As noted in AIPLA’s prior brief (Dkt. # 30-2 in No. 1:07cv1008), 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.

Trade secrets are property. In *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), in the context of a Fifth Amendment “taking” dispute, the Court identified several characteristics of trade secrets that are shared by more tangible forms of property: a trade secret is assignable; a trade secret can form the res of a trust; and a trade secret passes to a trustee in bankruptcy. *Id.* at

¹ While AIPLA focuses solely on the retroactive aspects of the new Rules, its silence on issues not addressed here should not be taken as acquiescence in the positions taken by Defendants.

1002. “This general perception of trade secrets as property is consonant with a notion of ‘property’ that extends beyond land and tangible goods and includes the products of an individual’s ‘labor and invention.’” *Id.* at 1002-1003 (citations omitted).²

The filing of a patent application does not immediately cause the loss of the trade secrets disclosed in the application. Applications initially must be kept in confidence by the PTO. 35 U.S.C. § 122(a). However, with one exception, pending utility 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 the property rights in thus-disclosed trade secrets are 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].

Consequently, owners of patentable subject matter make a series of decisions over time. First, should they commit the resources to file patent applications or instead rely solely on trade secrecy for protection? The public, of course, has a strong interest in obtaining disclosure of the technology. *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 information from the PTO about the scope, if any, of patent protection that may be afforded to their inventions.

² As shown *infra*, patent applications also have these and additional characteristics.

But even then patent applicants need 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 in 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.³ *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).

In summary, it cannot seriously be denied that patent applicants have filed applications, allowed publication of trade secret property, and committed substantial resources, in reliance on fundamental principles of law that have applied for more than a century.⁴

B. The New Rules Retroactively Impact Applicants' Substantive Rights

The new Rules restrict the ability of patent applicants to file continuation applications to seek adequate protection for the inventions they had elected to protect through the patent system, rather than relying on trade secrecy. Retroactive implementation of the new Rules will, as a

³ Prosecution laches represents a reasonable limitation on continuation practice as an equitable doctrine that permits a court to refuse to enforce a patent when it has issued only after an unreasonable and unexplained delay in prosecution. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1363, 1368 (Fed. Cir. 2002); *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002) (permitting the USPTO to apply this equitable doctrine). However, as this Court observed, the Federal Circuit cautioned it is to be used sparingly “lest statutory provisions be unjustly vitiated.” *Tafas v. Dudas*, 511 F. Supp.2d 652, 664-65 (E.D. Va. 2007) (*citing* “*Symbol IV*”).

⁴ AIPLA showed in its prior brief (Dkt. # 30 in No. 1:07cv1008) that 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. The supporting evidence is of record and is incorporated herein by reference.

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. The kind of loss that patent applicants will face is significant and their substantive rights will be affected materially.

1. **The Retroactive Impact on Common Prosecution Practices**

For many years, patent applicants have frequently elected to protect their intellectual property by including a number of patentably distinct inventions in a single 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*, § .5.18, Practising 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). Under such circumstances, applicants pay the PTO for the excess claims. 35 U.S.C. § 41(a)(1)(B). The end result of the new Rules, however, is that applicants with pending applications will have taken from them the right to protect the spectrum of inventions disclosed in their already-filed applications, despite having paid the fee set by Congress. Instead, their fate, and the risk of losing substantive rights, will be at the discretion of the PTO. Because those applicants will not be allowed to keep independent claims exceeding the retroactive cap, they will have lost the right to obtain any protection for inventions corresponding to the forcibly abandoned claims. Yet at the time those applications were filed, the applicants expected and

understood those other inventions could be protected by new claims filed in additional continuing applications. The applicant's investment in such inventions will be substantially or completely lost. *See generally Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054-55 (Fed. Cir. 2002) (en banc) (subject matter disclosed but not claimed is dedicated to the public and cannot be recaptured by the doctrine of equivalents).

Another longstanding and accepted practice by applicants has been the filing of multiple patentably indistinct embodiments of an invention in a single application. *See, e.g., Landis on Mechanics of Patent Claim Drafting* § 10.1. The GSK Plaintiffs are merely one of countless examples of businesses which have adopted this respected strategy – paying the statutory fee for “excess” claims. 35 U.S.C. § 41. 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.⁵ Because those applicants will not be allowed to devote additional independent claims to any other embodiment, they will have lost the right to obtain any form of protection for those embodiments, which ordinarily would be covered by new claims filed in additional continuing applications. *See Johnson & Johnston Assocs.*, 285 F.3d at 1054-55.

Still another such practice that will be ensnared as a consequence of the new Rules' retroactivity derives from decisions made a year or more ago by applicants 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*. In this instance also, applicants have paid the statutory filing fees for each

⁵ While an ESD could be filed to allow more claims, as discussed *infra*, that is not a realistic alternative.

application, and for any claims beyond the number encompassed by the base fee. 35 U.S.C. § 41. Under the new Rules, however, all the claims from all those existing applications will be counted as though they are contained in each application unless the applicant (a) commits the resources and is successful in arguing the inventions are patentably distinct, thus escaping the limitation in the new Rules or (b) combines the sets of claims into one application and abandons all other applications and limits claims to the total number permitted under the new Rules. Requiring applicants to analyze and explain why their claims are “patentably distinct” is not only expensive, but invites assertion of new invalidity arguments by accused infringers in subsequent infringement litigation, not to mention inequitable conduct claims, as described below.

2. Other Harm Resulting from Retroactive Application of the New Rules

Retroactive application of the new Rules also will harm substantive rights in other ways. *Tafas v. Dudas*, 511 F. Supp. 2d 652, 664-65 (E.D. Va. 2007) There will be situations that result in applicants having to abandon patent applications containing allowable subject matter or face charges of inequitable conduct. One such situation will arise, for example, when prior art 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)⁶ and receives a notice of allowance, that 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 consider the references, let alone reopen prosecution. The applicant must then choose between permitting

⁶ Defendants concede that under the new Rules, applicants may file, without a petition and showing, only 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 application if they have exhausted the allowed number of continuations prior to November 1, 2007. Memorandum in Support of Defendants’ Motion for Summary Judgment at 9 (Dkt. # 127).

issuance of potentially invalid claims and abandoning the application altogether (or filing a petition which is discretionary with the PTO).

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).⁷ 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.

3. Retroactivity Widely Impacts and Harms Innocent Applicants

Whatever can be said about the wisdom of imposing the PTO's proposed new restrictions prospectively, their retroactive application to those who have in good faith taken actions that were previously perfectly appropriate but suddenly cause substantial loss of rights is unconscionable. In Defendants' response to AIPLA's preliminary injunction brief (Dkt. # 55 in

⁷ 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."

No. 1:07cv1008), they downplayed the number of applications subject to retroactive treatment under the 5/25 rule. They now concede a “backlog of more than 700,000 unexamined patent applications in 2006.” Memorandum in Support of Defendants’ Motion for Summary Judgment at 33 (“Defendants’ Brief”) (Dkt. # 127). And the PTO’s statistics about agency backlog disclose that there are currently more than 760,000 pending applications awaiting a first office action and thus subject to the new Rules pertaining to claim limitations, in addition to the untold multitude of applications in later stages of prosecution filed in good faith based on century-old continuation practice. Defendants also contended in their response to AIPLA’s preliminary injunction brief that new Rules 78 and 114 will not apply to applications filed prior to November 1, 2007. They apparently now recognize the fallacy of that assertion since it is not repeated in Defendants’ Brief. *See, e.g.*, 72 Fed. Reg. at 46717, column 1, second and third full paragraphs.

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 for the vast majority of applicants illusory. Consequently, the PTO’s view that the new Rules “do not compel the abandonment of pending claims,” Defendants’ response to AIPLA’s preliminary injunction brief at 3, ignores the reality (discussed *infra*) that one of the two new options is unreasonably expensive and fraught with risk while the other exists only at the PTO’s discretion. This reality applies across the spectrum of technologies. The new Rules strip truly substantive rights from owners of patent applications who have relied on existing law to secure protection for all of the inventions disclosed in their patent applications.

C. The New Rules Do Not Provide Real Relief From Their Retroactive Impact

Defendants contend that the new Rules will not compel abandonment of pending claims because of two new procedures they contain. In particular, applicants who have adopted one or more of the traditional strategies noted above will be allowed to seek relief from the retroactive

impact of the unexpected limitation of the number of claims using one of two procedures: by filing a “Suggested Requirement for Restriction”⁸ or by filing an “Examination Support Document.”⁹ The first option (the “SRR”) would allow patent application owners to request that the PTO carve out separate applications to be prosecuted in parallel. However, the PTO is not obligated to accept such requests.

In their response to AIPLA’s preliminary injunction brief, Defendants concede that an examiner is not required to accept an applicant’s suggested restriction requirement, but counter that an examiner who did not accept an applicant’s proposal might issue one “of his or her own, dividing the multiple claimed inventions in a different way than proposed by the applicant.” Defendants’ response to AIPLA’s preliminary injunction brief, at 6. While anything is possible, AIPLA believes it would be highly unlikely that an examiner who rejects an applicant’s SRR will nonetheless go through the time and effort to issue an alternative restriction requirement. In all events, it remains undeniable that the PTO would have the right and discretion 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.¹⁰

⁸ 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. 72 Fed. Reg. at 46726.

⁹ 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 C.F.R. § 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 C.F.R. § 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 C.F.R. § 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.

¹⁰ Without a restriction requirement, applicants will be limited to the 5/25 rule and will not be able to file divisional applications, which would allow them the ability to start a new continuation chain.

That change, as applied to existing applications, is profoundly unfair and will cause patent applicants to lose substantive rights – inventive concepts constituting trade secret property disclosed in good faith as part of the patent application. If an examiner chooses not to permit the filing of separate applications, the applicant’s intellectual property – no longer protected 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 (another Hobson’s choice the new Rules impose on applicants). *Johnson & Johnston Assocs., supra*.

The new Rules also nominally allow applicants to seek relief from the limitations on the number of claims by 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. Reg. 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, Defendants’ Brief at 67, but practitioners estimate the cost to be much higher.¹¹ One possible reason for this disparity is the PTO’s failure to recognize that the additional risk imposed on a client submitting an ESD analysis will require far more careful consideration and analysis by counsel than if an attorney was preparing a preliminary patentability assessment for purely internal use by a client. The additional effort and analysis come at significantly increased cost.

This additional risk results from each ESD becoming part of the patent prosecution history, subject to detailed review by potential or accused defendants in future litigation, seeking to locate any arguable misstatements of fact about the prior art, the claims, or both, on which to

¹¹ *See* Response to Comment 219, 72 Fed. Reg. at 46798.

base allegations of inequitable conduct.¹² To minimize that risk in the event of downstream patent litigation, counsel will need to invest efforts of the type currently associated with well-funded litigation before (a) representing which references uncovered during the required search “the applicant deems to be the most closely related to the claimed invention;” (b) identifying “all the limitations of each claim (independent and dependent) that are disclosed by the reference(s);” and (c) representing “why the claimed invention is patentable over the listed references.” *See* note 9, *supra*, quoting new Rule 37 C.F.R. § 1.265 (emphasis added). This will significantly increase costs to patent applicants.

In their response to AIPLA’s prior brief, Defendants sought to dispel the risks created by the ESD with the assertion that the PTO will not use the disclosed information to “gin up reasons why an invention is unpatentable.” Defendants’ response to AIPLA’s preliminary injunction brief at 8. AIPLA did not suggest that was the PTO’s intent, but, in all events, Defendants’ response ignores patent litigation realities (not to mention the doctrine of unintended consequences). While it may not be the PTO’s intent “to trap applicants or their counsel into committing inequitable conduct,” *id.*, the risk comes from defense lawyers, not the PTO, deciding to make inequitable conduct accusations based on statements in an ESD. Assertions of inequitable conduct continue to be “a plague” on the legal system almost twenty years after the Federal Circuit’s observation in *Burlington Industries v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

To place the additional burdens imposed by new Rule 265 in context, AIPLA asks the Court to take judicial notice of the 2007 edition of an economic survey AIPLA periodically

¹² The additional risk stemming from accusations of misconduct can also diminish the value of the issued patent. Fed. Reg. at 46801 (comment 233).

conducts and publishes.¹³ (Each survey includes data on typical charges for many different types of IP services.) According to the 2007 AIPLA Report of the Economic Survey, in 2006, the typical cost for a novelty search was \$2,000. *Id.* at 21. By contrast, the mean cost for a validity/invalidity opinion, per patent, was \$15,241. *Id.* Because of the risks posed by the ESD process to the client and its patent the latter expense is more closely aligned with reality than even the PTO's most-recently revised number. Charges in that range, coupled with the increased risks to any issued patent, make the ESD process an illusory solution.

If, upon advice of counsel, the client instead elects to reduce the number of claims to conform to the new Rules, the client may be abandoning valuable IP rights. Notwithstanding disagreement, Defendants response to AIPLA's preliminary injunction brief at 7, this presents a Hobson's choice: either create a record potentially damaging to the patent property or abandon one's rights altogether.

Lastly, AIPLA recognizes that the new Rules in theory present a third option in that they 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

¹³ Many courts have recognized the AIPLA Economic Survey as a valuable resource in assessing attorney's fees in patent cases. *See, e.g., View Engineering, Inc. v. Robotic Vision Systems, Inc.*, 208 F.3d 981, 987 (Fed. Cir. 2000); *Mathis v. Spears*, 857 F.2d 749, 755-56 (Fed. Cir. 1988); *Eon-Net, L.P. v. Flagstar Bancorp, Inc.*, 2006 U.S. Dist. Lexis (W.D. Wa. 2006); *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 2005 U.S. Dist. Lexis 32621 (E.D. Va. 2005); *Advanced Display Systems, Inc. v. Kent State University*, 2003 U.S. Dist. Lexis 12505 (N.D. Tex. 2003); *Ultra Coachbuilders, Inc. v. General Security Insurance Co.*, 229 F. Supp. 2d 284, 287-88 (S.D.N.Y. 2002); *Rambus, Inc. v. Infineon Technologies AG*, 155 F. Supp. 2d 668, 688 (E.D. Va. 2001); *Ulead Systems, Inc. v. Lex Computer & Management Corp.*, 151 F. Supp. 2d 1192, 1211-12 (C.D. Cal. 2001); *In re Dahlgren Int'l, Inc.*, 811 F. Supp 1182, 1185 (N.D. Tex. 1992). *See also* National Academy of Science, A Patent System for the 21st Century at 103-106 (2004) (citing survey).

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 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);¹⁴ 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). The logical conclusion is that the petition process will not be a viable option to alleviate the impact on the universe of prejudiced applicants of the retroactive application of the new Rules.

Consequently, allowing retroactive implementation of the new Rules would result in loss of rights to 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.

Retroactive application of the new Rules also creates new and additional duties on owners of pending patent applications. These new duties collectively will require applicants to devote extraordinary amounts of time and incur unjustifiably excessive costs for compliance.

¹⁴ See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (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.

Those additional duties did not exist either when numerous applicants determined what inventive concepts to include in their applications or when they elected to allow their trade secret property to be disclosed through publication of pending patent applications. While Defendants may disagree with the precise cost of these additional duties, they cannot deny that the new Rules will impose new, additional and costly duties on owners of pending patent applications.¹⁵

II. THE RETROACTIVE PORTIONS OF THE NEW RULES ARE VOID

A. The Retroactive Application of the New Rules Violates *Landgraf*

Under *Landgraf v. USI Film Prods.*, 511 U.S. 244, 269 (1994), a statute is retroactive if, among other things it (1) “would impair rights a party possessed when he acted” or (2) “impose new duties with respect to transactions already completed.” *Accord Tafas*, 511 F. Supp. 2d at 666. In the course of its analysis, *Landgraf* noted “the axiom that ‘[r]etroactivity is not favored in the law’ and its interpretive corollary that ‘congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result.’” *Id.* at 264. While *Landgraf* analyzed the retroactivity of a statute (the Civil Rights Act of 1991), its analytic framework has since been applied to assess the retroactivity of agency actions. *See, e.g., Regions Hospital v. Shalala*, 522 U.S. 448 (1998); *Parkdale Int’l v. United States*, 475 F.3d 1375 (Fed. Cir. 2007) (Commerce Department anti-dumping order); *Princess Cruises Inc. v. United States*, 397 F.3d 1358 (Fed. Cir. 2005) (Customs Service ruling).

Defendants assert that the new Rules are not retroactive because they do not contravene the test set out in *Landgraf*, arguing that: (a) no “rights” are impaired because no patents have yet issued on the pending applications, (b) “rights” mean “vested rights,” and (c) no new duties have

¹⁵ The GSK Plaintiffs submitted evidence to the Court of the costs they are incurring. Additional evidence from the declarations of Messrs. Magen, Hetz, and Kappos, previously submitted by AIPLA (Dkt. # 30-4 through 30-6 in No. 1:07cv1008) confirms that costs of compliance expected to be incurred in other technology segments in the immediate future will be as much or even greater.

been imposed on “completed transactions.” Defendants also contend that the new Rules are not subject to the *Landgraf* analysis because they have “purely ‘future effect,’” and are procedural. Defendants’ Brief at 39-45.

This Court, however, already has recognized in this case that *Landgraf* “does not limit ‘the presumption against statutory retroactivity to cases involving ‘vested rights.’” *Tafas*, 511 F. Supp. 2d at 667 (citing *Landgraf*, 511 U.S. at 275 n.29). Moreover, recent changes in the patent statute, coupled with the indicia identified in *Ruckelshaus*, *supra*, establish that owners of pending patent applications have sufficient “rights” such that the new Rules “impair rights” in pending patent applications that existed when the owners acted. *Landgraf*, 511 U.S. at 280. Examples of rights in patent applications follow.

First, patent applications, like patents, are assignable. 35 U.S.C. § 261. Second, beginning with the Patent Act of 1946, Congress granted the Commissioner of Patents the authority to withhold publication of an application and the grant of a patent thereon when doing so might be detrimental to the national security. 35 U.S.C. § 181. Concomitantly, Congress granted any applicant subjected to such a secrecy order on a patent application the right to apply for compensation for the damage caused by the order of secrecy – while the patent application was pending. 35 U.S.C. § 183.

Third, Congress made a significant amendment to the Patent Act in 1999, subsequent to all the cases cited by Defendants, granting applicants significant additional rights in their applications. In particular, 35 U.S.C. § 154(d) created a new statutory right to recover reasonable royalties for infringement that occurred during the period between publication of a patent application and its issuance as a patent, subject to certain conditions. *Id.* Consequently,

since that 1999 legislation, patent applicants also have rights that begin to accrue as of the day they act to allow publication of the application (and the attendant loss of trade secret property.)

Fourth, patent applications also have been treated as property in several other contexts. As one example, the Internal Revenue Service has long treated both patent applications and patents as property under the tax code. *See, e.g., Commissioner v. Stephens-Adamson Mfg. Co.*, 51 F.2d 681 (7th Cir. 1931) (rejecting taxpayer argument that applications, unlike patents, are not property). As just another example, patent applications also have long been held to pass to a trustee in bankruptcy. *In re Myers-Wolf Mfg. Co.*, 205 F. 289 (3d Cir. 1913). *See also* Memorandum in Support of GSK's Motion for Summary Judgment at 34-35 (Dkt. # 142).

The current “bundle of rights” defined by a patent application meets and exceeds those found to make trade secrets property in *Ruckelshaus*. The Court need not decide whether these are “vested rights” or make patent applications “property” for “taking” purposes. The first *Landgraf* test for retroactivity is impairment of rights a party possessed when it acted. Particularly since the 1999 amendment noted above, AIPLA submits that the new Rules unquestionably impair rights a patent owner possessed when it acted by (a) filing a patent application containing trade secret property and (b) allowing the application to be published with the consequent loss of that property.

Defendants argue that any loss of trade secret property is the fault of applicants who “choose” to make their applications public to pursue foreign protection although “the USPTO would be willing to keep their applications in confidence”¹⁶ Defendants’ Brief at 33 (emphasis in original). Yet, the motivation underlying applicants’ decisions to reserve their

¹⁶ Publication is mandatory unless an applicant requests that the application not be published “upon filing [of the application], certifying that the invention disclosed in the application has not and will not be the subject of an application filed in another country” 35 U.S.C. § 122(b)(1).

rights to seek foreign patent protection (by not interfering with the USPTO's obligation to publish) should not be a relevant consideration. This issue isn't why applicants allowed their applications to be published. The critical reality is that the new Rules retroactively alter the bargain on which inventors relied in surrendering trade secret property in return for a guarantee from the PTO that they will have a full and fair opportunity to seek a spectrum of patent protection adequate to protect their investments. *Tafas*, 511 F. Supp. 2d at 667. In addition, the new Rules retroactively alter the bargain on which inventors relied in allowing their applications to be published with a spectrum of pending claims that could result in damages for infringement beginning as of the date of publication of the application. 35 U.S.C. § 154(d). Each of these circumstances fully meets the first test of *Landgraf* for retroactivity.

The new Rules also fail the third *Landgraf* test because they impose new duties that did not exist at the time applicants (a) filed their patent applications and (b) allowed the applications to be published. Defendants seek to avoid the third *Landgraf* test by claiming no "completed transaction" can exist until an application is granted, becomes abandoned or is finally rejected. Defendants' Brief at 44. *Landgraf* is not so restricted. Moreover, none of the cases cited by Defendants involve a situation analogous to the loss of trade secret property resulting from publication of a patent application.

Upon careful consideration, moreover, Defendants' view of "transaction" is consistent with the conclusion that both patent filing and publication constitute a "completed transaction." Defendants thus suggest that a "transaction" is an act involving two parties that reciprocally affects each other. Defendants' Brief at 43. The act of filing an application itself is a completed transaction. That act defines the "priority date" of the application, Defendants' Brief at 5, which in turn limits prior art the PTO (or the public) can cite against the application and defines the

“one year” window for applicants under 35 U.S.C. § 102(b). The PTO’s publication of a patent application also defines a completed transaction. At least two parties are reciprocally affected by that act: (1) the public, which gets access to what formerly constituted trade secret property, and (2) the applicant, who seeks patent protection in lieu of relying on trade secrecy both in this country and abroad. *See also Tafas*, 511 F. Supp. 2d at 667.

Alternatively, Defendants argue that even if the initial filing of an application is a “completed transaction,” the new Rules are not retroactive because they do not threaten the validity of any pending applications and each applicant has the option to using an ESD. Defendants’ Brief at 44. That is both incorrect and not a relevant consideration under the “new duties” prong of this analysis. It is incorrect because the new Rules do deprive applicants of the rights to obtain a spectrum of patent protection adequate to protect all of the disclosed inventions (and the investments therein) that existed when they filed their applications and allowed them to be published. *See* Section I(B)(1), *supra*. And as discussed above, an ESD actually imposes new duties at substantially enhanced costs and the substantially enhanced risks to any issued patents *See* Section I(C), *supra*. The third prong of the *Landgraf* retroactivity test also is met.

Finally, Defendants assert that the new Rules are merely “procedural” ones to which concerns about retroactivity are inapposite. On the contrary, the retroactivity of the new Rules makes them substantive ones. Limiting patent applicants who included multiple inventions in a single pending application to only two continuations (with limited claims), for example, severely impacts the substantive protections available to the applicants, who relied on established procedure at the time the applications were filed. The same is true for the other examples in Section I(B) involving retroactive application of the new Rules. Far from being merely procedural, because of their retroactive impact on pending applications the new Rules affect the

core rights sought by patent applicants. In all events, the “procedural” label does not excuse retroactive impact of rules. *Landgraf*, 511 U.S. at 275 n.26 (“Nor do we suggest that concerns about retroactivity have no application to procedural rules.”) The retroactive aspects of the new Rules fail under *Landgraf*.

B. Retroactive Application Of The New Rules Also Violates *Bowen*

In *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988), the Supreme Court considered and rejected retroactive rulemaking by the Secretary of Health and Human Resources. It started from the premise that “an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress. In determining the validity of the Secretary’s retroactive cost-cutting rule, the threshold question is whether the Medicare Act authorizes retroactive rulemaking.” *Id.* at 208. “Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.” *Id.* *Bowen* thus defines an “authority” test.

The record here is similar to the record before the Supreme Court in *Bowen*. This Court already has determined that “Congress did not expressly grant the PTO those powers [the power to promulgate retroactive rules]. See 35 U.S.C. § 2(b) (2).” *Tafas*, 511 F. Supp. 2d at 666. And the retroactive application of the new Rules is (1) inconsistent with the Patent Act; (2) at variance with case law; and, (3) belied by the PTO’s longstanding interpretation of continuation practice.¹⁷ *Henriksen, supra*. There is no language in the patent statute or its legislative history

¹⁷ Defendants erroneously assert that Section 120 cannot be construed to have allowed unlimited continuations because of three other provisions in the patent act, §§ 112, 121 and 251. Defendants’ Brief at 22-23. Section 112 has never been construed to require all claims to every disclosed embodiment be included with the application as filed. That would have inundated the PTO years ago. The discretion given to the PTO in Section 121 to require a divisional application is independent of an applicant’s rights under Section 120. Finally, Section 251 allows broadening of claims within two years after a patent has issued. That right is separate and independent of the right to years later seek a broadened claim because patent owners can only recover damages for the six years prior to the filing of suit, 35 U.S.C. § 286, and cannot file suit without an issued patent.

that authorizes the PTO to issue rules regulating the continuation practice with retroactive application. The PTO's past administrative practices provide no support for such retroactive limitations. The *Henriksen* court's closing observation was prophetic:

The action of the board [in limiting § 120 to three continuations] is akin to a retroactive rule change which may have the effect of divesting applicants of valuable rights to which, but for the change in Patent Office position brought about by the board's decision, they were entitled. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanctions such a result.

399 F.2d at 261-62 (emphasis added). Nothing authorizes the PTO to enact a rule to divest applicants of the valuable rights discussed above. The retroactive aspects of the new Rules are inconsistent with the Patent Act and void.

Landgraf and *Bowen* define two different tests for evaluating whether a regulation is invalid for its retroactive impact. AIPLA submits that a regulation must pass muster under both tests, but the retroactive aspects of the new Rules fail to pass either test.

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 hold the retroactive application of the new Rules to be impermissible.

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I hereby certify that on this 20th day of December 2007, I electronically filed in Case No. 1:07cv1008 (JCC/TRJ) the foregoing Brief For *Amicus Curiae* American Intellectual Property Law Association using the CM/ECF system, which will send notification by electronic means to the following counsel of record:

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