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

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

CONSOLIDATED WITH

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

GSK'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

In a mere two days, the Final Rules will go into effect, immediately and irrevocably harming GSK and innovator companies like it. The repercussions will be profound. The PTO attempts to minimize this harm, but it cannot dispute that the Final Rules will affect more than 700,000 pending patent applications.

The public interest weighs heavily in GSK's favor. The public has a strong interest in human health—an interest that will be damaged by the PTO's mechanical, arbitrary limits on patent prosecution. The public harm goes well-beyond the pharmaceutical industry as shown by the number of *amici*—AIPLA, PhRMA, BIO, and others—that have already filed motions in support of GSK's positions and the breadth of industries represented by the *amici* demonstrate that the public strongly favors enjoining the Final Rules.

Before filing this motion, in light of the harm to GSK and the public, GSK asked the PTO to voluntarily stay implementation of the Final Rules until adjudication on the merits. The PTO charged forward. Now, it appears, Congress is not supportive of the PTO's rush to implement either. On October 25, 2007, Senator Charles Schumer, a member of the Judiciary Committee, wrote to The Honorable Jon Dudas, Under Secretary of Commerce for Intellectual Property and Director of the PTO, asking the PTO to delay the Final Rules:

> Because concerns have been raised about the potential impact of the new rules and there is a pending lawsuit in the Eastern District of Virginia seeking an injunction of the new rules, I ask that the PTO consider a delay in their implementation.
>
> * * *
>
> I appreciate the PTO's goal to create the most efficient and effective process to ensure both continued innovation and protection for the research and development efforts of patentholders. The proposed rules, however, may have the unintended consequences of stifling such innovation, and I urge you to consider delaying their implementation.

Ex. A. Nonetheless, the PTO charges forward citing to investments it has already made to implement the Final Rules. This is money already spent regardless of the outcome in this case. Moreover, the PTO incurred these costs knowing that the Final Rules would be challenged, and would likely fail.

GSK has shown a likelihood of success on the merits. The PTO has not overcome this showing, nor did it expect to as it conceded during the rulemaking process that the rules only stood a 50-50 chance of surviving judicial review on both counts.

II. ARGUMENT

A. The Public Interest Favors Granting GSK's Request For A TRO And Preliminary Injunction.

The PTO argues that the public interest favors implementing the Final Rules. *See* Defs.' Opp. at 37-38. The PTO further argues that the Final Rules "promote innovation." *Id.* The PTO is incorrect on both counts.

GSK and other innovators like it invest massive amounts of time and money developing life-saving and disease-curing drugs. The PTO does not dispute this, nor can it dispute that GSK and other innovators will be forced to make strategic decisions regarding the research and development of those drugs based on the Final Rules' limits. To comply with these limits, given the undisputed long-term development cycle for drug products, GSK will be forced to make strategic decisions in the immediate future that will have repercussions years from now—repercussions that will redound to the public's detriment. *See, e.g.*, Ex. B at A02664 (NIH's comment expressing "concern that the [PTO's] regulations may disproportionately affect the arts[, such as the pharmaceutical, biotechnology, and related arts,] that most directly impact public health . . .").

Further, the nearly 2,500 pages of overwhelmingly negative commentary disapproving of the proposed rules belie the PTO's argument that the rules promote innovation. *See* A00591-3199. Large or small, almost all companies opposed the Final Rules. *See, e.g.*, Exs. C-G. Indeed, even IBM, one of only five previous supporters, now opposes the Final Rules. Defs.' Opp. at 30 n.21 (identifying IBM as a supporter); 2007-10-25 Decl. of David J. Kappos, On Behalf of IBM, In Support of AIPLA *Amicus* Brief, Dkt No. 30, ¶ 15. Further, the PTO's public interest analysis ignores the fact that the AIPLA, PhRMA, BIO, and private companies such as HEXAS LLC, The Roskamp Institute, and Tikvah Therapeutics, Inc., have all filed motions for leave to file *amicus* briefs and all support GSK's efforts to enjoin the Final Rules. Indeed, as recounted above, on October 25, 2007, even Senator Charles Schumer urged the PTO, on behalf of the public, to delay implementing the Final Rules until this Court's resolution of the case. Ex. A. Lastly, the PTO ignores the 700,000-plus pending patent applications that will be impacted by the Final Rules on November 1. Like GSK, the affected applicants cannot wait until the eleventh hour to begin complying with the Final Rules, but must begin immediately. In fact, as the PTO conceded, the public has already been harmed by the Final Rules, and that harm will only increase. Defs.' Ex. 7, Decl. of Robert Bruce Breneman ¶ 8 (conceding that applicants "will make filings ***on*** or after November 1, 2007, as if the Final Rules were in effect") (emphasis added).

B. The Final Rules Will Irreparably Harm GSK If They Are Implemented And Later Enjoined.

As discussed in GSK's opening brief, if the Final Rules go into effect on November 1, 2007, GSK will be immediately and irreparably harmed. GSK has approximately 2,000 patent applications currently pending and will immediately lose the right to file continuing applications to secure adequate and full protection for the inventions disclosed in more than 100 of these

pending patent applications. In addition, from those 2,000 applications, GSK will be forced to eliminate claims that exceed the five independent or twenty-five total claim ("5/25") limit.[1] Because GSK cannot recover these patent rights or be adequately compensated for their loss, GSK's harm will be irreparable.

Contrary to the PTO's brief, GSK does not argue that it is entitled to an injunction merely because it will incur compliance costs. While the financial burden of complying with *ultra vires* rules is indeed real, the primary harm at issue here is the loss of these substantial patent rights. Thus, the three cases the PTO cites regarding compliance costs to support its contention that GSK's argument "merits no discussion" are inapposite. Defs.' Opp. at 12-13.

The PTO never addresses the real harm. Should the Final Rules go into effect and later be invalidated, GSK would have no financial remedy available to it for the PTO's illegal rulemaking and destruction of its patent rights—a fact the PTO does not dispute.[2] *See Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 361 (4th Cir. 1991) (finding irreparable harm where an aggrieved party could not later recover monetary damages if a governmental action is later found to be unconstitutional or unlawful); *see also Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994) ("irreparable injury is suffered when monetary damages are difficult to ascertain or are inadequate").

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[1] As the PTO recognized, given the current state of the law of inequitable conduct, no one will file an ESD. Tafas Decl. Supp. Pls.' Opp Defs.' Partial Mot. Dismiss, Case No. 1:07-cv-846, Dkt. No. 31 ("Tafas Decl."), ¶¶ 70-71, Ex. I. Thus, the alternative for applicants is to eliminate claims, *i.e.*, forfeit protection afforded by the patent laws, to comply with the arbitrary 5/25 limit.

[2] Notably, the PTO does not rebut or even attempt to address *Rum Creek* in its extended opposition brief, even though it recognizes Fourth and Federal Circuit precedent to be in harmony on the governing equitable standards of preliminary injunctive relief.

Contrary to the PTO's suggestion, GSK cannot delay its compliance with the Final Rules. Decisions will need to be made immediately regarding the number of claims, claim scope, continuing applications, and other crucial decision points that will result in the irretrievable loss of otherwise patentable subject matter. Enjoining the Final Rules for a short period until the Court makes a final ruling on the merits could easily prevent this imminent and unrecoverable harm.

The PTO's contention that GSK will not be immediately affected by the examination support document ("ESD") requirement, *i.e.*, the 5/25 limit, is incorrect. *See* Defs.' Opp. at 16. In fact, anxious to get started, the PTO had already flagged GSK patent applications as violating the 5/25 limit when it prematurely implemented the Final Rules in the middle of October. *See, e.g.*, GSK Opp. Defs.' Mot. Strike Manbeck Decl., Dkt. No. 40, Exs. 11-15. Only after GSK filed its TRO papers did the PTO withdraw these improper flags. The PTO does not dispute that as soon as it flags these applications again on November 1, GSK must comply with the ESD requirement or forfeit claims. Given the number of applications it has pending, GSK cannot postpone making strategic decisions for months and then rush to comply at the eleventh hour. Rather, the Final Rules' effects will be immediate. *See, e.g.*, Defs.' Opp. Ex. 7, Decl. of Robert Bruce Breneman ¶ 8 (conceding that some applicants are already acting under the Final Rules).

The PTO does not dispute that the Final Rules limit continuing application practice or that GSK will be ethically barred from seeking additional continuing applications in many instances. Rather, the PTO argues that GSK should claim its inventions now. Defs.' Opp. at 13-14. Taking the '551 patent family as just one example, the PTO suggests three ways to prosecute the unclaimed inventions: (1) file all claims now pertaining to all inventions; (2) file a suggested restriction requirement ("SRR") concerning independent inventions, which the PTO may reject;

or (3) file a fourth continuation with a petition and showing. These suggestions, however, miss the point; none of them resolves the problem that GSK cannot fully protect its inventions without slamming into the Final Rules' limits. As the PTO recognizes, the three pending applications in the '551 family include the following claim counts: 1/24, 2/23, and 2/25, respectively. *See* Defs.' Leguyader Decl. ¶¶ 12, 16, 20. It is clear that if GSK sought to submit claims to cover all of its unclaimed subject matter, it would easily exceed the 5/25 limit. That would happen even if GSK were to file an SRR. Thus, the fact that the PTO may grant a restriction requirement as to distinct inventions is irrelevant. Finally, the PTO's argument that GSK should apply for a fourth continuation application ignores its own petition and showing standard and the undisputed fact that GSK theoretically could have submitted the claims earlier. *See* Knowles Decl. Supp. Pls.' Mot. TRO and Prelim. Inj. ¶ 44. Thus, GSK would likely be ethically barred from filing such a petition. In short, the Final Rules truncate GSK's patent rights by destroying its ability to fully protect its disclosed inventions, including the inventions disclosed in the '551 patent family.

C. The PTO Will Not Suffer Harm If The Court Preliminarily Enjoins the Final Rules.

The PTO raises several arguments why it would allegedly be harmed if the Court preliminarily enjoins the Final Rules: (1) the PTO has spent money and time (approximately nine hours), training each of its employees under the Final Rules; (2) the PTO spent money for over fifty people to code computer software that it cannot stop from going into effect on November 1; (3) the backlog of pending applications negatively affects the PTO's efficiency; and (4) the Final Rules are part of a larger group of initiatives that work best when implemented together. *See* Defs.' Opp. 17-20. These arguments are insufficient to demonstrate that the PTO will suffer immediate harm if the Court enjoins the Final Rules.

As an initial matter, all the financial costs the PTO identifies as harm it *will* suffer if the Court enjoins the rules, are costs the PTO has already incurred. As such, these are sunk costs that will be unaltered by the Court's decision to maintain the status quo. The PTO made these investments with full knowledge that the Final Rules would be challenged. In fact, the day after the PTO published the Final Rules, Mr. Tafas filed his lawsuit challenging their legality.[3] Nonetheless, the PTO charged forward and has heedlessly incurred these costs, regardless of the Final Rules' legality and whether this Court might enjoin them.

The PTO's other harm arguments are equally unavailing. First, the PTO argues that it will have to retrain its employees if the Final Rules are enjoined and then upheld. With the summary judgment arguments in this matter scheduled for December, it is highly unlikely that the benefits of this training will be lost. Instead, should the Final Rules later be upheld, the benefits of the training that occurred already will simply be postponed for a few months. Further, the fact that the PTO spent a mere nine hours training employees under the Final Rules in comparison to the decades of experience PTO examiners have under the current system counsels against this "harm" being given any weight.

Second, the PTO's argument that it will suffer computer problems if the new software is not allowed to go into effect on November 1 ignores the fact that the current system is still being implemented at the PTO, and can continue until there is a final resolution of the merits. Given

[3] The PTO incorrectly alleges that GSK delayed in bringing this suit. The Final Rules differ significantly from the PTO' proposed rules. Further, the Final Rules span 128 pages and are "extremely complex," as the PTO has admitted. Defs.' Continuance Mot., Dkt No. 17, at 3 ¶ 5. Indeed, the rules are so complex that the PTO has already issued more than 200 pages of material since August 21 to clarify the rules. GSK Opp. Defs.' Mot. Strike Manbeck Decl., Dkt No. 40, Exs. 1-9. In light of the complex issues, size of the administrative record, nature of GSK's business, and the ethical obligations of counsel to engage in a pre-complaint investigation, GSK did not delay in bringing its challenge. ("Tafas Decl."), ¶¶ 70-71, Ex. I.

the overwhelmingly negative criticism of the Final Rules, the fact that Mr. Tafas immediately challenged them by filing preliminary injunction papers, and the fact that the PTO believed the odds were 50-50 that a court would uphold the Final Rules, see exhibits H-I, the PTO fails to explain how it could employ over 50 people for four months and spend over $1 million to code a computer program whose start date cannot be reset or postponed. If the PTO describes the program accurately, it should not be rewarded for this error in judgment.

Third, the PTO's argument that efficiency will be undermined if the Final Rules are enjoined for a few months is without merit. There is no evidence that the PTO will meaningfully reduce the backlog of over 700,000 pending applications during the short pendency of this action. Lastly, the PTO's argument that the Final Rules are part of a group of initiatives is irrelevant. The Final Rules do not require any other initiatives to go into effect. By themselves, they irreparably injure GSK and others. Agencies cannot rely on future rules to justify the ones they are adopting now.

In short, the minimal harm that the PTO may face if the Final Rules are enjoined is either sunk costs that do not change if the rules are enjoined, or conduct that should not be rewarded. Moreover, even these sunk costs pale in comparison to the irreparable, immediate, and incalculable harm that GSK, other innovators, and the public face if the Final Rules go into effect. Thus, the balance of hardships tips decidedly in GSK's favor.

D. GSK Is Likely To Succeed On The Merits.

The PTO contends GSK is not likely to succeed on the merits. However, before this lawsuit was filed, Commissioner for Patents John J. Doll conceded that the Final Rules had only a 50-50 chance of surviving judicial review. Exs. H-I.

1. The Final Rules Are All *Ultra Vires* Because The PTO Exceeded Its Authority By Engaging In Substantive Rulemaking.

The PTO does not contest that it lacks substantive rulemaking power. *See* Defs.' Opp. at 21-23; *see also Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996). Instead, the PTO asserts that the Final Rules are not substantive but rather fall within its power to "'establish regulations, not inconsistent with law' to 'govern the conduct of proceedings in the Office,' to 'facilitate and expedite the processing of patent applications,' and to 'govern the recognition and conduct of . . . parties before the Office.'" Defs.' Opp. at 21, 23 (citing 35 U.S.C. § 2(b)(2)(A), (B), (D), respectively). This argument fails for three reasons.

First, the PTO argues that its assertions of authority to issue procedural rulemakings are entitled to *Chevron* deference. *See* Defs.' Opp. at 24, 29. But the PTO completely ignores the fact that its lack of substantive rulemaking authority triggers application of *Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990) and overrides *Chevron* deference. *See* Am. Compl. ¶ 104; GSK Op. Br. at 15-16. The PTO's opposition brief neither mentions that case, nor the Fourth Circuit's application of it in *A.T. Massey Coal Co. v. Holland*, 472 F.3d 148, 167 (4th Cir. 2006). *See* GSK Op. Br. at 18.

Adams Fruit holds that agencies that lack authority to regulate in particular areas gain ***no deference*** to their interpretations of law in those areas. It is not enough for an agency to possess a power to issue regulations over ***some aspects*** of a statute's coverage. As the Court explained in *Adams Fruit*:

> Congress clearly envisioned, indeed expressly mandated, a role for the Department of Labor in administering the [Agricultural Worker Protection Act ("AWPA")] statute by requiring the Secretary to promulgate standards implementing AWPA's motor vehicle provisions . . . . This delegation, however, does not empower the Secretary to regulate the scope of the judicial power vested by the statute. Although agency determinations within the scope of delegated

> authority are entitled to deference, it is fundamental "that ***an agency may not bootstrap itself into an area in which it has no jurisdiction***."

Adams Fruit, 494 U.S. at 650 (emphasis added) (citation omitted). In such circumstances, *Chevron* is inapplicable.

Here, the Patent Act and the Federal Circuit's authoritative construction of the statute over many years control the issuance of continuation applications, RCEs, and claims. The PTO cannot alter longstanding practice under those provisions without an express delegation from Congress. *See NLRB v. Lechmere*, 502 U.S. 527, 537 (1992) (Once courts "have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning."); *ITT Indus. v. NLRB*, 413 F.3d 64, 68 (D.C. Cir. 2005) (the *Lechmere* principle, where applicable, displaces *Chevron* deference).

The PTO argues that its Final Rules are procedural and urges the Court to restrict its inquiry to the grants of authority to issue rulemakings in 35 U.S.C. § 2(b)(2). As the Court held in *Adams Fruit*, however, the PTO may not bootstrap its powers to issue one kind of rule into the power to override substantive or procedural choices that Congress has delegated to the judiciary.

That the PTO has closed its eyes to *Adams Fruit* explains its other errors. The PTO argues that *Chevron* applies if the statute fails to expressly negate results it seeks to impose under the Final Rules, and that any other approach "turns *Chevron* on its head." *See* Defs.' Opp. at 29. Normally, when an agency acts pursuant to a delegated power, a statute's silence implicitly grants the agency authority to fill in regulatory gaps. The proviso, however, that an agency must be acting pursuant to a valid grant of delegated power is no small matter. Under *Adams Fruit*

and *A.T. Massey Coal*, Congress' delegation of the power to construe the Patent Act to the ***courts*** renders *Chevron* inapplicable and statutory silence irrelevant.[4]

The PTO also errs by overlooking *Adams Fruit* and invoking so-called *Skidmore* deference as an alternative argument. *See* Defs.' Opp. at 24 n.17 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). But *Skidmore* deference is irrelevant because the Supreme Court has held that ***no deference*** is due where the agency acts outside its delegated authority. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 162 (4th Cir. 1998) (discussing *Chevron* and *Adams Fruit*), *aff'd* 529 U.S. 120 (2000);[5] *see also Sac & Fox Nation of Mo. v. Norton*, 240 F.3d 1250, 1265-66 (10th Cir. 2001) ("Because the Secretary lacked authority to interpret the term 'reservation,' . . . we owe no deference to his interpretation . . . . Instead, we proceed to decide for ourselves the meaning of the term 'reservation,' as used in IGRA.").

Second, the authority the PTO cites does not support its substantive power grab. Instead, the cases were procedural in nature. *See Lacavera v. Dudas*, 441 F.3d 1380, 1382 (Fed. Cir. 2006) (concerning the PTO's refusal to register a foreign national to fully practice before it); and *Stevens v. Tamai*, 366 F.3d 1325, 1332 (Fed. Cir. 2004) (relating to the PTO's procedural requirement that a party submit a translation of a foreign language application during an interference proceeding). These procedure-oriented cases do not support substantive rulemaking.

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[4] *See* Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 Yale L.J. 969, 1022 (1992) ("In *Adams Fruit Co. v. Barrett*, the Court held that agency interpretations are entitled to no deference if they concern a topic that the agency has not been empowered to regulate. In effect, *Adams Fruit* carries *Chevron*'s presumed delegation theory to its ultimate conclusion. Since the delegation of regulatory authority gives rise to the duty to defer, where there is no delegated power ***there is no deference***.") (emphasis added) (footnote omitted).

[5] *Merck* is not to the contrary because it did not consider the issue of how the application of the *Adams Fruit* line of cases affected a claim by the PTO for *Skidmore* deference. The emphasis GSK lays on *Adams Fruit* requires that it be explicitly addressed and applied here.

The PTO then asserts that the Final Rules will not affect GSK's rights to receive a patent if its applications comply with 35 U.S.C. §§ 101, 102, 103, and 112. This is simply untrue. As previously explained, if GSK seeks to file more than two continuing applications, it is barred from doing so under the PTO's petition and showing requirement because (1) the PTO has indicated it will deny all petitions except in one instance, GSK Op. Br. at 19, Ex. A at 46769-77; and (2) in most cases, GSK likely will not be able to file the petition without violating the ethical rules under 37 C.F.R. § 10.85. Thus, GSK will be denied patents to the claims that would have been made in those continuing applications despite having satisfied the Patent Act. Moreover, the PTO itself has indicated that the Final Rules limit claims and continuing applications. *See, e.g.*, Ex. J at A00432 ("Why Limit Continuations?"), A00434 ("Why Limit Claims?").

The PTO further asserts that it can issue procedural regulations, even if such regulations may have substantive outcomes. Defs.' Opp. at 22-23. In reaching for that authority, the PTO relies on three inapposite cases. *In re Van Ornum* stands for the proposition that the PTO can issue procedural regulations that comport with statutory and case law. 686 F.2d 937, 945 (C.C.P.A. 1982). Here, the Final Rules do not comport with statutory or case law. The PTO cites *Stevens v. Tamai* for the proposition that the PTO may "set burdens of proof," Defs.' Opp. at 23, but *Stevens* merely condoned the PTO's requiring the submission of a translation of a foreign language application during an interference. Then, the PTO cites *Dethmers Mfg. Co., Inc. v. Automatic Equip. Mfg. Co.*, 293 F.3d 1364 (Fed. Cir. 2002) for the proposition that the PTO may impose a "threshold showing" in an application for reissue of a patent. Defs.' Opp. at 23. The PTO's citation to *Dethmers*, however, is to two separate ***dissents*** to the Federal Circuit's denial of a petition to rehear a case *en banc*. *See Dethmers*, 293 F.3d at 1364-67. In any event,

the one relevant dissent does not discuss the PTO's limited rulemaking authority; rather, it only discusses the examiner's misapplication of a procedural rule. *Id*. at 1366.

Finally, as stated below, and in GSK's opening memorandum (pp. 17-26), the Final Rules are "inconsistent with law" and, therefore, exceed the PTO's authority.

2. The Final Rules Are "Inconsistent With Law."

a. The PTO Lacks The Authority To Limit Continuing Patent Applications.

The PTO agrees that, in Section 120, "it is clear that the word 'shall' simply expresses that applicants will only benefit from the earlier application's filing date 'if' they comply with the requirements of the statute." Defs.' Opp. at 25 n.18. In other words, "if" an applicant meets the formal requirements of Section 120, the PTO ***shall***, *i.e*, must, accord the applicant the benefit of the earlier filing date. Thus, Final Rule 78's mechanical numeric limits on continuing applications contradict Section 120's express language. The issue of whether the PTO gets deference in interpreting Section 120 or any provision of the Act is critical because it is the PTO's reliance on *Chevron* which allows it to even make a straight-faced argument that it can add to Section 120's otherwise-exclusive list of requirements.

The PTO describes the new regime as one placing "reasonable limits" on the filing of more than two continuing applications. Defs.' Opp. at 26. The truth is that the PTO is limiting applicants to only two continuing applications regardless of the reasonableness of a particular case. As pointed out in GSK's opening memorandum (p. 22), the PTO has recognized only one instance in which it would grant a petition to allow more than two continuing applications. In fact, the PTO indicated that it will even reject petitions based on reasons that the Federal Circuit expressly endorsed in *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1378 (Fed. Cir. 2005) ("Symbol IV"). The administrative record also makes clear that the

PTO's intent, and the ultimate effect of the rule, is to limit applicants to only two continuing applications. Ex. J at A00432 ("Why Limit Continuations?).

While the PTO may reject applications in egregious cases on a case-by-case basis under the equitable doctrine of prosecution laches, *see Symbol IV*; *In re Bogese II*, 303 F.3d 1368 (Fed. Cir. 2002); *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361 (Fed. Cir. 2002) ("Symbol II"), these cases do not authorize the PTO to deny continuing applications using the mechanical bright-line of the Final Rules. *See* Defs.' Opp. at 25-26.

In fact, the Federal Circuit made clear that the PTO lacks the ability to impose "a mechanical rule based on a misconstruction of the statutory requirements." *Bogese II*, 303 F.3d at 1368 n.6 (distinguishing *Henriksen*). Here, the PTO has imposed a mechanical limitation in contradiction of the Federal Circuit's admonition and the express language of Section 120.

The Federal Circuit's pronouncements in *Symbol IV*, which followed *Bogese II*, clarify this principle. There, the Federal Circuit expressly cautioned that:

> There are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches, and the doctrine should be ***used sparingly lest statutory provisions be unjustifiably vitiated***. The doctrine should be ***applied only in egregious cases*** of misuse of the statutory patent system.

Symbol IV, 422 F.3d at 1385 (emphasis added). The Federal Circuit's *Symbol II*, *Bogese II*, and *Symbol IV* trilogy makes clear that the PTO may reject applications based upon the equitable doctrine of prosecution laches, but only in extreme cases, not in the Final Rules' mechanical across-the-board manner.

In short, Section 120 does not permit the PTO to impose an "arbitrary limit to the number of applications . . . provided that the applicant meets all the other requirements of the [§ 120]

statute.[6] *In re Henriksen*, 399 F.3d 253, 254 (C.C.P.A. 1968). In fact, as set forth in GSK's opening memorandum, the PTO itself recognized that "the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved." *Ex Parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975) (discussing *Henriksen*). Indeed, as the C.C.P.A. reiterated in 1977, limiting applications is a matter of policy for Congress . . . ."[7] *In re Hogan*, 559 F.2d 595, 504, n.13 (C.C.P.A. 1977). The PTO never attempts to explain why it was wrong before, which is arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Auto. Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (An agency changing course is "obligated to supply a reasoned analysis for the change ***beyond that*** which may be required when an agency does not act in the first instance.") (emphasis added).

b. The PTO Lacks The Authority To Limit RCEs.

The PTO argues that it may impose a "reasonable" restriction on an applicant's ability to file an RCE. First, the language of 35 U.S.C. § 132(b) demonstrates the contrary: the PTO "shall prescribe regulations to provide for the continued examination of applications for patent ***at the request of the applicant***" (emphasis added). Second, the PTO misdescribes new Final Rule

[6] Whether the PTO's authority permits the ability to limit continuations was another concern recently expressed by Senator Schumer in his October 25, 2007 letter to the PTO. Ex. A.

[7] The PTO minimizes H.R. 1908, asserting that "[t]he House bill does not suggest that the USPTO previously lacked power to regulate in this area." Defs.' Opp. at 23-24. But, H.R. 1908 is probative of the PTO's present lack of power. Also probative is the fact that, in 2005, the House considered vesting the PTO with authority to limit continuing applications, further evidencing that the PTO presently lacks such authority. *See* H.R. 2795, 109th Cong., § 123 (June 8, 2005) ("The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application . . . ."). Moreover, the PTO has stated that the Final Rules are an attempt to do that which Congress has chosen not to—legislate in the patent area. Tafas Decl. ¶¶ 70-71, Ex. I.

114 as one where "an applicant who has received a final Office action may, as a matter of right, file one [RCE]." That is not the case. Final Rule 114 allows an applicant one RCE per application family, not per application. The rule is anything but "reasonable." Thus, as with Section 120, the PTO cannot do what it has done here under Section 132—arbitrarily and mechanically limit applicants to one RCE per application family.

c. The PTO Lacks The Authority To Limit Claims.

The PTO's argument regarding its claim limits rests primarily on *Chevron* deference. As set forth in Section II.C.1., *supra*, the PTO is not entitled to *Chevron* deference. Moreover, even if entitled to deference, the PTO's limit on claims contradicts clear statutory language and, thus, fails under *Chevron*. Indeed, the PTO ignores the fact that Sections 102 and 103 of the patent laws entitle an applicant to a patent unless the claimed invention lacks novelty or is obvious in view of the prior art. 35 U.S.C. § 112 does not limit the number of claims; instead it simply requires that a patent application contain "one or more claims." The PTO itself agreed that the law did not limit the number of claims an applicant could seek, stating in 2005 that "[t]he patent statute and rules of practice do not limit the number of claims (independent or dependent) that may be presented in an application." Ex. K at A07333 (relevant portions only). The PTO has no authority, statutory or otherwise, to set arbitrary claim limits.

3. The Final Rules' Limits On Continuing Applications, RCEs, And Claims Are Retroactive.

The PTO does not dispute that it lacks the authority to engage in retroactive rulemaking. *See* GSK Br. 23-24. Instead, the PTO rests its defense on the proposition that the rules are not retroactive. The PTO argues that the Final Rules are not retroactive because they neither impact vested "rights" nor impose new duties with respect to "transactions already completed." Defs.' Opp. at 32-33 (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 n.4 (1994)). But the

Landgraf decision is not so limited. The Court expressly noted that it would ***not*** "restrict the presumption against statutory retroactivity to cases involving 'vested rights.'" *Landgraf*, 511 U.S. at 275 n.29. Here, the PTO compares GSK's patent rights to a mere licensee's "rights" in a license to use the public airwaves. *See* Defs.' Opp. at 33. This is not a valid comparison. The FCC has "always retained the power to alter the term[s]. . . by rulemaking," *see Celtronix Telemetry, Inc. v. F.C.C.*, 272 F.3d 585, 589 (D.C. Cir. 2001), but Congress has granted the PTO no rights to alter the scope or effect of a patent, nor granted the PTO the right to take away such protection through the promulgation of "procedural" rules. *See* GSK Br. at 17-25.

The PTO's citation to *Marsh v. Nichols, Shephard & Co.*, 128 U.S. 605, 612 (1888) is also inapposite. Defs.' Opp. at 33. GSK's argument does not turn on whether it has any rights ***in patents*** that it may have pending. GSK's argument instead turns on its rights to follow the statutory path that Congress has delineated for receiving patents, free and clear from illegal, agency-imposed roadblocks. In any event, even if GSK lacked such rights, *Landgraf* and its progeny make clear that property rights do not decide the retroactivity inquiry; an agency can also violate the retroactivity prohibition by "impos[ing] new duties" that did not exist in the prior regime. *Landgraf*, 511 U.S. at 280. The PTO cannot deny that imposing new duties is what it has done here—doing so is the very purpose of the Final Rules.

In fact, in comments submitted during the rulemaking, the Patent Public Advisory Committee, an entity that functions as part of the PTO, urged the PTO not to impose the Final Rules' requirements retroactively. *See* Ex. L at A01305. That the PTO's own internal experts acknowledge and bemoan the retroactive effect of the Final Rules calls into serious question the correctness of the PTO's litigation position, if it does not foreclose it altogether. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing

more than an agency's convenient litigating position would be entirely inappropriate."); *Akzo Nobel Salt, Inc. v. FMSHRC*, 212 F.3d 1301, 1304 (D.C. Cir. 2000) ("[C]ourts . . . defer to agency interpretations of ambiguous regulations . . . only where they reflect the agency's fair and considered judgment on the matter in question.").

The PTO also defends the Final Rules by arguing that, even though they have retroactive application, for "procedural" rules that is permissible. Defs.' Opp. at 33-34 (citing *Landgraf*). But, *Landgraf* does not support that position. *See Martin v. Hadix*, 527 U.S. 343, 359 (1999) (In *Landgraf*, the Court "took pains to dispel the 'suggest[ion] that concerns about retroactivity have no application to procedural rules.'") (quoting *Landgraf*, 511 U.S. at 275 n. 29); *see also Brown v. Angelone*, 150 F.3d 370, 373 (4th Cir. 1998) (citing *Landgraf*).

Regardless of the Final Rules' labels, they impose new duties (e.g., obligations to petition for continued applications after the first two are exhausted, to submit an ESD, etc.) on applicants that pertain directly to prior transactions (initial applications). "New legal consequences" attach to prior transactions, because in prior filings applicants could not have known that they were exhausting their last fair chance to obtain protection for the entire body of potential claims. That constitutes a serious, retroactive change to the "legal landscape" that applied before the Final Rules' effective date. *See Nat'l Mining Ass'n v. Dep't of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002) ("The critical question" in the retroactivity inquiry "is whether a challenged rule establishes an interpretation that 'changes the legal landscape.'") (citations omitted).

4. The ESD's Preexamination Search Requirement Is Vague And Does Not Put GSK On Notice As To How To Comply.

While regulations do not require "meticulous specificity," *see* Defs.' Opp. at 36, they do need to inform a reasonably prudent person how to comply. A reasonably prudent person cannot comply with the ESD requirement of the Final Rules. If read literally, it requires applicants to

search the patent literature of the entire world, as well as unspecified yet relevant "non patent literature," without regard to cost. The intrinsic vagueness of the Final Rules is demonstrated by their promise that "official guidance" on how to comply with the ESD requirement "would be forthcoming." *Id.* at 37 n.27. This is tantamount to an admission that the Final Rules are vague and fail to provide fair notice. Moreover, such guidance documents promulgated outside of the exclusive process of notice and comment rulemaking should be set aside as violating the APA. *See Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015 (D.C. Cir. 2000).

GSK has brought a pre-enforcement challenge here. (Notably, the PTO has opted not to contest that GSK's challenge is ripe or that GSK has standing to bring it, despite its extensive motion to dismiss on such grounds in *Tafas*. *See* Defs.' Opp. at 3 n.3.) To mount a preenforcement challenge, it is clear that GSK need not demonstrate that it already has an existing patent right that will lose protection under the Final Rules. The point of the challenge GSK brings here is that the vagueness of the Final Rules will ***frustrate*** GSK's ability to obtain patents that Congress has announced GSK has a right to obtain if it meets the statutory criteria—criteria that the PTO has a ***mandatory duty*** to carry out and not obstruct.

As the Supreme Court explained in *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972) (footnotes omitted), "[v]ague laws offend several important values," including that they "may trap the innocent by not providing fair warning." Those values are equally offended whether they are applied to frustrate the acquisition of rights or deployed to deprive parties of already perfected rights. We are aware of no cases that hold that a statute or regulation cannot be challenged on vagueness grounds if it merely frustrates the acquisition of property rights. The PTO here seeks to apply the line of Due Process cases holding that there is no due process right to be immune from a deprivation of something that is not life, liberty, or property. But GSK is

not the equivalent of a prisoner complaining that the inadvertent destruction by the guards of his hobby kit violated due process.[8] *See Daniels v. Williams*, 474 U.S. 327, 330-31 (1986) (overruling *Parratt v. Taylor*, 451 U.S. 527 (1981)).

Here, Congress made clear in establishing an agency with limited powers over the patent grant that an inventor's right to a patent, and an unfettered path to obtain a patent, is protected. The PTO's discretion is tightly circumscribed under the Patent Act, which goes so far as to deny the PTO any right to impinge such rights through substantive rulemaking. These strict rules and limits give rise to "a legitimate claim of entitlement" to a patent—granted by Congress—if the statutory path is followed.

[8] The PTO mis-cites *Willis v. Town of Marshall*, 426 F.3d 251, 261 (4th Cir. 2005), for the proposition that vagueness challenges must establish, as a threshold matter, that a claimant is proceeding based on a vested property interest. *See* Defs.' Opp. at 35 n.25. *Willis* issued no such broad holding. Instead, the Fourth Circuit rejected a vagueness challenge brought by a lewd dancer who wanted to perform on government property at weekly town-sponsored musical events. *Id*. at 261 n.3. Thus, *Willis* is no barrier to GSK arguing and being allowed to prove on the merits that this Court has the power to order the PTO to stop interposing vague obstacles on the clear statutory path Congress paved for obtaining a patent.

III. CONCLUSION

For the reasons GSK sets forth herein and in its moving papers, GSK respectfully requests that the Court enjoin implementation of the Final Rules.

Date: October 30, 2007 Respectfully submitted,

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