

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

TRIANTAFYLLOS TAFAS,

Plaintiff,

v.

JON W. DUDAS, et al.,

Defendants.

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1:07cv846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM
CORPORATION, et al.,

Plaintiffs,

v.

JON W. DUDAS, et al.,

Defendants.

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1:07cv1008 (JCC/TRJ)

**BRIEF OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION
IN SUPPORT OF GSK'S MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Amicus curiae Washington Legal Foundation (“WLF”) submits this brief in support of the Motion for Summary Judgment by SmithKline Beecham Corp. (“GSK”). This litigation involves significant public policy issues because improper limits imposed by the U.S. Patent and Trademark Office (“PTO”) by regulation will deny innovators the ability to fully protect their inventions. *See Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications*, 72 Fed. Reg. 46716 (Aug. 21, 2007). WLF supports GSK and other innovators whose property rights will be adversely affected by the Rule.

Protecting the property rights of inventors in their discoveries is specifically grounded in the Constitution, art. I, § 8, cl. 8. Congress is expressly empowered to promulgate laws “[t]o promote the Progress of Science and the useful Arts.” *Id.* The Patent Act directs the PTO to examine applications for patents. If the PTO determines that the claims presented by an inventor comply with the substantive requirements set forth in the statute, “the Director shall issue a patent therefor.” U.S.C. § 131 . While Congress has delegated limited discretion to the PTO to decide certain *procedural* questions, the PTO has *no* discretion to refuse to examine patent claims, and it has no discretion to withhold a patent grant for an invention that complies with the requirements of the law. The PTO’s recently promulgated Rule is anything but “procedural” – it goes to the heart of what, and how much, can be patented.

Patent rights turn on the *claims* that are granted. If the PTO denies inventors the right to *make* claims in their applications, as the new Rule does, the degree of potential patent protection available is inevitably lessened. That is why the new Rule is substantive, not merely procedural. It imposes arbitrary limits on the number and extent of inventions an application may claim. The

agency adopts these major changes for reasons of asserted administrative efficiency and convenience, not to assure greater protection for inventors. Under the new Rule, the inventor is limited to 25 claims in any single application and no more than two “continuation” applications based on an original filing. The Patent Act does not authorize either limitation. Moreover, by introducing various “presumptions,” the PTO diverges from existing law and improperly shifts legal burdens to applicants. These changes, if not set aside, will deprive patent applicants of substantial property rights and will constitute an unconstitutional “taking” without compensation.

The PTO, however, is oblivious to inventors’ property rights. The agency merely asserts, without conducting any analysis required under Executive Order 12630, that the Final Rule “will not effect a taking of private property.” 72 Fed. Reg. at 46834. For the reasons discussed below, the Rule does in fact preclude inventors from claiming the full measure of their reasonable, investment-backed property rights. The Rule thereby constitutes an uncompensated regulatory taking in violation of the guarantees of the Fifth Amendment.

The failure of the PTO to analyze and obviate this taking is grounds enough to set aside the Rule under the Administrative Procedure Act. Moreover, under the doctrine of constitutional avoidance, the PTO’s regulatory taking provides an additional reason for this Court to invalidate the Rule as *ultra vires*, not authorized by law, or arbitrary and capricious.

STATEMENT OF INTEREST

WLF, a non-profit public interest law and policy center, devotes a substantial portion of its resources to advancing free enterprise, individual rights, and a limited and accountable government. WLF has frequently appeared in federal and state courts to protect property rights, including intellectual property rights, against intrusion by governments and third parties. WLF has no financial interest in the outcome of this litigation.

ARGUMENT

I. The Rule Would Significantly Diminish the Value of Pending Patent Applications

A. Patent applications are valuable property

A patent application entails valuable property rights. *See* Nimmer, *Modern Licensing Law* § 15:6 (2007) (patent application is valuable asset that should be included in bankruptcy estate), citing *Keen, Inc. v. Gecker*, 264 F. Supp. 2d 569 (N.D. Ill. 2003).¹ The fact that a patent application is not tantamount to the full patent right – that is, the right to exclude others from making, using, selling, offering for sale, or importing a patented invention – does not negate the substantial value inherent in the application itself. Indeed, the Patent Act expressly provides that a patent application may be owned and assigned. 35 U.S.C. § 261. It further provides that an applicant or his assigns may “convey an exclusive right under his application for patent ... to the whole or any specified part of the United States.” *Id.* The very statutory scheme establishes that patent applicants have ownership and property rights.

Pending patent applications are routinely licensed for substantial sums – even without any assurance that patents will ever be granted. A review of any major university technology transfer website will reveal that pending applications are routinely made available for licensing.² The value of a pending application as a licensing property lies in the claims that one may reasonably expect to be granted. The value is real enough that people pay real money for rights in applications, long before any patents issue. No knowledgeable observer of patent transactions could credibly argue that pending applications do not represent substantial property value.

¹ *See also, e.g., Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999) (“Patents ... have long been considered a species of property”).

² For example, on 19 December 2007 the website for the technology transfer office for the University of Wisconsin (<http://www.warf.org/technologies.jsp>) listed approximately 110 pending applications or portfolios available for licensing.

The value of a pending patent application can be assessed with reasonable certainty.³ Patent attorneys do so regularly by reviewing the patent disclosures and prosecution histories, commissioning searches of existing technology, and evaluating the likelihood that particular claims will be found patentable. A license for technology covered only by a pending application may command substantial up-front licensing fee as well as royalties on future sales.⁴

The reason that claims in a pending application can be assessed reliably – even before the Patent Office takes any action on the application – is that the standards for assessing patentability are firmly set by statute. The Patent Office has no discretion to grant or deny claims based on its own assessment of commercial policy, agency objectives, or any other extrinsic considerations. Instead, Congress has charged the Director of the PTO with the precisely delineated task of examining applications to determine whether, and only whether, they comply with the statutory criteria for patentability. *See* 35 U.S.C. § 131 (“[I]f on ... examination it appears that the applicant is entitled to a patent [for an invention] under the law, the Director *shall issue a patent therefor*”)(emphasis added). The PTO may make no policy judgments in examining patents.

B. The value of applications reflects investment-backed expectations

Many companies rely on their intellectual property assets – including pending patent applications – to induce investors to commit risk capital to their businesses.⁵ To be sure, a patent

³ *See generally* Association of University Technology Managers [Invention] Valuation Manual, available at http://www.autm.net/aboutTT/aboutTT_valuation.cfm.

⁴ *See, e.g.*, 4/2005 IP Law & Business 18, “Big Deals: Pfizer Inc. Angiosyn Inc.,” on Westlaw at 4/2005 IPLBUS 18 (reporting \$537 million up-front payment to start-up to acquire rights in two patents and ten pending applications covering a treatment for blindness).

⁵ *See, e.g.*, Statement of the Biotechnology Industry Organization before the House Science and Technology Subcommittee on Science and Innovation on “The Bayh-Dole Act: The Next Twenty-five Years,” Aug. 27, 2007, available at <http://bio.org/ip/action/20070827.pdf> (potential licensing partner for a new biotechnology invention will “review the strength of the IP protecting the early-stage discovery to determine the worth of the investment”).

application may not result in a granted patent, and all other considerations being equal, a reasonable investor would assign greater value to a granted patent than a pending application. Real-world investors – often, sophisticated investors such as venture capital funds – can and do make substantial investments in early-stage companies based on the patent applications those companies have filed and, specifically, based on the claims in those applications.

C. Congress has provided “provisional” rights for the use of inventions claimed in published pending patent applications

The Government has cited cases for the proposition that pending patent applications do not confer the rights of a granted patent. *See* Def.’s Opp’n to Pl’s Mot. for a TRO and Prelim. Inj. at 33. But that argument is a straw man. In fact, patent applications have substantial value long before they become patents. Moreover, the cases cited by the Government predate the enactment of new statutory authority authorizing the publication of pending patent applications. *See* Pub. L. No. 106-113, Opp. I, Sec. 4502, 113 Stat. 1501A-561, 582 (1999) (S. 1948). As part of that legislation, Congress provided for “provisional rights” associated with claims in published patent applications. These rights – essentially a retroactive, compulsory license – mature on the grant of a patent. *See* 35 U.S.C. § 154(d). Specifically, a third party practicing an invention claimed in a published patent application is legally obligated to pay the owner of the application a reasonable royalty for the use of the invention, provided that the application matures to a patent having a granted claim that is “substantially identical” to the relevant claim of the application, and further that the third party had actual notice of the published application. *Id.* § 154(d)(1), (2). Though not as robust as the rights associated with a patent, these provisional rights manifest the property ownership rights associated with the application itself.

By the express terms of the statute, such rights depend on having both published application *claims* and granted patent *claims*. *See* 35 U.S.C. § 154(d)(2). If the PTO arbitrarily

limits the number of claims that can be presented or ultimately examined, as they have done in the new Rule, then the applicant's rights are diminished commensurately.

II. The PTO's Rule Would Improperly Restrict the Subject Matter in Pending Applications and Take Away Property Rights Enjoyed by Patent Applicants

The Rule limits the patent rights held by applicants through restrictions on the number of applications that may be filed; the number of claims permitted in each application; and the way claims to related subject matter may be pursued in different applications.

A. The number of applications and claims that may be presented is subject to new, arbitrary limitations

First, the number of claims in each application is effectively – and arbitrarily – capped at 25.⁶ *See* 37 C.F.R. § 1.75(b)(1).⁷ Second, the number of applications that may be filed based on an original application is effectively capped at three. *See id.* § 1.78(d)(1)(v)(B). Thus, an original application can result in – at most – 75 granted patent claims. This departure from current law and practice, which (apart from the equitable doctrine of prosecution laches, *see, e.g., In re Bogese*, 303 F.3d 1362, 1367 (Fed. Cir. 2002)) places no limits on the numbers of either claims or continuing applications that an applicant may present, inescapably and improperly constrains the ability of applicants to pursue claims to all of the inventions they have disclosed.

The Rule ostensibly provides a mechanism by which an applicant could present claims in excess of 25 in a given application. *See* 37 C.F.R. § 1.75(b)(1). This mechanism, however, is

⁶ The Government imposes these arbitrary cut-offs in the asserted interest of administrative efficiency and avoidance of examiner error. *See* 72 Fed. Reg. at 46717-18; *see also* Def.'s Opp. to Pl.'s Mot. for TRO and Prelim. Inj. at 1. These are thin reeds on which to deprive patent applicants of a significant measure of their property rights in their discoveries and inventions. The PTO has no authority to promote administrative convenience over the protections specified in the Patent Act. *See* 35 U.S.C. § 2(a)(2)(A).

⁷ Unless otherwise noted, all references to title 37 C.F.R., pt. I, are to the regulations as amended by the Final Rule published on Aug. 21, 2007.

not a real option because it is impossibly and unjustifiably burdensome. It would require the applicant to submit an “examination support document” (“ESD”), *id.* § 1.265, setting forth information relating to the claims in exhaustive detail, far exceeding that typically collected by the PTO’s own examiners. The PTO already complains that it receives more information from applicants than its examiners can process.⁸ The agency demands that applicants invest considerable resources to generate documentation that is, at most, marginally relevant to the examination process. The PTO would also require applicants to provide an affirmative justification as to why each claim is patentable. *See generally* Mem. in Supp. of Pl.’s Mot. for TRO & Prelim. Inj. at 10-11.

That this mechanism is unduly burdensome is not mere legal bluster. A representative of the PTO candidly acknowledged that the requirements of this cap-limiting mechanism are so prejudicial to applicants’ patent rights that no reasonable patent attorney would advise his or her client to provide the required ESD. *See* Pl. Tafas’s Mem. in Opp. to Def.’s Mot. for Issuance of Expedited Briefing Sch. at 14. In other words, the ESD mechanism was never intended to provide applicants a meaningful opportunity to preserve their rights to claim their inventions.

Similarly, a mechanism provided in the new Rule that would ostensibly allow the filing of more than two continuing applications based on an original filing, is also not a meaningful option. *See* 37 C.F.R. § 1.78(d)(1)(vi). The PTO itself envisions that it would permit a third continuing application in only the most exceptional of circumstances. *See* Mem. in Supp. of Pl.’s Mot. for TRO and Prelim. Inj. 9-10. Again, the PTO plainly intended the caps in its new Rule to be *effective* in restricting the ability of applicants to submit applications and make claims.

⁸ *See* “Changes to Information Disclosure Requirements and Other Related Matters; Notice of proposed rulemaking,” 71 Fed. Reg. 38808, 38809 (July 10, 2006)(discussing burdens on PTO of large submissions of information by applicants).

The Government may argue that the availability of restriction requirements under 35 U.S.C. § 121 mitigates the “two continuation” limit. However, under the new Rule, the PTO has recast its practice under § 121 to convert a statutory mechanism for the *agency* to allocate its examination resources (essentially internal procedures) into a binding requirement for patent *applicants* to limit the scope of their claims (which is obviously substantive). *See* 37 C.F.R. § 1.142(c).⁹

Indeed, the Rule is self-evidently designed to minimize the number of patent applications and patent claims presented to the PTO for examination. The inevitable result is that the Rule will limit the ability of applicants to fully claim the subject matter disclosed in their applications. This shift from the procedural to the substantive is clearly unauthorized and impermissible.

B. The PTO’s Rule inverts the presumption that claims in an application are patentable to the applicant

By statute, the Patent Office bears the burden of establishing that a claim is unpatentable. If it cannot do so, it must grant a patent. *See, e.g.*, 35 U.S.C. § 102 (“A person shall be entitled to a patent unless . . .”). The PTO must set forth a *prima facie* case of *unpatentability* before the applicant may be required to present any affirmative evidence in support of patentability. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Yet, in the new Rule, the PTO requires patent applicants to affirmatively justify their right to present more than an arbitrary number of claims.

⁹ Under 35 U.S.C. § 121, if the PTO determines that two claimed inventions are “independent and distinct” – that is, capable of supporting independent patents – it may require the applicant to remove the claims for one of the inventions to a “divisional” application. A divisional application will not be counted as one of the two continuing applications permitted under the Rule. *See* 37 C.F.R. § 1.78(d)(1)(ii). However, unless the applicant submits a “suggested restriction requirement” under § 1.142(c) – which the PTO still reserves the right to reject – the PTO will not even review an application containing more than 25 claims. And, the applicant may lose the right to file divisional applications altogether.

In doing so, it eviscerates the presumption that an applicant must be granted a patent right for any claim meeting the statutory requirements for patentability that the applicant presents.

The Rule also would require applicants to affirmatively justify the patentability of claims in certain circumstances, without any *prima facie* showing of unpatentability by the PTO. One such circumstance is the case where an applicant owns two or more applications directed to similar subject matter. Under current practice and controlling precedent, the propriety of maintaining such separate applications is analyzed under the doctrine of “obviousness-type” double patenting. *See, e.g., In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986); *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998).¹⁰

An applicant may overcome a rejection based on double patenting by arguing separate patentability on the merits, or by filing a “terminal disclaimer” as authorized by 35 U.S.C. § 253.¹¹ *See* M.P.E.P. § 804.02. The legal effect of such a disclaimer is that the patent applicant waives the right to assign the two applications or patents separately. Additionally, in the case that the second patent would expire after the first, the owner also disclaims the part of the term of the second patent that would extend beyond the term of the first. *See* 37 C.F.R. § 1.321(c).

Under the new Rule, the PTO will avoid examining claims for double patenting by requiring applicants to identify certainly commonly-owned, copending patent applications, and to prospectively “rebut[]” a “presumption” – dictated by rule – that claims in such applications

¹⁰ Under this doctrine, the claims in two patents or applications are compared to determine whether they can properly support separate patents. If a claim in one application is “obvious” over one or more claims in another application, the PTO will reject the claim as unpatentable – just as it does for claims that are unpatentable because of prior art under 35 U.S.C. §§ 102 or 103. *See* U.S. Patent and Trademark Office, Manual of Patent Examining Procedure (M.P.E.P.) § 804.

¹¹ This is true only for claims that differ in scope and effect. 35 U.S.C. § 101 has been construed to prohibit the grant of more than one claim to the “same invention,” *i.e.*, no identical claims are allowed. *See Kaplan*, 789 F.2d at 1579.

are *not* patentably distinct. *See id.* § 1.78(f)(2). If the applicant cannot do so,¹² the applicant is required to cede property rights in the application by filing a terminal disclaimer – all before the case is ever reviewed by an examiner. As required under § 1.321(c), a terminal disclaimer imposes a restriction on alienation. The right to assign a patent application is expressly acknowledged by statute, 35 U.S.C. § 261. Thus, the new Rule would compel the forfeiture of property rights that are inherent in pending *applications* – rights that are not conditioned on the application eventually becoming a patent.

The PTO seeks to avoid controlling precedent by characterizing these requirements as “procedural.” 72 Fed. Reg. at 46780 (response to comment 112). Indeed, the PTO takes the view that the applicant should be blamed for any question of double patenting that an examiner may raise. *See* 76 Fed. Reg. at 46722 (“if an Office action must include a double patenting rejection, it is because the applicant has not met his or her responsibility to resolve the double patenting situation”). But as the courts have instructed, double patenting is a patentability requirement on a par with those specified in the statute. It is not a mere procedural formality. *See Kaplan*, 789 F.2d at 1581 (reversing PTO rejection of claims for double patenting); *Berg*, 140 F.3d at 1437 (affirming rejection).

C. The Rule will improperly preclude some applicants from obtaining early patents – and in some cases, any patents – for their inventions

Patent applicants often describe and claim their inventions broadly, but also present claims to narrower aspects of the invention. In chemistry and biotechnology, this can involve the disclosure of a genus (*e.g.*, a class of compounds, typically numbering at least in the thousands),

¹² An applicant might also choose not to create the potential for prosecution history estoppel by “rebutting” a rejection that has not even been stated. Any argument by an applicant on the record can give rise to prosecution history estoppel, thus potentially limiting the scope or enforceability of the claims. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 568 (Fed. Cir. 2000) (en banc), *rev’d & remanded*, 535 U.S. 722 (2002).

and several species within the genus (*e.g.*, particular compounds, of which typically a few dozen might have potential commercial value). As a general rule, different chemical compounds are considered patentably distinct, and claims to the compounds are thus subject to restriction under 35 U.S.C. § 121 (*i.e.*, requirements to file divisional applications). The requirement for restriction will only become binding on the PTO if the genus claim is not found allowable. Thus, separate patents containing claims to different species within a disclosed genus may be granted.

Current practice allows applicants to obtain patent rights to potentially valuable species at an early date, and to continue prosecuting claims to the genus (which have considerable commercial value, but which also generally raise a greater number of patentability issues) in a continuing application.¹³ Experience has shown that this practice benefits both the public and innovators in the chemical and biotechnology sectors.

The new Rule imposes draconian limitations on this aspect of current practice. If the applicant does not have the benefit of a restriction requirement, there can be no more than three applications in the series. Under the new Rule, applicants who chose to pursue a genus claim after *any* species claim would not have the protection of such a requirement. In that case, it would become effectively impossible for an applicant who discloses hundreds or thousands of useful compounds to obtain specific patent claims to more than a handful of those compounds.

To address this concern, the PTO's "solution" is that an applicant who wishes to pursue claims to a genus invention should do so completely in its first application – exhausting appeals to the PTO Board of Appeals and the Federal Circuit, if necessary – before it presents any applications claiming any of the disclosed species. *See* 72 Fed. Reg. at 46727. If the applicant is

¹³ If a claim to a genus that includes a patented species is presented later, a question of double patenting will arise. The applicant will ordinarily file a terminal disclaimer in the second application to obviate the double patenting issue.

ultimately successful, it will be able to claim a limited number of species in the same patent with the genus claims. If the genus claims are ultimately held unpatentable, the applicant will have preserved the right to rely on a restriction requirement as between the species, and may then file as many separate divisional applications to patentably distinct species as it wishes.

Alternatively, the applicant may forgo claims to the genus entirely, securing the right to rely on the restriction requirement for subsequent divisional applications claiming only species.

The problem with this “solution” is that it forces the applicant to choose between waiting for several years to obtain enforceable patent rights covering species, or abandoning the possibility of ever obtaining a patent to the generic invention. Most applicants would find both alternatives unacceptable. Indeed, chemistry and biotechnology applicants often find it advantageous to procure patents for “lead compounds” – promising species – at an early date. Such first patents provide a measure of commercial protection, and in the case of a start-up company, they provide assets that can help secure venture capital funding. The early patents, in turn, provide sufficient commercial certainty to allow patent owners to invest in the (often) more extended and resource-intensive process of procuring broader claims in later patents. This commercially effective approach to ensure full patent protection is exactly what the new Rule prohibits.

III. The PTO’s New Rule Effects a “Regulatory Taking”

Amicus curiae WLF fully supports plaintiffs’ arguments that the Rule should be set aside as an *ultra vires* exercise of *substantive* policymaking by the PTO. Even if the PTO’s policy were a good idea – which it is not – only Congress may impose such limits, and even then, only with due regard for established property rights. What the PTO has done, however, is to exceed

its authority in a manner that deprives inventors of their property rights. The Constitution and existing law do not allow that.

The Patent and Copyright Clause, U.S. Const. art. I, § 8, cl. 8, guarantees the “exclusive Right [of authors and inventors] to their respective Writings and Discoveries.” The text of the Constitution codifies the importance the Framers placed on protecting intellectual property rights – rights that the PTO may not cavalierly abridge in the name of efficiency or administrative convenience.

The Patent Act and the jurisprudence construing it demonstrate that Congress has delegated *no* legislative, policymaking authority relating to the patent laws to the Executive. *See* 35 U.S.C. § 2(b)(2)(A); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996); *Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003). The Final Rule would alter rights affirmatively provided to patent applicants by statute under express constitutional authority – they are fundamentally legislative in character. The PTO simply cannot arrogate to itself the authority to promulgate such substantive regulations.¹⁴

Apart from the question of whether the Rule is *ultra vires*, arbitrary and capricious, or otherwise contrary to law, this Court must consider whether it should be set aside as an unconstitutional taking of property rights without just compensation. The PTO purports to promulgate the new Rule under a delegation of procedural rulemaking authority, 35 U.S.C. § 2(b)(2)(A). But as explained below, the PTO’s “procedural” rule deprives patent applicants of

¹⁴ By setting substantive patent policy, the PTO has violated the separation of powers mandated by the Constitution. *Amicus curiae* WLF will not elaborate here on the separation of powers violation entailed by the PTO’s new Rules, other than to note that by cloaking important substantive changes under the mantle of mere “procedural” change, the PTO has usurped the role expressly assigned by the Constitution to Congress. Thus, the separation of powers doctrine provides further support to set aside the Rule as *ultra vires*.

substantive rights and effects an uncompensated taking of property. Applying the canon of constitutional avoidance, the Court should reject the PTO's proffered construction of its rulemaking authority. *See, e.g., Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such a construction is plainly contrary to the intent of Congress"); *see also, United States v. Deaton*, 332 F.3d 698, 705 (4th Cir. 2003). Here, it is abundantly clear that Congress did not intend to delegate substantive rulemaking authority to the PTO. Section 2(b)(2)(A) of the Patent Act should be construed to avoid an unconstitutional result.

A. The PTO's Rule eliminates investment-backed expectations concerning property rights

The arbitrary new limits on claims and continuations apply to patent applications that have already been filed, but which have not yet received a first Office action. 72 Fed. Reg. at 46716-17. Moreover, the new Rule applies to newly-filed applications that claim (or would seek to claim) priority under 35 U.S.C. § 120 to original applications filed before the Rule was published – original applications that were filed with the reasonable expectation that they could be prosecuted fully. This expectation extends to the applicants' ability to file and prosecute as many continuing applications – and as many claims in those applications – as needed to fully and properly claim the subject matter they disclose. Moreover, this expectation underlies not only the applicant's property rights, but also business and investment decisions by venture capitalists, purchasers and licensees of patents and patent applications, and entities such as plaintiff GSK that develop and patent inventions that they intend to commercialize themselves. *See Dec. of Sherry M. Knowles in Supp. of Pl.'s Mot. for TRO and Prelim. Inj.* ¶ 4.

1. The requirement to forgo some number of claims would materially reduce the value of pending patent applications

The Rule limits the number of claims that an applicant ultimately may present for examination. There are many proper reasons that an applicant may choose to file additional claims in a continuing application, including patenting previously unclaimed subject matter and claiming aspects of a product that the applicant has commercialized. The ability to obtain such claims in a future patent application has real-world, present-day value for patent applicants.

The Rule would extinguish *ex ante* property rights in patent claims that can never be presented for examination. Limiting patentees to only some, but not necessarily all, of the claims that would cover their inventions may not provide commercially relevant protection, and is not a result authorized by law.

It is a bedrock principle of patent law that each claim is an independent property right. Both validity and infringement of a patent are assessed on a claim-by-claim basis. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373-74 (1996). A single infringed claim can serve as the basis for recovering the full measure of profits lost on account of the infringement. *Id.* And, if a patentee fails to claim all of the aspects of an invention described in a patent application, the unclaimed aspects are deemed to be dedicated to the public. *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (*per curiam*) (*en banc*). Every claim that would be prohibited by the new Rule represents actual value lost to the owner of the application – value that can never be realized through licensing, investment, or eventual commercial activity.

The extinction of rights in inventions that cannot be claimed is an unreasonable interference with the enjoyment of property rights. The whole of the rights in each claim barred by regulation is lost forever. Accordingly, the Rule denies all economically beneficial

productive use of property and amounts to an uncompensated constitutional injury. *See, e.g., Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015-16 (1992).

The harm is not mitigated by the fact that applicants may choose the limited claims they will pursue. The statute limits neither the number of claims nor continuing applications that an applicant may ultimately present. Congress has delegated no authority to the PTO to deem some number of claims “sufficient” to protect applicants’ inventions. *See* 72 Fed. Reg. at 46746.

B. The requirement to defer prosecution of certain genus or species claims would impermissibly withhold patent rights in patentable inventions

As explained above in section II.C., the Rule forces the owners of applications claiming genus-species inventions to choose between unreasonable alternatives. The PTO advises applicants to fully prosecute all claims to the generic inventions in their first filings, or to abandon the claims to the generic inventions to begin prosecuting claims to various species in divisional applications. *See* 72 Fed. Reg. at 46727. Thus, in the best case, applicants who desire both genus and species claims must wait, typically years – until genus claims are determined to be allowable, or all appeals have been exhausted – before they can *begin* prosecuting species claims. These years correspond to lost patent term that can never be recovered.

Deferring a grant of patent rights to which the applicant is entitled under the law completely deprives the applicant of the enjoyment of property rights for the full period of the deferral. Even the temporary deprivation of rights may be an uncompensated taking. *See, e.g., First English Evangelical Lutheran Church of Glendale v. L.A. County*, 482 U.S. 304, 317-18 (1987); *see also Penn Central Transp. Co. v. New York City*, 438 U.S. 104 (1978) 438 U.S. at 124-25 (setting forth the principal factors that govern an assessment of takings); *Tahoe-Sierra Preservation Council, Inc. v. Tahoe Regional Planning Ag’cy*, 535 U.S. 302, 337 (2002) (“we do

not hold that the temporary nature of a land-use restriction precludes finding that it effects a taking”).

C. Requiring a terminal disclaimer to address an improper administrative “presumption” effects a taking of vested property rights

As explained in section II.A. above, 37 C.F.R. § 1.78(f)(2) would establish a “presumption” by Rule that claims in certain copending, commonly-owned patent applications are not patentably distinct. The applicant would be afforded an opportunity to “rebut []” this “presumption.” 37 C.F.R. § 1.78(f)(2) (2007). A reasonable patent attorney could choose to forgo an argument on the merits, *e.g.*, to avoid the possibility of creating prosecution history estoppel, particularly inasmuch as proposed § 1.78(f)(2) does not require the PTO to articulate a particularized basis for the “presumption.”¹⁵ If the applicant does not “rebut” the “presumption,” a terminal disclaimer over the copending application will be required.

A terminal disclaimer, *inter alia*, waives the applicant’s right to assign the disclaimed patent separately from the reference patent. The right to transfer property as the owner chooses is one of the important “sticks” in the “bundle” of rights associated with intellectual property. *See Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). In the case of a pending patent application, the *present* monetary value of an application that has not been patented depends significantly on the owner’s right to assign the application to a third party. This is, moreover, a present right that is specifically enumerated in the statute. 35 U.S.C. § 261. A restriction on alienation significantly impairs the value of the patent asset, and it interferes with reasonable investment-backed expectations as to how its owner may use a patent granted on the application.

¹⁵ Compare 37 C.F.R. § 1.104(a)(2) (“The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant ... to judge the propriety of continuing the prosecution.”).

Accordingly, an administrative mandate that certain applicants be required to disclaim rights in their applications is a taking of a protected property interest.

D. The PTO's Final Rule fails to analyze takings implications

In the face of this deliberate shrinkage of inventors' rights, the PTO blithely asserts that its Final Rule "will not effect a taking of private property or otherwise have taking implications under Executive Order 12630." *See* 72 Fed. Reg. at 46834; *see also* "Executive Order 12630 of March 15, 1988," 53 Fed. Reg. 8859 (Mar. 15, 1988) (setting forth the Executive's policy concerning takings implications of regulatory action).

The PTO's lack of analysis of the takings implications appears to reflect the agency's negligible interest in ensuring that inventors receive the full spectrum of the patent protection to which they are entitled by law. The *pro forma* takings statement provides no evidence that the agency actually gave the question any meaningful consideration. Thus, the PTO's failure to perform the required takings analysis, as well as its conclusory dismissal of the takings implications, render the new Rule defective because the agency "entirely failed to consider an important aspect of the problem" before it. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43, 48-49 (1983); *see also Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1285-86 (D.C. Cir. 2005) (remanding regulations that failed to conduct analysis of impacts on small entities required under the Regulatory Flexibility Act). Moreover, the PTO's failure to properly address the takings issue is contrary to law. *See Nat'l Wildlife Found. v. Interstate Commerce Comm'n*, 850 F.2d 694, 705-06 (D.C. Cir. 1988) (agency "must consider the effects of the ... [r]ules on the property rights of ... owners, rather than deny that such effects are legally cognizable"). As in *NWF*, this Court should not *assume* that the PTO's flawed interpretation of the statute was not affected by its (lack of) analysis of the takings

issue. *Id.* at 708. Rather, the insufficiency (indeed, absence) of the PTO's takings analysis was likely instrumental to the agency's erroneous decision to impose improper limits on patent claims.

E. Uncompensated regulatory takings, like that effected by the PTO Rule, are unconstitutional

In *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005), the Supreme Court addressed and clarified the jurisprudence of "regulatory takings," explaining that

[o]utside the[] relatively narrow categories [of physical invasions of land or 100% deprivations of economic value] ..., regulatory takings challenges are governed by the standards set forth in *Penn Central Transp. Co. v. New York City*, 438 U.S. 104 (1978).

Lingle also reaffirms two key points that are relevant to this case: (1) the Takings Clause of the Constitution protects personal as well as physical property, *id.* at 537, and (2) regulations can violate the Constitution even if they do not "completely deprive an owner of 'all economically beneficial us[e]' of her property" *id.* at 538 (internal citation omitted) (alteration in original).

Regulatory takings are assessed on a case-by-case basis. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984); *Andrus v. Allard*, 444 U.S. 51, 65 (1979) ("[r]esolution of each case ... ultimately calls as much for the exercise of judgment as for the application of logic").

The magnitude of the economic harm suffered by the claimant, the extent to which the regulation interferes with investment-backed expectations, and the character of the governmental action all factor into determining whether an unconstitutional taking has occurred. *Penn Central Transp. Co. v. New York City*, 438 U.S. 104 (1978).

Crucially, the Supreme Court has acknowledged that the devaluation of *intellectual property* through government regulation can effect a taking.¹⁶ The “notion of ‘property’ ... extends beyond land and tangible goods and includes the products of an individual’s ‘labour and invention.’” *Monsanto*, 467 U.S. at 1003. The Court specifically held that an intangible intellectual property right, namely a trade secret, was a “property right ... protected by the Taking Clause of the Fifth Amendment.” *Id.* at 1003-04.

The Government may argue that the value of a patent application arises only after a patent is granted. But this argument does not justify the regulatory taking here. First, as shown above, patent applications have real, current value that can be – and frequently is – assigned or licensed. Second, the fact that an asset’s economic value will only be fully returned in the future does not excuse uncompensated takings today. It has long been recognized that the Constitution protects economic benefits that can be extracted from the owner’s property in the future.

In *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 414 (1922), a law limiting the plaintiff’s right to mine coal to preserve subsurface support for above-ground structures was held to be an unconstitutional taking of the property right. “‘For practical purposes, the right to coal consists in the right to mine it.’ ... To make it commercially impracticable to mine certain coal has very nearly the same effect for constitutional purposes as appropriating it or destroying it.”

¹⁶ *Zoltek Corp. v. United States*, 442 F.3d 1345 (Fed. Cir. 2006) (per curiam), *reh’g denied*, 464 F.3d 1335 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2936 (2007), is not to the contrary. At issue in that case was the scope of waiver of sovereign immunity for acts of patent infringement under 28 U.S.C. § 1498. Specifically, whether the alleged infringement of a particular process patent by the U.S. Government could be brought as a takings claim under the Tucker Act. The court found that section 1498, which is not at issue here, disallowed jurisdiction on the facts of that case. This case does not concern alleged patent infringement by the Government; thus, *Zoltek* is not germane. Moreover, *Zoltek* did not – and indeed, could not – undermine the holdings of the Supreme Court in *Monsanto* and other precedents that intellectual property (including patents) is “property” subject to the protections of the Takings Clause.

Id. (citation omitted). Indeed, even if the “extent of the taking ... is ... speculative,” the taking is suspect unless “‘there [is] at the time of taking ‘‘reasonable, certain and adequate provision for obtaining compensation.’’’” *Dames & Moore v. Regan*, 453 U.S. 654, 689 (1981) (discussing without deciding whether Presidential suspension of individual claims against Iran was an unconstitutional taking). The PTO’s Final Rule, unjustifiably and without compensation, deprives patent applicants of vested and future property rights that are the foundation of reasonable, investment-based expectations relating to patent assets.

IV. CONCLUSION

For the reasons set forth above, *amicus curiae* Washington Legal Foundation respectfully urges this Court to grant Plaintiff GSK’s Motion for Summary Judgment.

Dated: December 27, 2007

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, I electronically filed in Case Nos. 1:07cv1008 and 1:07cv846 (JCC/TRL) the foregoing Motion of *Amicus Curiae* Washington Legal Foundation for Leave to File its Brief in Support of GSK's Motion for Summary Judgment using the CM/ECF system and that service was thereby accomplished on:

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