LEGAL UPDATE

TAFAS V. DUDAS AND *TAFAS V. DOLL*: THE PROBLEM OF EFFICIENT INNOVATION

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I. INTRODUCTION

On August 21, 2007, the United States Patent and Trademark Office (USPTO) proposed significant changes to the existing patent system, imposing unprecedented limitations on an inventor's ability to file patent applications.[1] Faced with a voluminous and increasing number of applications each year, the new rules sought to streamline the patent process by forcing innovators to efficiently file their stated applications.[2] In this sense, the goal of the rules seems logical. Patent applicants, however, objected that limiting applications created substantial barriers to innovation. Future inventions might not fit neatly into a set number of claims, and the new rules, along with the additional

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[1] *See* Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008) [hereinafter "Tafas I"].

[2] *See* Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and the Examination of Claims in Patent Applications, 72 Fed. Reg. 46, 716-21 (Aug. 21, 2007) (temporarily codified at 37 C.F.R. pt. 1) [hereinafter "Final Rules"].

filings they entailed, would impose higher costs.[3] As such, important innovative industries, such as the biotechnology and pharmaceutical fields, would face difficulty "securing full coverage for their inventions."[4] The proposed rules, they argued, impermissibly stretched the essential patent law goal of "progress in science."

A day after the USPTO published the "Final Rules" on August 22, 2007, GlaxoSmithKline ("GSK") and Triantafyllos Tafas ("Tafas") sought injunctions prohibiting their implementation.[5] On April 1, 2008, the District Court for the Eastern District of Virginia decided that the rules were void because they substantively altered existing law,[6] an action that the USPTO did not have the authority to undertake.[7] On appeal, however, the Federal Circuit Court of Appeals decided that the rules were not substantive alterations to the Patent Act, but were rather procedural in nature.[8] The USPTO, they asserted, could enforce procedural policy initiatives and the new rules were not beyond the scope of the agency's power. Following the Federal Circuit opinion, Tafas and GSK filed a petition for rehearing *en banc* and on July 6, 2009, a poll of circuit judges granted *en banc* consideration.[9]

Surprisingly, prior to the rehearing, on October 8, 2009 the USPTO announced that it would unilaterally rescind the Final Rules due to vehement opposition from patent applicants.[10] The Patent Office instead wanted to "engage the applicant community more effectively on improvements that will help make the USPTO more efficient, responsive, and transparent to the public."[11]

The abrupt end to this significant string of litigation leaves both the USPTO and innovators to ponder the future of the patent application process. The Patent Office apparently abandoned efforts to increase the efficiency of the patent application process in response to opposition from innovators. The power shift between the two parties warrants a close examination of the rationales and opposition underlying the USPTO rules. As such, this update will outline the requisite patent application rules, and then discuss both the District Court opinion in *Tafas v. Doll* and the corresponding Court of Appeals

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[3] Tony Dutra, *Patent and Trademark Office: Patent Community Applauds PTO's Decision to Rescind Continuation, Claims Rules*, 10/13/2009 PTD d6, 2.

[4] *Id*.

[5] Tafas I, 541 F. Supp. 2d at 810.

[6] *Id*. at 817

[7] *Id*.

[8] Tafas v. Doll, 559 F.3d 1345, 1364-65 (Fed. Cir. 2009) [hereinafter "Tafas II"].

[9] Tafas v. Doll, 328 Fed. Appx. 658 (Fed. Cir. 2009) [hereinafter "Tafas III"].

[10] USPTO Press Release #09-21 (Oct. 8, 2009) *available at* http://www.uspto.gov/news/09_21.jsp.

[11] *Id*. (the parties intend to file a joint motion to dismiss).

decision of *Tafas v. Dudas*.[12] To conclude, this update will discuss the implications of future USPTO changes to the patent application process and how potential changes could profoundly affect the frequency and acceleration of innovation in the United States.

II. BACKGROUND – ALTERATIONS IN PATENT APPLICATION RULES

To obtain patent protection, an applicant must first file a parent application with the USPTO.[13] A parent application contains one or more claims that delineate the scope of protection sought for the invention, and also contains specifications that describe the invention in useful detail.[14] Independent claims state a new concept, while dependent claims expound on a previous independent claim.[15] If an applicant does not meet the required elements for patent protection, he receives an office rejection and may amend his claims.[16] If the USPTO issues a final rejection, an applicant has three options to continue pursuit of a patent: (1) an appeal to the Board of Patent Appeals, which would then lead to the United States Court of Appeals for the Federal Circuit; (2) a request for continued examination ("RCE") of the original application; or (3) a continuation or continuation-in-part application that amends existing applications to either avoid restatement and/or add new information.[17] Significantly, the original Patent Act does not numerically cap any type of claim.[18]

The USPTO Final Rules modified two key aspects of the patent application process. First, the 2+1 Rule permitted, by right, two continuation applications and one RCE after the parent application.[19] If an applicant wished to file further applications, the applicant was required to prove a previous inability to file the supplemental information,[20] or to file for a complete waiver of the 2+1 Rule.[21] The 2+1 Rule also required that the applicant submit related patent applications at the time of the original application.[22] The second major

[12] The USPTO party name changed due to a change in the Agency's Acting Director between the case decisions.

[13] 35 U.S.C. § 112 (2006).

[14] *Id*.

[15] *Id*.

[16] *Id*. § 151.

[17] *Id*. §§ 120, 132(b), 134, 141, 145.

[18] *See id.* §§ 120, 132(b), 134, 141, 145.

[19] 37 C.F.R. §§ 1.78(d)(1)(i)-(iii), 1.114(f) (the "2+1 Rule" is a colloquial combination of Rules 78 and 114).

[20] *Id*. §§ 1.78(d)(1)(vi), 1.114(g), 1.183.

[21] *Id*.

[22] *Id*. § 1.78(f).

modification, the 5/25 Rule, allowed a total of either five independent claims or twenty-five total claims as a matter of right.[23] Exceeding this limitation required filing a separate document to assist the examiner.[24]

III. THE DISTRICT COURT OPINION

Presented with GSK and Tafas' challenge, the District Court for the Eastern District of Virginia found that the Final Rules exceeded the scope of the USPTO's grant of authority in 35 U.S.C. § 2(b)(2) and were thus void.[25] This conclusion required two findings: (1) the USPTO was not granted substantive rulemaking power in this statute; and (2) the Final Rules were a substantive change to the existing patent system.[26]

A. The USPTO's Arguments

The USPTO first argued that substantive and procedural rules are not distinguishable.[27] The Patent Act provided the USPTO with the power to "govern the conduct of proceedings in the Office" through a method that "facilitat[ed] and expedit[ed]" the patent application process.[28] If there was not a distinction between procedural and substantive rules in the Act, then the Patent Act did grant the USPTO broad power to regulate the patent application process.

The USPTO argued that the agency's interpretation of the Patent Act should be subject to *Chevron* deference, under which the court defers to the agency's interpretation of the statute governing the agency's rulemaking authority.[29] *Chevron* requires that the relevant statute be made pursuant to a congressional delegation of administrative authority.[30] As Congress delegated the procedural rules of the Patent Act to the USPTO, the USPTO felt that the court should defer to its interpretation.[31]

Alternatively, the USPTO argued that the new rules were simply procedural alterations as they did not directly implicate substantive patent provisions.[32] Procedural rules with "collateral substantive consequences" are within the

[23] *Id.* § 1.75(b)(1).

[24] *Id.* § 1.265.

[25] Tafas I, 541 F. Supp. 2d at 811.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 812-13.

[29] *See generally id.*; Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[30] Adams Fruit Co. v. Barrett, 494 U.S. 638, 649 (1990).

[31] Tafas I, 541 F. Supp. 2d at 811.

[32] *Id.* (substantive patent provisions include novelty and nonobviousness).

Congressional grant of procedural power.[33] The application process, they argued, is within the principal power of the USPTO, and is separate from substantive rules that affect the granting of a patent.[34]

B. The USPTO Does Not Have Substantive Rule-Making Power Under 35 U.S.C. § 2(b)(2)

To begin its analysis, the District Court determined that there was a relevant difference between substantive and procedural rules based on Federal Circuit precedent.[35] The court then discussed the USPTO grant of power in 35 U.S.C. § 2(b)(2). The court asserted that the USPTO statutory grant of power consists of "promulgat[ing] regulations directed only to 'the conduct of the proceedings in the [USPTO],'" and that "it does not grant the Commissioner the authority to issue substantive rules."[36] The notice and comment rulemaking provisions of the statute also do not grant substantive powers.[37] Finally, the court asserted that legislative history revealed that Congress previously considered granting the USPTO substantive power.[38] Congressional inaction on this issue, however, strongly indicated Congressional intent not to grant the USPTO that power.[39]

C. The Final Rules Are an Impermissible Exercise of Substantive Rule-Making

Having found a distinction in rule type, District Court then discussed whether the Final Rules were procedural or substantive.[40] A substantive rule is any rule that "affect[s] individual rights and obligations."[41] The 2+1 Rule affected patent application rights by limiting the number of continuation applications.[42] While the Rule did not definitively cap such applications, the heightened requirement that the USPTO must approve applications beyond a certain number raised an additional, and impermissible, hurdle in the

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[33] *Id*.

[34] *See In re* Van Ornum, 686 F.2d 937, 945 (C.C.P.A.1982).

[35] Tafas I, 541 F. Supp. 2d at 813 (citing Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1549-50 (Fed.Cir.1996); Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed.Cir.1991)).

[36] *Merck* , 80 F.3d at 1549-50 (quoting *Animal Legal Def. Fund*, 932 F.2d at 930).

[37] Tafas I, 541 F. Supp. 2d at 812.

[38] *Id*.

[39] *Id*. (citing Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ., 550 U.S. 81, 89 (2007)).

[40] *Id*.

[41] *Id*. at 814 (citing Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979)).

[42] *Id*. at 814.

application process.[43] The 2+1 Rule, for instance, would deny continuing applications whose sole purpose was to encompass a competing product currently in the market.[44] The Federal Circuit, however, has expressly approved this type of continuation.[45] The court further noted that the language of the Patent Act, such as "shall" and "at the request of the applicant," suggests that Congress never intended to limit continuing applications.[46] Thus, any numerical limitation violates an applicant's rights.[47] By implicating such rights, the 2+1 Rule was not a procedural rule with substantive implications, but was instead wholly substantive.

The District Court next analyzed the new 5/25 Rule, which limited the number of permissible application claims. The Patent Act permits filing of "one or more claims," but gives the USPTO the power to reject claims due to "undue multiplicity."[48] The 5/25 Rule, however, flatly rejected applications that did not satisfy the additional ESD filing.[49] The ESD requires a search of prior art, coupled with an explanation of "how each of the independent claims is patentable over the cited reference."[50] The ESD requirement thus "affects rights" by altering an applicant's burden of proof.[51] Furthermore, under the Patent Act, an applicant has no duty to conduct a prior art search, or make an initial showing of patentability.[52] Since the 5/25 Rule and the 2+1 Rule altered the underlying rights of patents applicants, the District Court granted an injunction against the substantive USPTO Final Rules.[53] *Chevron* deference, the court decided, did not apply because the rules were considered substantive.[54]

III. THE COURT OF APPEALS OPINION

The USPTO appealed the District Court's injunction against the Final Rules to the Federal Circuit Court of Appeals. The Federal Circuit reviewed the

[43] *Id*. at 815.

[44] *See* Final Rules, 72 Fed. Reg. at 46775.

[45] Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed.Cir.1988).

[46] Tafas I, 541 F. Supp. 2d at 815.

[47] *Id.*

[48] 35 U.S.C. § 112 (2006); *see In re* Chandler, 319 F.2d 211, 225 (1963).

[49] *See* 37 C.F.R. § 1.75(b)(3).

[50] Tafas I, 541 F. Supp. 2d at 816.

[51] *Id*.

[52] Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005); *In re* Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967) (the initial burden of proof in a patent examination rests on the USPTO to make a prima facie case of unpatentability).

[53] Tafas I, 541 F. Supp. 2d at 817.

[54] *Id*. at 811 n.4.

District Court judgment *de novo*.[55]

A. The Final Rules Are Procedural and Subject to Deference

The Federal Circuit agreed that the Patent Act does not grant substantive rulemaking power to the USPTO.[56] They believed, however, that *Chevron* deference should apply since the Rules governed the "conduct of proceedings in the Office," which was expressly delegated to the USPTO.[57] Furthermore, the Appeals court stated that the District Court's definition of "procedural" was too narrow. Procedural changes, according to the Federal Circuit, can "alter the manner in which the parties present themselves or their viewpoints to the agency."[58] A substantive rule must "foreclose effective opportunity to make one's case on the merits."[59] Conversely, the Final Rules simply required greater effort on the part of the applicant, which the Federal Circuit permits.[60] The Rules consequently did not foreclose applications, and thus were not substantive.[61]

B. Some Portions of the Final Rules Are Consistent with the Patent Act

After concluding that the Final Rules were procedural, the Federal Circuit also stated that the Rules must be consistent with the Patent Act.[62] Under *Chevron* deference, the Rules were a reasonable interpretation of power when not explicitly in conflict with the Patent Act.[63] The 2+1 Rule, according to the Federal Circuit, partially conflicted with the Act[64] as the Patent Act grants an applicant unlimited continuing applications.[65] By limiting this express right, the continuing applications portion of the 2+1 Rule clearly conflicted with the

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[55] Tafas II, 559 F.3d at 1351.

[56] *See id*. at 1352.

[57] *Id.* at 1354.

[58] *Id*. at 1356 (citing JEM Broad. Co. v. FCC, 22 F.3d 320, 326 (D.C. Cir. 1994)).

[59] *See* Lamoille Valley R.R. Co. v. Interstate Commerce Comm'n, 711 F.2d 295, 328 (D.C. Cir. 1983).

[60] *See* Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1282-84 (Fed. Cir. 2005) (the USPTO was permitted to place the burden of submitting information on the applicants).

[61] Tafas II, 559 F.3d at 1356.

[62] *Id*.

[63] *Id*. at 1360.

[64] *Id.*

[65] *Id.* (the requirements are: (1) the invention claimed must have been properly disclosed in a prior application; (2) the application must have been filed by the inventor named on the prior-filed application; (3) the application must have been "filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the first application;" and (4) the application must contain or must be amended to contain a specific reference to the prior-filed application).

plain meaning of the Patent Act.[66] That said, nothing in the Patent Act expressly grants a right to unlimited RCEs.[67] Consequently, only the RCE portion of the 2+1 Rule was permissible.[68]

In assessing the 5/25 Rule, the Federal Circuit first considered whether the USPTO could impose the ESD requirement to search prior art.[69] The court again refused to assume that imposing an additional requirement on applicants would foreclose some patent applications.[70] ESDs conceivably fall within the USPTO power to require "such information as may be reasonably necessary to properly examine or treat the matter."[71] The ESD rule, the primary limitation within the 5/25 Rule, therefore did not conflict with the Patent Act.[72] A majority of the court thus concluded that, of all the Final Rules, only one portion of the 2+1 Rule was invalid.[73]

C. Concerns Mentioned in Concurring Opinions

In a concurring opinion, Judge Bryson voiced concern over the court's emphasis regarding the distinction between substantive and procedural rulemaking powers.[74] The only required analysis, he argued, is whether Congress granted the USPTO the power to make the rules in question.[75] While Congress had not expressly granted or denied any specific powers in this area, Bryson noted the there was a trend of granting the USPTO a fairly expansive rule-making authority.[76] Bryson concurred that the continuation limitation in the 2+1 Rule was the only invalid portion, but he wanted to clarify the narrow scope of the court's ruling.[77] Bryson argued that the continuation rule was only invalid as to co-pending applications, not serial continuances, in which each continuation application is only considered with its immediate predecessor.[78] If the continuation portion was amended to govern only serial continuances, which are not expressly granted the same rights, Bryson

[66] *See id*. at 1361.
[67] *Id*. at 1362-63.
[68] *Id*. at 1362.
[69] *Id*. at 1363.
[70] *Id*. at 1363-64.
[71] *Id*. at 1364.
[72] *Id*. at 1364.
[73] *Id*.
[74] *See id*. at 1365-67.
[75] *Id*. at 1365.
[76] *Id*. at 1365-66.
[77] *Id*. at 1366-67.
[78] *Id*. at 1367.

suggested that the whole 2+1 Rule might be valid.[79]

In a separate concurrence, Judge Rader agreed with the district court that the Final Rules were impermissibly substantive, and thus only concurred to the result for the continuation rule.[80] He applied a different definition: procedural rules must have "sufficiently grave" substantive effects to be invalid.[81] Consequently, the substantive/procedural inquiry depends on the facts of each case, and is not the bright line rule that the Appellate majority seems to apply.[82] Rader then applied his definition to conclude that each rule was substantive because it "gravely" affected individual rights and obligations.[83]

IV. CONCLUSION – IMPLICATIONS OF THE OUTCOME

After a string of uncertain litigation, the USPTO voluntarily rescinded the Rules. The USPTO's ultimate decision seemingly grants a victory to innovators, but leaves both sides of the debate with significant questions concerning the continued effectiveness of the USPTO.

A. The USPTO Perspective

Going forward, the USTPO must decide whether streamlining the current patent application process is a significant enough interest to introduce changes to the longstanding patent system. Given the rising application numbers, however, can the Patent Office afford to simply forego a change? The USPTO has faced a dramatic increase in patent applications. In 2006, they hired 1,193 employees, exceeding their hiring goal by nearly 200.[84] The USPTO received 419,760 patent applications that year, up from 380,000 the year before, and just 330,000 only three years prior.[85] This increase caused significant time delays, which ultimately prompted the attempted overhaul of the application process.

The USPTO seemingly rescinded the proposed rules because it believed that the rules would burden innovators and thus stifle the rate of innovation. While innovation is the primary goal of the patent system, timeliness of application processing also influences the "progress of science." Due to both monetary and infrastructure constraints, the USPTO cannot simply hire examiners to stem the tide of applications. Additionally, the changes in the Final Rules were

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[79] *Id*. at 1367-68.

[80] *Id*. at 1368.

[81] *Id*. at 1369-70 (citing JEM Broad. Co. v. FCC, 22 F.3d 320, 327 (D.C. Cir. 1994)).

[82] *Id*. at 1370.

[83] *See id*. 1371-74.

[84] UNTIED STATES PATENT AND TRADEMARK OFFICE, 2007-2012 STRATEGIC PLAN 6, http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf.

[85] *Id*.

also intended to promote efficiency by limiting bad faith patent applications. An applicant can conceivably file application continuances until the market is ripe to exercise his patent, thus undermining competitors.[86] The decision to rescind the Final Rules thereby leaves the USPTO in a deepening hole of inefficiency. Although rescinding the Final Rules maintains traditional patent policy, the vast inefficiencies that remain in the USPTO still present an ominous problem.

B. The State of Innovation and Protection

Innovators primarily objected to the disparate impact the Final Rules would impose on burgeoning fields of innovation.[87] Biotechnology, a topical and dynamic area of innovation, presents difficult challenges in defining the scope of new inventions.[88] Inventors could adequately make a claim for a patent, and yet not know the full scope of their innovation. Inventors only realize an incentive to innovate if granted protection for the total scope of their invention. Consequently, continuing applications are vital. Public interest, for instance, supports timely patents in biotechnology. Not only does society have an interest in preventing other inventors from usurping inventions – thus undermining the incentive to innovate – but society also seeks to introduce potential life-saving inventions as early as possible. Limiting the number of permissible continuation applications may undercut an important and concentrated area of progress. Biotechnology is just one area that benefits from the USPTO's decision to rescind the Final Rules. If we are to create an optimal innovative atmosphere, and fully realize the benefits of these innovations, we must leave the patent system uninhibited, despite its inefficiency.

[86] Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 76 (2004).

[87] Ted Agres, *New Patent Rules Hurt Biotech?*, THE SCIENTIST, Aug. 21, 2007, http://www.the-scientist.com/news/home/53497/.

[88] *Id.*