

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

Alexandria Division

TRANTAFYLLOS TAFAS,
Plaintiff,

v.

JON W. DUDAS, et al.,
Defendants.

Civil Action No. 1:07cv846(L) (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM
CORPORATION, et al.,
Plaintiffs,

v.

JON W. DUDAS, et al.,
Defendants.

Civil Action No. 1:07cv1008 (JCC/TRJ)

**BRIEF OF *AMICUS CURIAE*
INTELLECTUAL PROPERTY OWNERS ASSOCIATION
IN SUPPORT OF THE PLAINTIFFS' ANTICIPATED MOTIONS
FOR SUMMARY JUDGMENT**

Amicus curiae Intellectual Property Owners Association (“IPO”) respectfully submits this brief in support of one aspect of the Plaintiffs’ anticipated motions for summary judgment that the Final Rules¹ published by the United States Patent and Trademark Office (“USPTO”) were promulgated without proper legal authority.

¹ “Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule,” 72 Fed. Reg. 46716, 46716-46843 (Aug. 21, 2007).

INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (“IPO”) is a nonprofit, national organization of more than 140 large and midsize companies and more than 550 small businesses, universities, inventors, authors, executives, law firms, and attorneys who are interested in patents, trademarks, copyrights, and other intellectual property rights. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the United States Patent and Trademark Office (“USPTO”) to U.S. nationals. IPO regularly represents the interests of its members before Congress and the PTO, and it has filed *amicus curiae* briefs in the Supreme Court of the United States and in other courts on significant issues of intellectual property law. The members of IPO’s 50-member Board of Directors, which approved the filing of this brief, are listed in Appendix A.²

SUMMARY OF THE ARGUMENT

The present brief addresses just one provision of the Final Rules. For at least two reasons, Final Rule § 1.78(f)(2)³ should be barred from being implemented. First, § 1.78(f)(2) will impermissibly be applied retroactively, imposing on applicants substantial new duties with respect to patent applications that have already been filed. Second, § 1.78(f)(2) contradicts applicants’ rights under the patent statute and case law.

² IPO procedures require approval of briefs by a three-fourths majority of directors present and voting.

³ 72 Fed. Reg. at 46840. IPO anticipates that other relevant issues will be briefed by the parties and other *amici curiae*. IPO’s silence with respect to sections other than § 1.78(f)(2) should not be interpreted as agreement that other sections are proper, appropriate, or within the PTO’s rulemaking authority.

Congress did not grant to the USPTO the power to promulgate retroactive rules. *See* 35 U.S.C. § 2(b)(2); *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988). Section 1.78(f)(2), however, imposes on applicants substantial new duties with respect to applications that were filed even before Section 1.78(f)(2) was published. *See* 72 Fed. Reg. at 46717 (listing effective dates of Final Rules provisions). The USPTO has long encouraged different inventions to be claimed in different patent applications. *See* 37 C.F.R. § 1.141(a). Section 1.78(f)(2), however, retroactively penalizes this innocent practice by requiring applicants to identify any such applications with overlapping filing dates or priority dates and to justify to the USPTO the very existence of these applications. *See* § 1.78(f)(2)(i)-(ii). Compliance is enforced with the threat of presuming claims in these applications to be unpatentable. *See* § 1.78(f)(2)(i). Because of this retroactive effect, § 1.78(f)(2) exceeds the rulemaking authority of the USPTO. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994).

Section § 1.78(f)(2) also contradicts several provisions of the patent laws, including the statute requiring the USPTO to examine applications (35 U.S.C. §§ 131-132), the statute granting applicants the right to reconsideration and judicial review of rejections (*id.* §§ 134, 141), and the statute protecting applicants from inconsistent double-patenting rejections (*id.* § 121).

The patent statute requires the USPTO to examine patent applications. *See* 35 U.S.C. § 131 (“The Director shall cause an examination to be made of the application . . .”). The USPTO has admitted, however, that § 1.78(f)(2) is designed to shift the burden of examination onto the applicant, “thus saving the examiner time by eliminating the need to . . . analyze the potentially conflicting claims, and make the rejection.” 72 Fed. Reg. at 46780. Additionally, when claims are rejected, the statute requires the USPTO to “stat[e] the reasons for such rejection.” 35 U.S.C.

§ 132(a). Section 1.78(f)(2) reverses this responsibility, making it the applicant's burden to explain why his claims should *not* be rejected.

Second, § 1.78(f)(2) would defeat a patent applicant's statutory right to *de novo* review of "double patenting" rejections by the Board of Patent Appeals and Interferences (hereinafter "the Board of Appeals"), *see* 35 U.S.C. § 134(a), and by the Court of Appeals for the Federal Circuit, *id.* at § 141. Under § 1.78(f)(2), the double patenting rejections are treated not as a question of law, but as a procedural failure, reviewable only under an "abuse of discretion" standard through an Administrative Procedure Act (APA) challenge. *See Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1285 (Fed. Cir. 2005).

Third, the presumption that claims are patentably indistinct contradicts § 121 of the patent statute by its application to "divisional applications" filed in response to USPTO restriction requirements. Divisional applications inevitably have overlapping disclosures, filing dates, and inventors with their respective parent applications. Section 121 of the patent statute was enacted specifically to prevent an application from being used against its corresponding divisional application, *see* 35 U.S.C. § 121, in direct conflict with the USPTO's new presumption.

IPO appreciates the USPTO's desire to reduce delays between the filing and issuance of patent claims and to take other steps to improve patent quality. However, restricting the statutory rights of applicants and retroactively imposing new duties on applicants are not options available to the USPTO. The presumption of patentably indistinct claims and the corresponding requirement for explanation – particularly when applied to already-pending applications – are directly in conflict with case law and the patent statute, and they exceed the USPTO's authority to "establish regulations, not inconsistent with law" under 35 U.S.C. § 2(b)(2).

For these reasons, the USPTO should be permanently enjoined from enforcing § 1.78(f)(2).

BACKGROUND

A. The Legitimacy of Filing Related Inventions in Different Applications

It is common for the specification of a single patent application to describe several different inventions. Indeed, the patent statute requires applicants to provide “a written description of the invention, *and* of the manner and process of making and using it.” 35 U.S.C. § 112, ¶ 1 (emphasis added). Often, the processes of “making” and of “using” the invention are themselves separately patentable inventions, required by statute to be described in a single application.⁴

In defending its authority to promulgate Final Rule 1.78, the USPTO has not objected to the description of multiple inventions in a single application. Nevertheless, section 1.78(f)(2) imposes substantial new duties on applicants who have followed the practice that – until now – has been favored by the USPTO: initially filing claims to those separate inventions in separate patent applications. *See* 37 C.F.R. § 1.141(a) (“Two or more independent and distinct inventions may not be claimed in one national application. . . .”). Because the term of a patent is now measured from an application’s priority date, rather than its date of issuance, prosecuting related

⁴ The level of detail required for these descriptions varies with the knowledge already possessed by those of ordinary skill in the relevant technology. *See* 35 U.S.C. § 112, ¶ 1.

applications at the same time – rather than one after the other – is the only way to enjoy the “[p]atent term guarantees” enacted by Congress. *See* 35 U.S.C. § 154(b)(1).⁵

B. The Burden of Compliance with § 1.78(f)(2)

Section 1.78(f)(2) erects a presumption that claims in two applications are not patentably distinct – i.e. that they are obvious variations of one another – if four conditions are met:

- there is an overlap in any of their associated filing dates (including the dates of any foreign, international, or provisional filings from which priority is claimed), *see* § 1.78(f)(2)(i)(A);
- there is an overlap between any two inventors, *see* § 1.78(f)(2)(i)(B);
- they are owned by the same person, *see* § 1.78(f)(2)(i)(C); and
- they contain substantial overlapping disclosure, *see* § 1.78(f)(2)(i)(D).

This presumption goes into effect automatically and retroactively as to the hundreds of thousands of applications currently pending in the USPTO – with no advance notice to the applicant – and it must be overcome within four months of the application’s filing date. § 1.78(f)(iii)(A); *see also* 72 Fed. Reg. at 46783. Because failure to overcome the presumption can result in claims being deemed invalid on the grounds of “double patenting,” IPO members and other patent applicants must undertake elaborate precautions to ensure that patent rights – both in future applications and in applications already on file – are not inadvertently lost through non-compliance with § 1.78(f)(2).

⁵ The term of a patent ordinarily runs 20 years from its priority date. 35 U.S.C. § 154(a)(2). If applications to two related inventions are prosecuted at the same time, and each takes 3 years to prosecute, the applicant receives two patents with a 17-year term. If the USPTO requires applicants *not* to prosecute the applications at the same time, the second application would issue six years from the priority date and would have only a 14-year term.

To comply with § 1.78(f)(2), applicants must first identify which of their applications are at risk for inadvertent invalidity. To do so, they must search through all pending applications, identifying those having any overlapping filing dates and overlapping inventorship. This search must look not only at *actual* filing dates, but also at any date from which priority is claimed. 72 Fed. Reg. at 46735. The applicants then need to determine whether the identified applications have “substantial overlapping disclosure.” § 1.78(f)(2)(i)(D). This section defines “substantial overlapping disclosure” in terms that require interpretation by skilled patent practitioners: “Substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under the first paragraph of 35 U.S.C. 112 for at least one claim in the nonprovisional application.” § 1.78(f)(2)(i)(D). The burden of “clearing” applications with non-overlapping subject matter is significant. As an example, if four applications share overlapping inventorship and overlapping filing dates, and if each of these applications includes five independent claims (as would be permitted even under Final Rule 78), an attorney could clear these applications only after making *sixty* separate comparisons between independent claims and disclosures.⁶ This is no simple task, particularly as applicants and practitioners were never aware of the importance of this combination of information before § 1.78(f)(2) was published, so they have not tracked this information, and they lack the tools to track this information. The burden of complying with § 1.78(f)(2) grows disproportionately with the size of an organization: the likelihood that applications will be presumed patentably indistinct by mere coincidence greatly increases as the number of applications within an organization increases, and as the average number of inventors contributing to each application increases.

⁶ Each of the five independent claims, in each of the four applications, is compared against three other disclosures. $5 \times 4 \times 3 = 60$.

For applications that do have (or in the exercise of caution, may have) substantial overlapping disclosure, the applicants would be required to provide an explanation for the overlapping applications. These explanations are required to be substantive and comprehensive. “Merely explaining that some of the claims are patentably distinct would not be sufficient to rebut this presumption.” 72 Fed. Reg. at 46780. Using the above example of four applications with five claims each, the applicant would need to provide substantive explanations for the presence of *one hundred fifty*⁷ pairs of claims that otherwise will be presumed to be indistinct.

The burden of compliance will be particularly acute when adding new claims during the prosecution of a family of related applications. The ownership, inventorship, and subject matter and filing dates of such applications would almost inevitably trigger the presumption of patentably indistinct claims. Whenever any *new* claim is added to one of these applications, it must be accompanied by a justification of its existence with respect to every other claim in the application family.

C. The Cost of Retroactively Implementing § 1.78(f)(2)

The USPTO intends to apply § 1.78(f)(2) retroactively, to all applications pending on or after November 1, 2007. *See* 72 Fed. Reg. at 46717. Compliance with this section will have a substantial retroactive impact on applications that have already been filed. A majority of IPO members responding to a survey on compliance with the Final Rules anticipates that, to comply with § 1.78(f)(2) as to existing applications, *each* of them will need to (i) cancel pending claims in at least ten percent of those applications (ii) file at least 100 papers with the USPTO to overcome the presumption of patentably indistinct claims, and (iii) incur costs of more than

⁷ There are six different ways to pair four applications (i.e., 1&2, 2&3, 3&4, 4&1, 1&3, 2&4). Within each pair of applications, there are $5 \times 5 = 25$ pairs of claims. $6 \times 25 = 150$.

\$50,000. *See* Letter from Herbert C. Wamsley to Hon. Jon W. Dudas (Sept. 28, 2007)⁸. At least a quarter of IPO members expect to file more than 1,000 papers with the USPTO to overcome the presumption of patentably indistinct claims. *See id.*

In the review and comment process, the USPTO did not indicate that § 1.78(f)(2) would be applied retroactively, not only against applications filed before the Final Rules were to go into effect, but even against applications filed before the corresponding “Notice of Proposed Rulemaking” was published. 71 Fed. Reg. 48 (Jan. 3, 2006). In responding to public comments pointing out the burden of § 1.78(f), the USPTO has not explained any need to apply the rule retroactively; instead, it explained that the rule was intended to affect applicants’ *future* conduct, noting the expectation that “many applicants will be proactive by filing fewer applications containing patentably indistinct claims.” 72 Fed. Reg. at 46781.

ARGUMENT

Section 1.78(f)(2) of the Final Rules is impermissibly retroactive, and it extends applicants’ duties far beyond the bounds permitted by statute. Applicants have long undertaken the practice of filing related applications with overlapping filing or priority dates. These actions were undertaken with the innocent expectation of benefiting from Congress’s “[p]atent term guarantees,” 35 U.S.C. § 154(b)(1), and to comply with the USPTO’s own rule against claiming different inventions in a single application. *See* 37 C.F.R. § 1.141(a). Section 1.78(f)(2), however, retroactively requires applicants to justify *why* they followed a practice counseled by the USPTO’s own rules and encouraged by statute. Failure to provide an adequate explanation to the USPTO puts these already-filed applications at risk of invalidity in light of a newly-created

⁸ *For letter and survey see* www.ipo.org/USPTORulesClaimsAndContinuations.

presumption of invalidity. Moreover, § 1.78(f)(2) impermissibly restricts applicants' rights that are protected under the patent statute. Whereas the statute requires the USPTO to examine applications and to provide reasons for any claim rejections, § 1.78(f)(2) places that burden on the applicants. *See* 35 U.S.C. § 131, 132(a). Absent substantive examination by the USPTO, applicants are denied their statutory right of review by the Federal Circuit. *See* 35 U.S.C. §§ 134(a), § 141. Moreover, § 1.78(f)(2) purports to give the USPTO discretion to reject divisional applications for double patenting, but that discretion was specifically taken away from the USPTO by Congress. *See* 35 U.S.C. § 121. With due respect to the challenges of examining large numbers of patent applications, IPO submits that § 1.78(f)(2) of the Final Rules exceeds the USPTO's rulemaking authority and that enforcement thereof should be permanently enjoined.

A. Section 1.78(f)(2) Has an Impermissibly Retroactive Effect

Section 1.78(f)(2) has an impermissibly retroactive effect. It imposes substantial duties of compliance on applicants, who will now – at the risk of patent invalidity – be forced to justify completely legitimate filings, often years after those filings were made.

Congress did not grant to the USPTO the power to promulgate retroactive rules. *See* 35 U.S.C. § 2(b)(2); *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988) (“[L]egislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules. . . .”). Section 1.78(f)(2), however, imposes on applicants substantial new duties with respect to applications that were filed even before Section 1.78(f)(2) was published. *See* 72 Fed. Reg. at 46717 (listing effective dates of Final Rules provisions). The USPTO has not offered any justification for the proposed retroactivity; instead, it justifies the burdens imposed by the rule as an effort to affect applicants' *future* conduct. *See*

72 Fed. Reg. at 46781 (expressing the intent that “many applicants will be proactive by filing fewer applications containing patentably indistinct claims”).

It is common for an inventor’s patent disclosure to give rise to a number of different patentable inventions, and the USPTO has long encouraged these different inventions to be claimed in different patent applications. *See* 37 C.F.R. § 1.141(a) (“Two or more independent and distinct inventions may not be claimed in one national application. . . .”). In contrast, § 1.78(f)(2), retroactively penalizes this practice by requiring applicants, first, to identify any such applications with overlapping filing or priority dates, *see* § 1.78(f)(2)(i)(A)-(D), and second, to justify to the USPTO the very existence of these applications, *see* § 1.78(f)(2)(ii). Failure to comply gives rise to a presumption that at least one set of claims is unpatentable. *See* § 1.78(f)(2)(i). Because § 1.78(f)(2) would “impose new duties with respect to transactions already completed,” with invalidity as the cost of noncompliance, it is impermissibly retroactive and exceeds the rulemaking authority of the USPTO. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994).

As described in the Background, above, compliance with these new duties would unduly impose new and significant burdens on IPO members and other patent applicants, particularly as the USPTO intends to impose the rule retroactively on applications already pending. These new burdens are shifted onto applicants even where they could much more efficiently be borne by the USPTO. For example, to reject a claim for double patenting, the USPTO need only point out a single patentably indistinct claim in another case. To show that a claim should *not* be rejected for double patenting, however, an applicant must explain how that claim is patentably distinct from *all* claims in *all* other relevant cases. *See* 72 Fed. Reg. at 46780 (noting the insufficiency of “[m]erely explaining that some of the claims are patentably distinct”). Applicants would be

saddled with this burden of compliance not because of any attempted delay, but merely because they attempted to follow the USPTO’s own rules against claiming two inventions in one application, *see* 37 C.F.R. § 1.141(a), or because they sought the benefits of Congress’s patent term guarantees. 35 U.S.C. § 154(b)(1).

Implementing § 1.78(f)(2) would be unduly burdensome not only to applicants, but also to the practitioners representing them. Patent practitioners are admonished that they “shall not disregard or advise a client to disregard any provision” of the USPTO rules. 37 C.F.R. § 10.89(a). To avoid triggering the § 1.78(f)(2) presumption, the USPTO advises that an “[a]pplicant has the option of filing a single application to claim patentably distinct inventions.” 72 Fed. Reg. at 46784. This suggestion, however, is in tension with the rule against claiming “independent and distinct inventions . . . in one national application.” 37 C.F.R. § 1.141(a). Practitioners are asked either to disregard the rules against claiming multiple inventions or to put their clients’ rights at risk under § 1.78(f)(2).

B. Section 1.78(f)(2) Evades the USPTO’s Statutory Responsibility to Examine Patent Applications and to Provide Reasons for Rejections

The patent statute sets forth the central responsibility of the USPTO:

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

35 U.S.C. § 131. If the Director issues a rejection, the statute requires the Director to “notify the applicant thereof, stating the reasons for such rejection.” 35 U.S.C. § 132(a). One legal ground for rejecting a claim in a patent application – or for holding a patent claim invalid in infringement litigation – is “obviousness-type double patenting.”

Obviousness-type double patenting is a judicially-created doctrine of substantive patent law, designed to prevent applicants from unfairly extending their patent rights by filing separate patent applications containing patentably indistinct claims. *See Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed. Cir. 1990). Thus, if an applicant has filed two cases, and the first has issued as a patent, then any patentably indistinct claims in the second case may be rejected on the grounds of obviousness-type double patenting. *See* M.P.E.P. 804(II)(B)(1) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001)). If neither case has issued as a patent, then these claims may be “provisionally” rejected for double patenting, the provisional status being dropped upon issuance of the first patent. *See* M.P.E.P. 804(I)(B),(C). The central issue of law in a double-patenting rejection, then, is whether the claims of the respective cases are “patentably indistinct” from one another. *See In re Metoprolol Succinate Patent Litigation*, 494 F.3d 1011, 1016 (Fed. Cir. 2005).

The USPTO is statutorily required to examine applications to determine whether “the applicant is entitled to a patent under the law,” 35 U.S.C. § 131. However, § 1.78(f)(2) effectively eliminates this statutorily created duty by raising a presumption that the applicant is *not* entitled to a patent, because the presumption of patentably indistinct claims is a presumption of double patenting. *Cf. In re Longi*, 759 F.2d 887, 895-96 (Fed. Cir. 1985) (requiring that USPTO makes out a “prima facie case of obviousness” when issuing a double-patenting rejection). The USPTO, in fact, admits that § 1.78(f)(2) was intended to shift the responsibility of examining for double patenting away from the USPTO and onto the applicant.

Therefore, with the benefit of § 1.78(f)(2), double patenting issues could be resolved more expeditiously . . . thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection.

72 Fed. Reg. at 46780. More succinctly, the USPTO views § 1.78(f)(2) as a means of “requiring the applicant to ferret out which claims are indistinct from each other,” 72 Fed. Reg. at 46815.

The USPTO has argued in this case that its rulemaking authority includes the authority to “set burdens of proof.” USPTO Opp’n at 23. The single authority it cites, however, provides no support for this proposition. In *Stevens v. Tamai*, the Federal Circuit noted (in dicta) that the USPTO can place the burden of proving priority on parties to an interference.⁹ See 366 F.3d 1325, 1333 (Fed. Cir. 2004). In that instance, however, the statute itself places this burden on the parties. See 35 U.S.C. § 102(g)(1) (noting that a later inventor is not entitled to a patent if, “during the course of an interference . . . another inventor involved therein *establishes*” his priority (emphasis added)).

Whereas the USPTO is required by statute to examine applications and provide reasons for any claim rejections, § 1.78(f)(2) requires applicants to examine their own applications and provide reasons why claims should not be rejected. Cf. 35 U.S.C. §§ 131, 132(a). The statute requires the USPTO to give applicants at least thirty days to respond to any rejection or other action, see *id.* § 133, but the presumption of § 1.78(f)(2) springs into effect with no notice to the applicant. Because it is “inconsistent with the law” under the USPTO’s rulemaking authority, enforcement of § 1.78(f)(2) should be enjoined. See 35 U.S.C. § 2(b)(2). See *In re Weber*, 580 F.2d 455, 458-59 (C.C.P.A. 1978) (“[I]n drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.”).

⁹ An “interference” is a proceeding conducted by administrative patent judges of the Board of Appeals to determine priority between two different applicants claiming the same invention. See 35 U.S.C. §§ 6, 102(g), 135.

C. Section 1.78(f)(2) Deprives Applicants of Judicial Review of Claim Rejections

Congress has erected a system in which, if an applicant disagrees with any claim rejection, he has the statutory right to several levels of reconsideration and review. *See* 35 U.S.C. §§ 134, 141 & 145. By casting double patenting rejections as the result of a *procedural* defect, rather than a substantive examination, § 1.78(f)(2) deprives applicants of these statutory rights of review.

Applicants are entitled under the law to *de novo* review of double patenting rejections. After an initial rejection of an applicant's claims, the applicant may "persist[] in his claim for a patent," even "without amendment," and the statute requires that "the application shall be reexamined." *See* 35 U.S.C. § 132. If the claims are rejected again, the applicant has the right of appeal to the Board of Appeals. *See* 35 U.S.C. § 134(a). If the applicant is unsuccessful before the Board of Appeals, he may appeal to the Court of Appeals for the Federal Circuit. *See* 35 U.S.C. § 141. As the Federal Circuit has repeatedly held when reviewing double-patenting rejections entered by the USPTO, "Obviousness-type double patenting is a question of law reviewed *de novo* by this court." *See In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993).

Contrary to established law, § 1.78(f)(2) transforms double patenting from a question of law to a question of procedure. Attempting to circumvent the USPTO's burden of examining for patentably indistinct claims, the USPTO takes the position that "requiring the applicant to ferret out which claims are indistinct from each other" is merely "procedural in nature," 72 Fed. Reg. at 46815. Although it labels § 1.78(f)(2) as a "procedural tool," 72 Fed. Reg. at 46815, the USPTO has made it clear that procedural failures will result in substantive rejections:

[W]hen an applicant files multiple applications that are substantially the same, the applicant is responsible for assisting the Office in resolving potential double

patenting situations, rather than taking no action until faced with a double patenting rejection. Thus, 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.

72 Fed. Reg. at 46722. This position derogates the statutory scheme through which applicants can seek review of claim rejections. Section 1.78(f)(2) treats a double patenting “situation” as the result of a *procedural* defect: the failure of an applicant to file a preemptive explanation under § 1.78(f)(2)(ii). The USPTO’s refusal to issue a patent on procedural grounds can be challenged only by bringing an APA action in the district court, where the USPTO’s decision is reviewed under the liberal “abuse of discretion” standard. *See Star Fruits*, 393 F.3d at 1281. The statute and Federal Circuit law, however, promise *de novo* review of double-patenting rejections at the appellate level. *See Berg*, 140 F.3d at 1432; 35 U.S.C. § 141.

Controlling case law prevents the USPTO from rejecting claims as a consequence of purportedly procedural defects. USPTO Rule 78(b) (prior to amendment by the Final Rules at issue here) provides that, when “two or more applications filed by the same applicant contain conflicting claims [i.e., patentably indistinct claims], elimination of such claims from all but one application may be required” 37 C.F.R. § 1.78(b) (July 1, 2007). The predecessor to the Federal Circuit¹⁰ held that Rule 78(b), labeled as a procedural “requirement,” could not be used in place of a legally-deficient double patenting rejection. *See In re Mott*, 539 F.2d 1291, 1295-1296 (C.C.P.A. 1976).

In Rule 78(b), *supra*, the Commissioner has stated that he may “require” elimination of conflicting claims from all but one application of the same applicant. “Requirements” are not reviewable by the board or by this court unless they amount in fact to rejections. . . . [B]y refusing to permit further prosecution of the appealed claims in this application without the performance by appellant of

¹⁰ The Court of Appeals for the Federal Circuit adopted the body of precedent of the Court of Customs and Patent Appeals. *See South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (*en banc*).

an act wholly extrinsic to this application [the USPTO] has, in legal effect, rejected these claims finally.

539 F.2d at 1296; *see also In re Haas*, 486 F.2d 1053, 1056 (C.C.P.A. 1973) (holding that a requirement to withdraw claims was “a defacto [sic] rejection . . . made without statutory basis”). The USPTO has effectively recognized that Rule 78(b) cannot be used in place of a substantive double patenting rejection. Since the *In re Mott* decision more than thirty years ago, only a single published case reflects any attempt by the USPTO to invoke Rule 78(b). *See In re Driscoll*, 562 F.2d 1245 (C.C.P.A. 1977). Because the applicant in that case had agreed to cancel claims as requested, *see id.* at 1248 n.6, the court had no occasion to rule on the propriety of the requirement.

Contrary to law, a double patenting rejection triggered by a presumption under § 1.78(f)(2) denies the applicant’s right under the law to *de novo* review on appeal. Instead, it sets a strict time limit within which the “patentably indistinct” presumption must be overcome. *See* § 1.78(f)(2)(iii). The most draconian provision of this section requires the presumption to be overcome on the very day a new claim is added. *See* § 1.78(f)(2)(iii)(C). “[I]f an applicant subsequently files an amendment that adds a new claim after four months from the filing date of the application, applicant must rebut this presumption for such a claim *when applicant files the amendment.*” 72 Fed. Reg. at 46783 (emphasis added). By casting all double-patenting rejections as procedural defects, the USPTO, with one blow, sheds its own statutory duty to “reexamine” rejected applications and divests the Board of Appeals and the Federal Circuit of their statutorily-conferred jurisdiction to review double-patenting rejections *de novo*. Because the USPTO does not have the authority to enact rules that are contrary to law, it should be permanently enjoined from promulgating § 1.78(f)(2).

D. Section 1.78(f)(2) Directly Contradicts 35 U.S.C. § 121

Section 121 of the patent statute was specifically designed to remedy the injustices that result when the USPTO reverses its position as to whether two claims are patentably distinct. The Final Rules, § 1.78(f)(2), defeat both the intent and the literal requirements of this statute.

The USPTO has long followed the practice of requiring patentably distinct claims to be divided into separate patent applications by issuing a “restriction requirement.” Before the modern patent statute was enacted in 1952, this practice led to unjust results when the USPTO erred or changed its position on whether claims were patentably distinct. The USPTO often required applications to be divided, and later it rejected the divided applications on the grounds of double patenting. *See In re Eisler*, 203 F.2d 726, 728-29 (C.C.P.A. 1953); *In re Seebach*, 88 F.2d 722, 723-24 (C.C.P.A. 1937) (affirming USPTO’s rejection for double patenting, while recognizing that the rejection “is tantamount to a decision that the requirement for division of the parent application was improper”).

To protect applicants against the USPTO’s reversals in determining whether claims are patentably distinct, Congress enacted 35 U.S.C. § 121. *See Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 360 (Fed. Cir. 1986) (Newman, J., concurring) (“[F]rom the practical viewpoint § 121 is particularly important when the restriction requirement is asserted to have been imposed in error.”). To create that protection, § 121 “effects a form of estoppel that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent.” *Id.* at 361.

Section 1.78(f)(2) of the Final Rules circumvents this statutory protection. Under § 1.78(f)(2), the presumption of patentably indistinct claims will inevitably apply to divisional applications, which share disclosures, filing dates, inventorship, and ownership with their

respective parent applications. If the USPTO follows its own Final Rules, it will be required to presume that the claims of divisional applications are patentably indistinct from those of their parent applications: exactly the situation that § 121 was designed to prevent. Even if the USPTO hesitates to enter a double-patenting rejection on the precise claims against which the restriction requirement was applied, with each *new* claim added during prosecution of the divisional or parent application, the presumption of patentably indistinct claims arises anew, and it must be rebutted on the very day the new claim is submitted. *See* § 1.78(f)(2)(iii)(C). If the rebuttal is not successful, then according to the Final Rules, the application would lose its status as a “divisional” and thus – in the eyes of the USPTO – lose its protection under § 121 altogether. *See* Final Rules, § 1.78(a)(2) (defining “divisional application”). *Cf. Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348 n.1 (Fed. Cir. 2004) (“[T]he question whether the requirements of section 121 have been satisfied is a question of law that we have addressed *de novo*. . . .”)

Under § 121 of the statute, the USPTO *cannot* require applicants in a divisional application to demonstrate that their claims are patentably distinct. Under the Final Rules, however, applicants in a divisional application *must* demonstrate that their claims are patentably distinct even to merit the protection of § 121. Section 1.78(f)(2) defeats both the letter and the intent of § 121, and thus exceeds the scope of the USPTO’s rulemaking authority. *Cf. Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (“The judiciary . . . must reject administrative constructions which are contrary to clear congressional intent.”)

E. Conclusion

For the foregoing reasons, IPO supports the issuance of a permanent injunction against the promulgation of § 1.78(f)(2).

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