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New Rules 75, 78 Unfairly Penalize Research Entities

Monday, Oct 29, 2007 --- This article argues that Rules 75(b)(4) and 78(f) are contrary to 35 U.S.C. § 103(c).

Further, this article focuses on the practical complexity and unfairness of new rules 75(b)(4) and 78(f) as applied to entities engaged in ongoing research.

Brief Summary of Rules 75(b)(4) and 78(f)

By now, most readers will have already studied Rules 75(b)(4) and 78(f). Under Rule 75(b)(4), if at least one claim in an application is patentably indistinct from a claim or claims in a commonly owned, co-pending application, the Office will count all the claims from all such applications when determining compliance with the requirement that no application contain more than five independent and twenty five total claims without an Examination Support Document.

Under 37 CFR § 1.78(f), an applicant must identify other pending or patented applications having a filing date that is the same or within 2 months of the filing date of the subject application where there is one overlapping inventor and common ownership or an obligation of common ownership. Rule 78(f)(1).

If the filing date of any such applications is the same (taking into account all priority applications) and the specifications substantially overlap, a rebuttable presumption exists that at least one claim in the subject application is patentably indistinct from at least one claim in the other application(s). Rule 78(f)(2).

In the absence of a good and sufficient reason why two or more commonly owned applications should exist with indistinct claims, the Office may require elimination of the indistinct claims from all but one of the applications. Rule 78(f)(3).

Finally, if two or more applications are permitted to remain pending with claims directed to patentably indistinct inventions, the Office will treat each application as having the total of all the claims for purposes of determining compliance with Rule 75(b)(4).

What has perhaps not been fully appreciated by some is that Rule 75(b)(4) also operates independently outside the confines of the Rule 78(f)(2) two month window.

As stated by the Office at page 46726 of the publication in the Federal

Register on August 21, 2007, [t]he provisions of § 1.75(b)(4) apply regardless of whether the filing dates of the applications are the same, are within two months of each other (cf. § 1.78(f)(1) and (f)(2)), or are not within two months of each other.

In other words, the provision of § 1.75(b)(4) does not depend on the filing dates of the respective applications. In addition, the provisions of § 1.75(b)(4) are applicable regardless of any continuity relationship between the application...

As argued below, Rules 78(f)(3) and 75(b)4 are contrary to section 103 (c) of the patent statute. Also discussed below is a hypothetical demonstrating that Rule 78(f) provides a burdensome and ongoing monitoring requirement that increases in complexity as a company's patent portfolio grows with time.

The hypothetical further demonstrates that Rule 75(b)(4) has the rather odd effect of acting as an outright penalty against companies engaged in ongoing research.

Rules 78(f) And 75(b)(4) Are Contrary To 35 U.S.C. § 103(c)

As mentioned above, according to Rule 78(f)(3), where two or more commonly owned applications contain patentably indistinct claims, the Office may, without citing any statutory or judicial authority to support the "rejection", require elimination of all patentably indistinct claims from all but one of the applications.

Moreover, under 75(b)(4), even if two or more such applications are permitted to remain pending, if a first application contains five independent claims and twenty five total claims, the Office will not issue a patent to a commonly-owned co-pending second application if it contains at least one claim that is patentably indistinct from at least one claim in the first application.

Thus, Rules 78(f)(3) and 75(b)(4) can effectively act as an outright bar to obtaining a follow-on patent claiming an obvious variation of a previous discovery.

This bar against obtaining such improvement patents is contrary to statute.

On three different occasions Congress has enacted legislation specifying when an applicant may obtain a patent claiming obvious variations of previous discoveries.

In 1984, Congress amended 103 to disqualify events falling exclusively within 102(f) or (g) from use as prior art under 103.

This exemption from prior art, which can now be found in subsection (c) of 103, was enlarged by the American Inventors Protection Act of 1999 (AIPA), to include a disqualification of obviousness rejections based on 102(e).

In particular, 103(c) was amended to provide subject matter developed by another person, which qualifies as prior art only under one ore more of subsections (e), (f), or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

In 2004, Congress once again broadened the 103(c) exemption via the Cooperative Research and Technology Enhancement Act (CREATE Act).

Under the CREATE Act, the meaning of "owned by the same person or subject to an obligation of assignment to the same person" appearing in 103(c) was extended to include situations where the invention under consideration was made pursuant to a written joint research agreement that had been entered into with the party who developed the prior art.

Thus, by the statutory authority provided by 103(c), a party can obviate an obviousness rejection based on subsections (e), (f), or (g) of 102 and obtain a patent to obvious variations of earlier discoveries provided, at the time the obvious variation was made, there was common ownership, an obligation of common ownership, or a written joint research agreement in place.

Accordingly, based on the fact that the 103(c) exemption was not only enacted but also broadened twice by subsequent legislative enactments, it clearly follows that Congress envisioned that patent applicants are entitled by law to obtain issued patents directed to obvious variations of earlier discoveries where the conditions of 103(c) are met.

As discussed above, however, under Rule 78(f)(3), the Office has provided itself with absolute discretion in deciding whether a party will be permitted to maintain commonly owned separate applications with patentably indistinct claims.

Moreover, even if such separate applications are permitted, the Office's limit on the number of independent and total claims under Rule 75(b)(4) means an applicant who maintains five independent and twenty five total claims in one application will be completely barred from pursuing a second application containing one or more claims encompassing obvious subject matter.

Importantly, these bars under Rules 78(f)(3) and 75(b)(4) apply even if an applicant otherwise would have been permitted to obtain separate patents via the §103(c) statutory exemption. Accordingly, it follows that Rules 78(f)(3) and 75(b)(4) run contrary to statute and should be repealed.

Hypothetical

* The Genus First/Later-Discovered Species Hypo *

A simple hypothetical that commonly arises when prosecuting biotech and chemical patent applications illustrates how Rule 75(b)(4) penalizes entities involved in ongoing research. It also illustrates how two application families must be monitored for Rule 78(f) compliance even where, as in this hypo, the initial filing dates are more than two months apart.

Assume that a first non-provisional application is filed directed to a discovery that three compounds (Compounds A, B and C) inhibit cancer cell growth in a mouse model. The first application, owned by Company, includes, as claim 1, a compound claim generically defined by structure that encompasses the three compounds as well as other compounds falling within the genus. Intermediate and narrow dependent claims encompassing Compounds A, B and C are also included as are various claims directed to methods of making and methods of using the compounds.

Over a year after the filing date of the first pending application, the same investigator at Company discovers a novel fourth compound (Compound D) that also falls within the genus defined by claim 1 of the first application. Compound D, a novel compound, not only inhibits tumor growth, but unexpectedly eradicates the tumor in mouse models.

Patent attorneys for Company file a second non-provisional application a year and a half after the filing date of the first non-provisional application including claims of varying scope encompassing Compound D, as well as methods of making and using Compound D. Since Compound D is not disclosed in the first application and to benefit from a longer patent term, the second application does not claim priority to the first application.

An analysis of this commonly encountered factual situation under the new rules requires reviewing for compliance with Rule 75(b)(4) and 78(f).

Rule 75(b)(4) Analysis

Under Rule 75(b)(4), since both applications are commonly owned, the Office will compare the claims of the two applications to determine if any are patentably indistinct with a claim in the other application.

A critical issue is whether the Office will perform a "one-way" patentability analysis or a "two-way" patentability analysis.

Under a one-way analysis, if any claim in the first application is patentably indistinct from any claim in the second application or if any claim in the second application is patentably indistinct from any claim in the first application, then the Office will only permit Company to prosecute a total of five independent and twenty five total claims in the two applications combined (e.g., three independent claims and twelve dependent claims in the first application and two independent and eight dependent claims in the second application).

In contrast, under a two-way analysis, Company would be entitled to a full set of five independent and twenty five total claims in each application unless the claims were found to be patentably indistinct "both ways."

According to Frequently Asked Questions J19 and J26 appearing in the "Questions and Answers-Claims and Continuations Final Rule" published on the Office's Web site, the Office will apply a one-way test when Rule 75(b)(4) is applied within the confines of Rule 78 (f) (i.e., when two applications are filed within two months of each other).

Moreover, discussions between the present author and an official at the Office of Patent Legal Administration confirmed that, according to this official anyway, the Office intends to perform a one-way analysis regardless of the relative filing dates between the two applications.

Clearly, a one-way test has major implications in the present hypothetical. Even if the later discovered Compound D is novel and non-obvious over the earlier claimed genus and Compounds A, B, and C, the earlier claimed genus will never be patentably distinct from Compound D since a species always anticipates a genus.

Thus, under a one-way test, in the present hypothetical the Office will always combine the claims from both applications (provided that their pendency overlaps) when determining compliance with Rule 75(b)(4).

That Rule 75(b)(4) penalizes entities engaged in ongoing research is readily seen by slightly changing the hypothetical.

Assume the exact same fact pattern with the following exception: rather than an investigator at Company, assume that a different investigator at Company 2 discovered Compound D. In this altered scenario, the two applications would not be commonly owned and Rule 75(b)(4) would not apply.

Thus, Company 2 would be entitled to a complete set of five independent and twenty five total claims in the second application.

However, there is no logical basis for treating these two situations differently. In each, an application directed to the discovery of novel and nonobvious Compound D should get the benefit of a full claim set without having to file a costly Examination Support Document.

Rule 78(f)(1) Analysis

Under Rule 78(f)(1)(i), an applicant must identify all pending or patented applications having a filing date within two months of each other if the applications have at least one overlapping inventor and are commonly owned or subject to an obligation of common assignment.

In the present hypothetical, the first and second applications were not filed within two months of each other and thus would not trigger the identification requirement under Rule 78(f)(1)(i), although Company would be well advised to cross-cite the two applications anyway via the traditional Rule 56 route for the reasons provided above.

However, compliance with the Rule 78(f)(1)(i) identification requirement does not end after a comparison of the filing dates of two applications. Indeed, the identification requirement under 78(f)(1)(i) would be triggered in the future if any later filed application that claims priority to the first non-provisional is filed within two months of the filing date of the second non-provisional or the filing date of any application that claims priority to the second non-provisional.

It is also important to note that Rule 78(f) compliance is an absolute requirement in the sense that one must comply any time there is common ownership and an overlapping inventor.

Thus, even if the inventions claimed in two applications are completely unrelated, compliance is still required.

Thus, in effect, the filing dates, the inventorship and ownership status of every application in a company's entire patent portfolio must be reviewed each time a new non-provisional application, a continuation application or a divisional application is filed to determine if any of the filing dates are within two months of each other.

Needless to say, such a monitoring requirement is burdensome and will increase in complexity as a company's patent portfolio grows.

While it is true that a company's patent portfolio must already be monitored and co-pending applications and issued patents cited to comply with Rule 56, this is now done "on the merits" depending on whether the co-pending application actually contains claims that are material to claims in the application under examination.

Arguably, the only thing Rule 78(f)(1)(i) really achieves is carving out an extra and much broader mechanistic monitoring requirement that will not result in the Office receiving any more RELEVANT information than it already receives under Rule 56.

To further elucidate the complexity associated with Rule 78(f)(1)(i), assume that Company has exclusively licensed the second application to Company 2. Under the terms of the agreement, Company 2 has agreed to pay for all further prosecution costs.

Thus, Company 2 transfers the second application for further prosecution to its usual counsel, which is a different law firm than the law firm used by the first company.

This scenario or variations of it occur with regularity in the industry. It will be extremely complicated for different law firms to coordinate CONTINUAL efforts to comply with Rule 78(f)(1) for multiple clients and multiple portfolios.

Concluding Remarks

The exemption in 103(c) was originally enacted in 1984 and then enlarged in 1999 (AIPA) and 2004 (CREATE Act) to create an incentive to file applications early and to encourage ongoing team research both within and between corporations, businesses and universities.

Thus, Rules 78(f)(3) and 75(b)(4) frustrate the intent of a statutory right that has been 20 years in the making.

The above discussion also sheds light on the massive complexity compliance with Rules 75(b)(4) and 78(f) will entail.

This will be particularly true for companies and universities having large portfolios with families of applications being prosecuted at different law firms.

Moreover, the above discussion illustrates that Rule 75(b)(4) acts as a penalty for institutions involved in ongoing research.

In sum, Rule 78(f) and 75(b)(4) should be repealed.

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