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The author reviews patent rules recently issued by the Patent and Trademark Office and offers advice on how practitioners may alter their patent prosecution strategies to best maneuver through the new requirements.

New Prosecution Paradigms Under the New Patent Office Rules

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The new Patent and Trademark Office rules, published Aug. 21, may dramatically change patent prosecution as we know it, particularly in the biotech and pharmaceutical fields (74 PTCJ 493, 8/24/07).

As a rules package that is not driven by statutory changes or new treaty obligations, it is notable for its substantive impact. The rules do not merely set forth new formalities requirements, new deadlines to monitor, or new forms to complete, but also impose strict limitations on patent prosecution strategies that require new paradigms to preserve patent rights.

The Constraints of the New Rules

The new rules fall under three main categories: (1) the limitations on the number of continuation applications and requests for continued examination (RCEs) that can be filed as a matter of right; (2) the limitation on the number of claims that can be presented without an examination support document (ESD); and (3) the heightened scrutiny of related applications.

Standing on their own, any one of these categories would require applicants to implement new practices. As a trifecta, their effect is exponentially greater, and may require a new approach to patent prosecution, particularly because obvious strategies for avoiding the constraints of one new rule are prevented by another new rule.

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For example, the continuation or claims limits cannot be avoided by simultaneously filing parallel applications, because the PTO may require applicants to consolidate claims in related applications with a common filing or priority date, if any claims are not patentably distinct. Additionally, if two co-pending applications have any patentably indistinct claims, the PTO will count all claims in both applications as if they were filed in each application.

This ''fuzzy math'' cannot be avoided by filing applications a few days (or a few months) apart, because the new claim counting rules apply without regard to respective filing dates. Avoiding the related applications scrutiny by filing a ''jumbo'' application may be an attractive option, but that approach may run up against the claim limits or ESD requirement if the PTO does not issue a restriction requirement that would permit some claims to be pursued in divisional applications.

Implications for Biotech and Pharma

The biotech and pharmaceutical industries may feel particularly pinched by the continuation and RCE limits.

The PTO projects that these rules will have minimal impact, reporting that only 3 percent of continuations and RCEs filed last year might not have been permitted under the new rules. These statistics, however, do not take into account the combined effect of the RCE limits.

For example, with only one RCE permitted per patent family, applicants may be filing more continuations to carry on with prosecution. This may be particularly true in biotech and pharmaceutical applications, where ne-

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gotiating with the examiner usually takes more time, because issues of appropriate claim scope, enablement, and utility in these fields can be complicated.

An applicant who has ''spent'' its one RCE to obtain allowance in the original application in a family, may find itself having to file a second continuation in order to advance prosecution in the first continuation. Thus, applicants may find themselves running through the permitted two continuations and one RCE more quickly than the PTO projects.

The Promise of Petitions

The new rules provide that an additional continuation or RCE may be obtained by a petition showing why the new amendment, argument or evidence to be submitted could not have been presented earlier. However, applicants counting on being able to file a petition to obtain additional continuations or RCEs should be forewarned by the commentary published with the final rules.

The PTO comments deem inadequate a surprising number of seemingly legitimate reasons for requesting an additional continuation or RCE. According to the comments, additional continuations generally will not be granted to permit correction of inventorship or to copy claims to provoke an interference.

Remarkably, an additional RCE generally will not be granted to permit the filing of a ''late'' information disclosure statement (IDS), although the PTO reminds applicants that the new IDS rules (expected before year's end) will change the timing requirements for IDSs. Petitions founded on more strategic reasons also may be denied.

For example, according to the comments, an additional continuation generally will not be permitted merely because an applicant is not satisfied with the claim scope allowed by the examiner, and would like to pursue broader coverage in a continuation, or merely because the applicant recently discovered that unclaimed embodiments are commercially feasible or are being pursued by a competitor. Petitions founded on more mundane reasons also may be denied.

According to the comments, additional continuations generally will not be granted merely because the application is assigned to a new examiner, the applicant obtains new patent counsel, or the applicant's financial situation improves.

On the other hand, the PTO comments indicate that petitions for an additional continuation may be granted where the applicant needs more time to obtain evidence to support patentability. In reviewing such petitions, however, the PTO is likely to hold applicants to a standard of diligence.

For example, the PTO may consider how aggressively the applicant prosecuted the original application and two continuations permitted as a matter of right, going so far as to consider whether the original claims were in proper form for examination, or whether the examiner made objections or indefiniteness rejections. The PTO e also may consider whether the applicant challenged any objections or rejections by petition or appeal, or merely presented the same (unsuccessful) arguments throughout prosecution. It also may scrutinize how quickly the applicant began obtaining the evidence at issue.

In the context of evidence of non-obviousness, the commentary suggests that applicants should commence experiments when the rejection is first made, and not wait until their initial arguments prove unconvincing. In the context of evidence of enablement or utility, the commentary suggests that applicants should commence experiments during prosecution of the original application, and should pursue an appeal to at least the examiner's answer stage before filing a continuation.

The PTO also reminds applicants of the ability to file a request to suspend prosecution, which may be appropriate if particularly lengthy experiments are required to support patentability.

New Prosecution Paradigms: Examiner Interviews, Petitions, Appeals

Applicants who adopt new paradigms for their patent prosecution strategies may be the most likely to survive these rule changes unscathed. The most obvious change for biotech and pharmaceutical applicants would be to accept reasonable restriction requirements, instead of traversing the multi-way restrictions often issued in this field.

Under the new rules, a restriction requirement will support a divisional application to each non-elected invention, and each divisional application can be the basis of two continuations and one RCE. Thus, applicants may come to welcome restriction requirements as an opportunity for additional prosecution via divisional applications.

Another change that may prove useful for all applicants would be an increased use of examiner interviews, including telephonic interviews, particularly early on in prosecution. Instead of waiting to interview an application until after a final office action (when a continuation or RCE may be required to obtain entry of any amendments or evidence discussed during the interview), applicants may decide to request interviews before responding to the first office action (when amendments and evidence can be entered as a matter of right).

Another paradigm shift encouraged by the new rules would be to front-load prosecution efforts by responding to first office actions with all available amendments (perhaps presented in dependent claims, if within the new claim limits), arguments and evidence. Applicants will have to determine whether the increased costs of such responses outweigh the risks that arguments alone will not sway the examiner, and may adopt different practices depending on whether additional continuations or RCEs are available.

Additionally or alternatively, applicants may turn more frequently, and earlier, to petitions (e.g., against the finality of an office action or against a refusal to enter an amendment after final) and appeals. Indeed, the PTO commentary suggests a strategy that includes pursuing an appeal in the original application in a given patent family, and filing continuations later, if the appeal is unsuccessful or if other claims are desired. This is directly contrary to current practice, where many applicants file continuations and RCEs if they believe that any further progress can be made with the examiner, and only file appeals as a last resort.

Pre-Filing Strategies

The new rules also encourage more strategic planning before a patent application is filed. Applicants who file large numbers of applications, or who file several applications surrounding the same core technology,

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may be most affected by the related applications and claim limitation rules.

While it may be possible to avoid the brunt of these rules by careful application drafting and selective filings, applicants accustomed to more ad hoc approaches may find themselves having to unravel complicated knots of related applications and having to conduct complicated claim counting exercises. For example, even if the PTO permits an applicant to pursue one application to a genus and a separate application to a patentably distinct species, the PTO may count the species and genus claims together, if the genus is not patentable over the species.

The rules also will require coordination of response strategies in all related applications throughout prosecution, because any claim added or canceled in one related application may affect the number of claims that can be presented in the other related application.

Of course, no single strategy will be suitable for all applicants, or even for all patent applications filed by a given applicant, and all options must be considered and evaluated on a case-by-case basis. Moreover, many of these new strategies may require applicants to invest more resources in patent prosecution, or at least in earlier stages of prosecution. Nevertheless, the investment may prove invaluable in navigating the new rules while preserving the ability to obtain valuable patent rights.