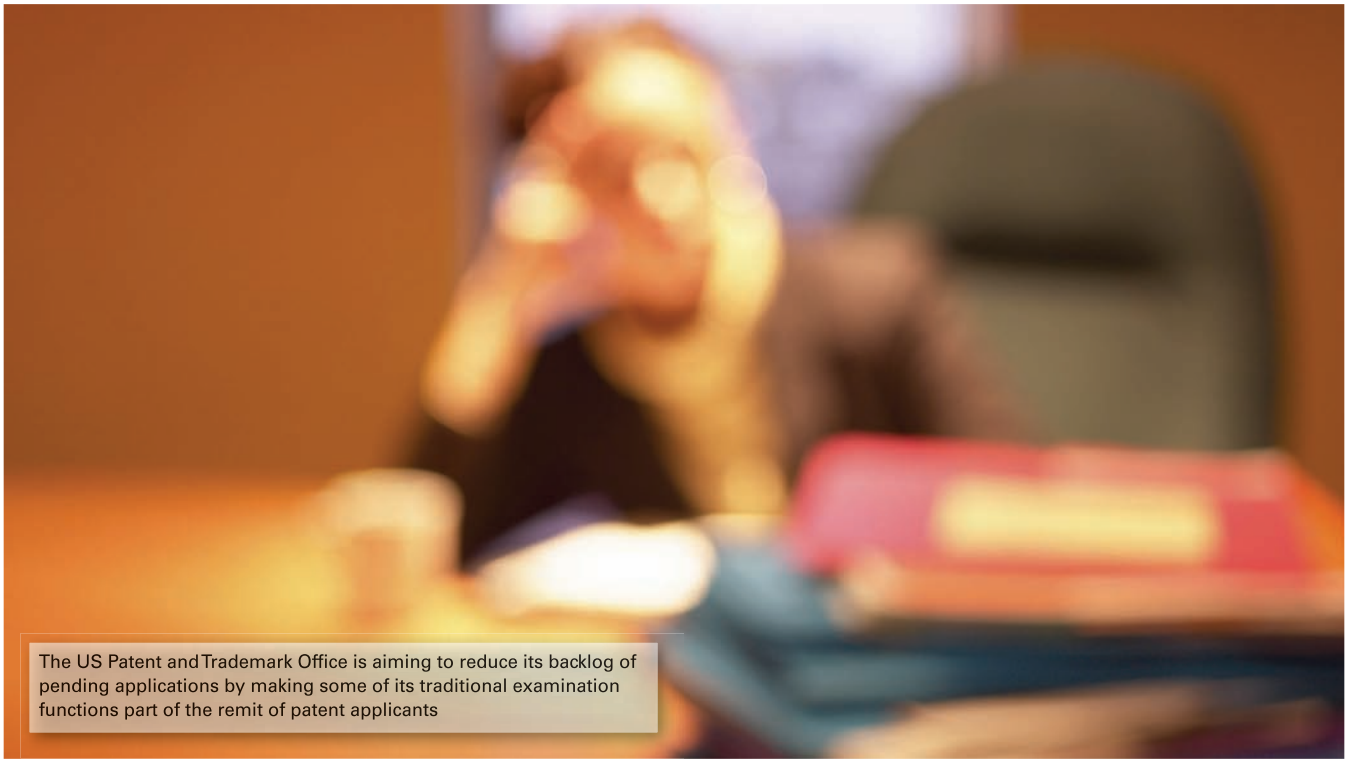
New USPTO rules: change for the better?

Patent applicants in the US have spent the past few months getting to grips with new rules intended to streamline the application process. **Thomas Edman** and **Dr William T Slaven IV** consider whether the changes are a positive step for the biotech community



The US Patent and Trademark Office is aiming to reduce its backlog of pending applications by making some of its traditional examination functions part of the remit of patent applicants

On August 21st 2007, the US Patent and Trademark Office (USPTO) issued a sweeping set of rules and rule revisions for patent practice that is likely to necessitate a significant strategy shift in how applicants approach patent protection. These new rules took effect on November 1st and will affect both newly filed and many previously filed applications pending as of that date.

The USPTO's stated purpose for issuing the rules was to allow its patent examiners to focus on new cases and to reduce its backlog of pending applications. In that regard, applicants and practitioners may applaud the USPTO's move. In the past, some classes of patent applications stuck in the backlog have had to endure years of inactivity before finally receiving an initial substantive review on the merits. According to the USPTO, the rule revisions will provide more effective and efficient examination for the typical patent applicant. These new rules, however, come with significant trade-offs. Namely, the rule changes may result in applicants incurring substantial additional costs and effort before filing their applications and, more importantly, they may limit prosecution options and/or the scope of patents. Even more significantly, it is widely believed by many patent practitioners and industry players that the new rules will artificially and unnecessarily limit the applicants' rightful scope of patent protection. In fact, various lobbying efforts and litigation are already underway, seeking to prevent enactment of the new rules. (See, for example, SmithKline Beecham Corp *vs* Jon W Dudas, 1:07-cv-01008 (E.D.Va. filed October 9th, 2007), where GlaxoSmithKline has sued the USPTO to stop implementation of the new rules, arguing that the USPTO has exceeded its limited rulemaking authority. See also, Tafas *vs* Dudas, No. 1:07-cv-00846 (E.D.Va. filed August 22nd, 2007)).

Although the new rules are ostensibly designed to reduce the USPTO's burden of examining applications, they do so by attempting to shift that burden to applicants. In furtherance of this objective, the new rules make a number of substantive changes to existing USPTO rules and protocol, including:

1. A new limit on the total number of claims for new applications;
2. A constraint on the number of continuing applications (i.e. continuation and continuation-in-part applications) during prosecution; and
3. Tighter restrictions on applications with overlapping subject matter.

The 5/25 rule

Generally, the new rules set a limit of five independent claims and 25 total claims for any single application (the "5/25 rule"), although these are not "hard" limits. Applicants are

permitted to exceed the 5/25 limit if they assist the USPTO by providing an examination support document (ESD) that covers all of the claims in the application or alternatively by filing a suggested restriction requirement (SRR).

The ESD essentially requires the applicant to perform many of the examination functions that were traditionally carried out by the USPTO. In this regard, the ESD is similar in scope to the support document required for the USPTO's accelerated examination procedures that were introduced in 2006. Specifically, for the new ESD, the applicant must conduct a search of the prior art (including US patents and published applications, foreign patent materials and other non-patent literature) and provide a list of all references that are "material to patentability." From that list of references, the applicant must – for every claim of the application – identify the reference(s) deemed most closely related to the subject matter of the claims and submit an element-by-element comparison of the claim with the closest references.

In essence, therefore, an ESD entails disclosing, in the applicant's opinion, why each and every claim of an application is distinguishable over the art. In addition to the considerable costs associated with performing the necessary art search (which, for example, can necessitate extensive database searching in the case of chemical and biotechnology patent applications), such statements by the applicant regarding the scope of patent claims can potentially have significant estoppel effects concerning claim scope in, for example, licensing and/or litigation contexts.

Patent practitioners typically have sought to avoid such statements during prosecution except to the extent minimally necessary to overcome art cited by the USPTO. Indeed, once the patent issues, adverse parties frequently attempt to use statements from the prosecution to characterise the scope of patent to the disadvantage of the patent holder, rather than allowing the patent claims to speak for themselves. It is therefore certainly not preferable for applicants to have to make potentially limiting and/or disadvantageous statements at the outset of prosecution and without provocation by the USPTO. Put another way, the filing of an ESD likely requires applicants to unnecessarily characterise their invention vis-à-vis art that the USPTO may not or would not have otherwise cited against the applicant.

As an alternative to the ESD, applicants are permitted to file an SRR, thus 'breaking up' any claim set exceeding the 5/25 rule. In essence, the SRR represents the applicant's belief that the application should be subject to a restriction along the lines of the SRR so as to allow the filing of divisional applications (as discussed below, divisional applications are not subject to the limit on continuation applications). If, however, the USPTO does not agree with the SRR, the applicants would then need to either comply with the 5/25 rule by amendment (i.e. by deleting claims) or by filing an ESD.

Perhaps of greater concern is that the new 5/25 rule is retroactive to applications that had not received a first Office Action on the merits prior to November 1st, 2007. The USPTO has indicated that it plans to notify applicants with applications in violation of the 5/25 rule after this date. These applicants will be required to provide an ESD, an SRR or an amended claim set complying with the 5/25 rule in order to avoid abandonment.

The 2+1 rule

The new rules also impose a limit for filing continuation applications (CON) or continuation-in-part applications (CIP), and requests for continued examination (RCE) in an "application family" without a showing of special circumstances. In particular, for any application family (i.e. any single patent application), only two CON or CIP applications and a single RCE may be filed (the "2+1 rule"). Divisional applications are not part of an application family, but instead constitute a base application for a separate application family. Any third or subsequent CON or CIP application and/or any second or subsequent RCE in the application family can only be filed upon petition and a showing as to why the amendment, argument or evidence sought to be entered via the CON, CIP or RCE could not have been previously submitted. Thus, up to 15 independent claims and 75 total claims are available for any single application family, assuming no additional CON or CIP applications are permitted by petition.

According to the USPTO, this aspect of the new rules is intended to prevent applicants from employing a patent strategy (common in the biotech industry) in which expansive applications are filed with a limited initial claim set, so that the applicant can later 'mine the application' for additional subject matter and make claims in future continuing applications in view of changes within the commercial market.

Similar to the 5/25 rule, the 2+1 rule is not a "hard" limit. Additional CONs, CIPs or RCEs can be filed if they are supported by evidence that the additional filing could not have been submitted previously. At this time, it remains unclear exactly what types of arguments may support the required showing. As noted on its website, the USPTO was still "clarifying certain provisions of the rules and making some procedural adjustments" even in late October 2007. Consequently, additional continuation applications may not be allowed for some applicants after November 1st, 2007.

The 2+1 rule is also retroactive, but it includes a grace provision. First, applications exceeding the 2+1 rule as of August 21st (the day the rules were published) were able to file "one more" continuing application on or after November 1st without the required showing that the claims in such a continuation could not have been earlier presented. Second, the new rule does not impose a limit on the number of continuing applications that could be filed before November 1st. Continuing applications filed between August 21st and November 1st, 2007 would count toward the "one more" part of the rule, but would not be subject to the required showing. Thus, applicants had to consider whether to file a series of continuation applications prior to November 1st, 2007, subject to the imposed limits on overlapping applications (discussed below).

The Omnibus rule

Under the new rules, the USPTO may require an applicant to group together and/or consolidate claims in multiple applications. Under this rule (which we have dubbed the "Omnibus rule"), if multiple applications contain "patentably indistinct" claims, the USPTO will treat the multiple applications as a single application for the purpose of determining whether each of the multiple applications meets the 5/25 rule. This provision is intended to preclude an applicant from submitting multiple applications with claims that are patentably indistinct, each with five or fewer independent claims or 25 or fewer total claims at the same time, in order to avoid needing to file an ESD or SRR. This is common practice in the biotech sector.

The Omnibus rule applies to new and currently pending applications for which no first action on the merits was issued by November 1st, 2007. Applications subject to this rule are those with:

1. The same claimed filing or priority date (or that have a filing or priority date within two months of one another);
2. Substantial overlapping disclosure;
3. At least one common inventor; and
4. Common ownership.

Such applications will trigger a "rebuttable presumption" that the applications contain at least one patentably indistinct claim. Consequently, patent application families,

even if they are directed to different subject matter, nonetheless may be grouped together artificially and presumed to violate the 5/25 rule (and, therefore require an ESD, SRR or claim deletions). Applicants then will need to establish that the "grouped patent applications" are, in fact, distinct.

That said, the USPTO has yet to provide details as to exactly what will be needed to make such a showing, but given the stated intent of the new rules, these requirements may be substantial. If the applicant cannot rebut the presumption, the applicant will be required to submit a terminal disclaimer and explain why there are two or more pending non-provisional applications with patentably indistinct claims. The deadline for filing a rebuttal or terminal disclaimer is February 1st, 2008.

The most notable changes in the new USPTO rules include a limit to the claim count of new applications (the 5/25 rule), a limit to the number of continuing applications and RCEs (the 2+1 rule) and the grouping of certain applications with patentably indistinct claims (the Omnibus Rule). The new rules include numerous other details and exceptions – including certain exceptions for qualifying small entities, additional rules for divisional applications and disclosure obligations – that may impact an applicant's patent filing strategy.

The patent community is only just beginning to assess the overall impact of the new rule changes for both pending applications and new filings. Although it is too early to determine the precise impacts these particular rule changes will have on the biotechnology, biomedical and chemical/pharmaceutical IP communities, it is hard to imagine they will have anything but a chilling effect on the ability of pharma and biotech companies to protect their discoveries.

To this end, these rule changes need to be viewed in the broader context of other recently announced USPTO initiatives and guidelines for patent practice, all of which likely negatively impact the ability to obtain patent and which appear to make it progressively more difficult and expensive to obtain patent protection. For example, on October 10th, 2007, the USPTO published in the Federal Register its "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co *vs* Teleflex Inc." A review of this document reveals that although the USPTO will be required to provide a "rational underpinning to support the legal conclusion of obviousness" as required by KSR, the threshold for what qualifies as a "rational underpinning" will be fairly low. Thus, it will now be far easier for the USPTO to make and maintain an obviousness rejection, and applicants will not have the recourse of, for example, filing continuation applications to overcome such rejections.

Potentially even more concerning in view of the above-discussed new rules, is the USPTO's proposed rule changes regarding Markush claims. In this new set of proposed rules, the USPTO essentially seeks to limit the ability of applicants to employ alternative claim language because such can require separate examination of each alternative. Obviously, in conjunction with the 5/25 rule and 2+1 rule, these proposed changes will also likely negatively impact the ability of applicants to effectively and fully claim new inventions, especially in the chemical and biotech arts.

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