

Biotechnology industry wary of patent office 'streamlining'

The biotech industry warily awaits the U.S. Patent and Trademark Office's (USPTO) decision on two proposed rules intended to improve and accelerate the cumbersome, often backlogged patent application process.

With filers often waiting two years before the USPTO acts on their applications, there is no dispute that change is needed. USP-

TO attributes part of the backlog to the common practices of filing several "continuation applications" (amendments and re-examination requests) pursuant to the initial filing and of including numerous patent claims in each application.

In hopes of reducing the long delays, the USPTO has proposed two major changes.

First, the proposed rules would severely limit an applicant's ability to demand continued examinations of a single application. Second, they would raise the hurdle for multi-claim applications.

USPTO hopes these proposals would force inventors to design their "claims" earlier and more clearly, making the entire process more efficient. But many in the biotech community are highly skeptical that the changes would bring about that desired result.

To begin with, biotech companies and their intellectual property counsel generally view the proposed rules as interfering with the present practice of fine-tuning one's claims in reaction to patent office examination and in parallel with ongoing research and development. As more information regarding a discovery is learned in the lab, and as the efforts of other inventors come to light, a prudent company will likely want to amend its initial application by filing continuations that reflect these developments.

Under the proposed rules, patent applicants would be permitted only a single continuation as a matter of right. Beyond that, an applicant would have to show why the amendment or evidence "could not have been previously submitted."

In addition, the proposed "examination of claims" rule would limit the number of independent claims within each application, forcing applicants to select ten representative claims for examination.

The Biotechnology Industry Organization (BIO) and others have opposed the changes. The USPTO is being pressed to hold further public hearings. BIO has expressed the concern that the rules would "discourage investors from investing money in biotech innovations."

A "continuation," if accepted by the USPTO, can clarify or improve an earlier patent application. An inventor may craft an excellent initial application with well-designed claims. But that inventor will often later

be faced with newly discovered prior art, conflicting requests from foreign patent offices, and USPTO comments and claim rejections. The inventor needs to be able to react to these curveballs.

The biotech industry attracts start-up financing and achieves value in licensing transactions based in large part upon a clearly defined patent portfolio. Many biotechs fear that the USPTO "improvements" would create a more muddled IP landscape.

Furthermore, many believe that the proposed rules could actually worsen the backlog at the USPTO. Biotechs would need to consider filing separate, additional patent applications if they are unable to expand and clarify existing ones. Additional applications will lead to increased patent costs and even greater burdens upon the USPTO.

The USPTO should instead increase the number and quality of patent examiners. This could be accomplished by ensuring that patent filing fees, which now flow to the general government coffers, stay within the USPTO. Coordinating examination efforts with foreign patent offices and permitting applicants to request deferred examinations would also help solve this pressing problem.

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