

## New Rules — What Now?

*Thursday, Oct 18, 2007* --- What do you need to be doing now with your pending patent applications?

The United States Patent & Trademark Office (USPTO) has finalized new rules that will substantially impact the way some patent applications will be prepared and the options available for all currently pending and future applications.

In summary, the new rules limit the number of applications that can be filed within a patent family and the number of claims that may be filed on a particular invention, regardless of the number of separate applications directed to that invention.

Because the effective date of the rules is Nov. 1, 2007, every medical device company should be aware of options they have now that disappear on the effective date as well as steps they should be taking now to best preserve their rights.

As with any new government rules package that occupies more than 125 pages in the Federal Register, there are numerous options and exceptions that apply to any attempt at a concise explanation of the rules.

Therefore, those having pending patent applications at the USPTO are encouraged to consult with their patent counsel regarding how the rules impact their currently pending applications.

*\* File Any Desired Applications That May Be Impossible to File as of November 1, 2007 \**

The strategy of keeping one application pending in a chain of related applications, in order to keep options open, will soon be severely limited.

The new rules establish a limit of two continuation applications and one request for continued examination (RCE) per patent family (defined by U.S./PCT non-provisional priority date) as a matter of right.

Divisional applications, filed in response to a restriction requirement, do not count as part of the parent's patent family. The divisional application is directed to a different invention and therefore starts a new family with respect to the new continuation, RCE, and claim limits.

The new rules prohibit filing a continuation-in-part (CIP) application claiming priority to a divisional application. However, this option remains available

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before November 1, 2007.

Consider filing an RCE before November 1, 2007. If an RCE has already been filed in the family (including parent, sister, or child cases), no further RCEs are permitted as a matter of right as of November 1, 2007.

Despite the limits on continuations noted above, the rules provide for one more continuation across the family on or after August 21, 2007, which can be filed anytime, including after November 1, 2007.

However, if you would like to file more than one continuation per family, or have already filed a continuation in the family on or after August 21, 2007, you may want to consider filing other continuation application(s) or CIP(s) before November 1, 2007.

**\* Claim Limits for Patent Families \***

The new rules establish a limit of 5 independent and 25 total claims per application, but the USPTO may count claims in other applications toward the 5/25 limit if any claims between the applications are not “patentably distinct.”

This 5/25 limit applies to any case without a first Office Action mailed by November 1, 2007 that has not received a Notice of Allowance, and applies after any Restriction Requirement.

The 5/25 claim limit is waived in an application if a new Examination Support Document (ESD) is filed before the first Office Action on the merits.

To reduce the effective claim count of an application without canceling claims, applicants can encourage, and simultaneously commit to, a Restriction Requirement and election by filing a new Suggested Restriction Requirement (SRR) document.

Any unclaimed embodiments are best addressed and claimed now, to permit a CIP if needed. Earlier action also can give more time to prompt a restriction requirement and/or factor new claims into the 5/25 claim limits.

**\* Office Action and Restriction Responses \***

Consider the new rules, and their limits on claims and further application/RCE filings, in any Office Action response or plan to file a continuation or RCE in current negotiations with examiners.

Any pending or newly filed application is subject to the claim limits, unless a first Office Action on the merits, or allowance, is mailed before November 1, 2007.

There is a benefit to not traversing restriction requirements in order to permit filing of divisional applications.

\* Gather Application Data for Reporting Obligations and to Determine Patent Families \*

There will be mandatory reporting obligations for pending cases generally, not just new or recently filed cases, that are: (1) commonly owned, co-pending applications with a common inventor and any priority dates within two months of each other, regardless of application content; or (2) commonly owned, co-pending applications with a common inventor, any same priority date, and overlapping content. There also are reporting obligations for CIP applications.

Companies who use in-house and outside counsel, or who use more than one outside counsel for patent prosecution, should start gathering information now, and may need to establish information-sharing procedures to ensure compliance.

Start your planning now and involve your entire IP team, including outside counsel, that have a role in filing cases.

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