-----Original Message-----
From: Pagliery, Richard [mailto:rpagliery@neurocrine.com]
Sent: Monday, May 08, 2006 12:21 PM
To: AB93Comments
Cc: Patent Practice
Subject: RE: Comments re Proposed Rules re Continuation Practice

Dear Ms. Dey:

Thank you for your message. Attached is a PDF copy of the comments we submitted on May 2nd. If there are any problems with this file please let me know and I will send the comments via fax.

Sincerely,

Richard Pagliery

From: Patent Practice [mailto:PatentPractice@USPTO.GOV]
Sent: Saturday, May 06, 2006 8:28 AM
To: Pagliery, Richard
Subject: RE: Comments re Proposed Rules re Continuation Practice

Dear Mr. Pagliery,

It appears that page 2 of your document did not properly convert to a pdf since the page is blank. Please resend the document to the AB93Comments email mailbox.

Thank you,

Ms. Terry J. Dey
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy
United States Patent and Trademark Office

> -----Original Message-----
> **From:** Pagliery, Richard [mailto:rpagliery@neurocrine.com]
> **Sent:** Tuesday, May 02, 2006 1:39 PM
> **To:** AB93Comments
> **Subject:** Comments re Proposed Rules re Continuation Practice
>
> Robert W. Bahr, Esq.
> Senior Patent Attorney
> Office of the Deputy Commissioner for Patent Examination Policy
>
> Dear Mr. Bahr:

Attached please find our comments regarding the Office's proposed rules regarding continuation practice.

Sincerely,

Richard H. Pagliery
Senior Patent Counsel
Neurocrine Biosciences, Inc.

The following comments are submitted in response to the United States Patent and Trademark Office's Notice of Proposed Rule Making advising the public of its proposed "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims." (See Fed. Reg., 71, No.1, January 3, 2006).

We understand the Patent Office's need to address the backlog of unexamined patent applications. However, we believe that the proposed rules likely would have a detrimental effect on patent protection for potentially valuable new drugs. Moreover, because the proposed rules would restrict the substantive rights afforded to patent applicants under federal statutes, we believe that it is highly doubtful that the Office even has statutory authority to enact the proposed rules. Lastly, we believe that there are alternative rule changes that the Office could enact that would address the Office's backlog concern without negatively affecting patent applicants' substantive rights.

As the Office knows, the drug discovery and development process can take several years. A common practice within the pharmaceutical industry, for both patentability and competitive reasons, is to file a patent application early in the process. This original application may recite dozens or even hundreds of specific compounds. The current U.S. continuation practice - which is in accord with European divisional practice - allows applicants to develop drug candidates in sequence and, upon establishment of a lead compound, file a continuation application having claims narrowly focused on the lead compound. In instances where the original and first continuation application proceed promptly to issuance, the lead compound may not be identified before the first continuation application is allowed. This is particularly likely where, for example, the first lead compound fails in pre-clinical tests and is replaced by a second or subsequent lead compound. Under such circumstances, the proposed rules would preclude applicants from filing a continuation application with claims narrowly directed to the lead compound.

There are mitigating steps that drug discovery organizations could take to reduce the likelihood of such circumstances occurring, but none is without significant drawbacks. The organizations could, for example, seek to delay initiation of U.S. prosecution by filing only PCT applications at the 12-month date and delaying entry into the U.S. national stage until the 30-month date. However, this approach contains at least two significant drawbacks. First, it deprives applicants the opportunity to obtain early allowance and issuance of valuable claims to a new genus of compounds. Second, it deprives applicants the opportunity for two thorough searches of the claims (i.e., a U.S. Patent Office search in a § 111 case and an EPO search in a concurrent PCT case).

Other potential mitigation steps, such as filing a series of dependent claims (e.g., compound, pharmaceutical composition and methods of treatment) to each compound specifically disclosed in the original application, would be prohibitively costly in most applications. And still others, such as filing original applications with only enough specific compounds to support the entire breadth of the broadest compound claim (in order to enable the later filing of a selection invention application to the lead compound), would potentially raise § 112 concerns as well as unnecessarily expose the applicant to the risk of losing the drug discovery race to a competitor. This latter risk would be particularly enhanced if Congress were to change the current first-to-invent system to a first-to-file system, a change that is under consideration.

Regardless of the mitigation step(s) chosen with regard to filing strategy, patent applicants likely would have to discontinue the current practice of canceling rejected claims - particularly where the rejected claims include all of the pending claims of a given class, such as method of treatment claims - to obtain allowance of allowable claims. This practice, which permits allowable claims to issue while focused prosecution of contested claims proceeds separately in a continuation application, would no longer be advisable in many, if not the vast majority of, applications. Instead, in order to preserve the opportunity to file a continuation application with narrowed claims to the lead compound, applicants would likely have to appeal a high percentage of original applications. A further reason to file appeals whenever possible would be to delay

prosecution, thereby allowing more time for identification of a lead compound. Consequently, the proposed rules likely would have the unintended consequence of shifting the workload burden from the Patent Office to the Board of Patent Appeals and Interferences.

We also believe that the Office lacks statutory authority to implement the proposed rules. Applicants' right to file a series of continuation applications is provided by federal statutes (i.e., 35 U.S.C. §§ 120 and 365), not Patent Office rules. Neither of these statutes, properly interpreted, grants the Office authority to impose substantive restrictions on continuation practice. Absent such statutory authorization, the Office lacks authority to deprive patent applicants of a right granted to applicants by Congress.

Finally, we believe that there are alternative measures that the Office can take to address its understandable concern regarding the current and projected backlog of unexamined patent applications. For example, the Office could impose increased filing fees for each successive continuation application, just as it imposes increased fees for each successive month of extension under 37 C.F.R. § 1.136(a). Alternatively, or in addition, the Office could amend 37 C.F.R. § 1.103(c) and (d) to permit applicants to delay examination of applications for a period longer than is currently provided in those sections (i.e., 3 months for an RCE under section (c) and 3 years from the earliest priority date claimed under section (d)). Both of these measures likely would reduce the number of continuation applications filed without reducing patent applicants' substantive rights or increasing the Board of Patent Appeals and Interferences case load.

Respectfully submitted,

Richard H. Pagliery
Senior Patent Counsel
Neurocrine Biosciences, Inc.