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From: Sean Brennan [mailto:smb@sangamo.com]
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Sean Brennan, Ph.D.
Senior Director, Intellectual Property
Sangamo BioSciences, Inc.
501 Canal Blvd., Suite A100
Richmond, CA 94804

Phone: (510) 970-6000, ext. 252
FAX: (510) 236-8951
smb@sangamo.com

Sangamo BioSciences, Inc.

COMMENTS ON PROPOSED RULE CHANGES RELATING TO CONTINUING APPLICATIONS, REQUEST FOR CONTINUED EXAMINATION AND APPLICATIONS CONTAINING PATENTABLY INDISTINCT CLAIMS

The following comments are presented by Sangamo BioSciences, Inc. in response to the USPTO's proposed changes in its rules governing continuing applications, requests for continued examination (RCEs) and applications containing what it refers to as "patentably indistinct claims," as presented in the Federal Register Vol. 70, No. 1 (70 Fed. Reg. 48) on January 3, 2006.

Introduction: Sangamo BioSciences, Inc.: its use of, and experience with, continuing applications

Sangamo BioSciences, Inc. is a small biotechnology company (approximately 65 employees) conducting research and development in gene regulation and genome modification. Sangamo successfully obtained venture funding, made an initial public offering and a subsequent registered direct offering, and has entered into partnerships with large health care and agricultural organizations. A key driver of Sangamo's successes in raising capital and obtaining strategic partnerships has been its ability to obtain patent coverage in a rapidly-advancing and technologically complicated field.

Approximately 25% of the United States patent applications filed by Sangamo are continuation or continuation-in-part applications. Sangamo files these types of continuing applications for a number of reasons, a major one being that we have become accustomed to receiving extremely narrow search and examination of our claims from the USPTO. Therefore, we often file relatively narrow continuing applications to avoid the expense and delay of division and piecemeal examination.

A relatively common course of events for Sangamo is to have an original application subjected to Restriction (sometimes into more groups than there are claims in the application), and then to have the elected invention searched and examined narrowly with respect to a single species. Traversals and/or petitions of these requirements are rarely successful. A first Office Action is then issued, and amendments and/or arguments

are submitted in response. If the Response is not deemed persuasive,[1] a final Office Action is issued and subsequent amendments and/or arguments are generally refused entry. Thus, in terms of the "bites of the apple" metaphor, Sangamo has received only a single "bite" in its original application (in this example) and must file either a continuation or a RCE to obtain a second bite.[2] This problem is often exacerbated because many examiners refuse to discuss cases both prior to issuing a first Office Action and subsequent to issuing a Final Office Action.

Another reason that Sangamo often finds it necessary to file continuing applications is because of examiner error. The PTO's own statistics show that, in 2005, one out of every five office actions in TC 1600 (biotechnology) contained an error having significant adverse impact on prosecution.[3] Additional PTO statistics indicate that from 50-60% of appeals involve an examiner error.[4] In our experience, both scientific and legal errors are made by examiners.[5] Examiner errors also include failure by the examiner to consider the totality of the record, and the use of unsupported personal assumptions, by examiners, to support and sustain rejections. Not only must such errors be corrected in subsequent prosecution; but it often requires multiple exchanges with the Examiner (sometimes up to and including appeal) before such errors are corrected (if, indeed, they are ever corrected).

Another type of Examiner error which necessitates the filing of continuing applications relates to claim scope. Sangamo has experienced many cases[6] in which a broad claim is repeatedly rejected in an original application (in which narrower claims

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[1] often erroneously, see below

[2] An orange might provide a more apt analogy than an apple, inasmuch as, in this fairly typical example, examination has so far been confined to a single species; thus, applicant has therefore received only a single bite out of one section of the orange.

[3] *See*, for example, presentation by Commissioner Doll on Feb. 1, 2006 at slide 16

[4] *See*, for example, statement of Undersecretary Dudas to the House Subcommittee on Intellectual Property, Committee on the Judiciary, April 21, 2005

[5] Scientific errors often result from a lack of understanding of the invention, which can be remedied through further prosecution. Most recently, the legal errors we have experienced relate to application of 35 U.S.C. § 112, first paragraph, in which heavy reliance is placed on cases such as *U.C. v. Lilly*, but examiners seem to be less aware of cases such as *Union Oil v. Atlantic Richfield* and *Capon v. Eshhar v. Dudas*.

[6] which, in the experience of the author, are not unique to Sangamo

are allowed), eventually to be allowed in a continuing application. This strongly suggests that an error was made in initially rejecting the broader claim that was later allowed. Alternatively, additional evidence and/or arguments might have been needed to convince the examiner to allow the broad claim. In the latter case, the applicant does not know that such additional evidence or argument is required until at least the first Office Action and often later. This is particularly true in cases in which initial examination is confined to a single species, for which it may require the entire course of prosecution in an original application and even one (or more) continuing applications simply to obtain examination of additional species, let alone of a generic claim.

In summary, the primary reason for the use of continuing application practice by Sangamo is that we have found such practice to be absolutely necessary to obtain full search and examination across the entire scope of our claims. We also often find it necessary to file continuing applications to correct errors by examiners. Finally, certain continuing applications are filed to cover products or processes that we have invented and fully disclosed in the specification as filed, but not claimed in an original application. When we subsequently discover that such unclaimed inventions are being made, used and/or sold by competitors, we file a continuing application to rightfully claim what we have already invented. Such practice is legal, is fully supported by the statute[7] and has been approved by the Federal Circuit.[8]

Impact of proposed rule changes

In light of Sangamo's experience, as discussed in the previous section, the primary anticipated consequence of the proposed rule changes, should they become effective, is that Sangamo will not be able to obtain patent protection for the full scope of their inventions. Inventions which are disclosed in an application, but which we are prohibited from claiming due to limitations on continuation practice, will be lost forever,

[7] 35 U.S.C. § 120: "An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States . . . shall have the same effect, as to such invention, as though filed on the date of the prior application . . ."

[8] *See*, for example, *Kingsdown Med. Cons, Ltd. v. Hollister, Inc.* 863 F.2d 867, 9 USPQ2d 1384 (Fed. Cir. 1988)

as it will not be possible to file a new application claiming such inventions. Despite the PTO's disclaimer that second and further continuing applications are not being prohibited, it is anticipated that not all petitions for second or further continuations will be approved. Furthermore, the time and expense of obtaining the limited coverage that will be available will be increased.

It is difficult to assess the full impact of the proposed changes, because many details of how the proposed practices will be carried out have not been presented. For example, criteria for granting or denying the proposed petitions have not been set forth. In addition, it has not been specified who will decide the proposed petitions. If it is the examiner, there is little reason to believe that a large number of such petitions will be granted. Indeed, in contrast to the argument that a persistent applicant can "wear down" an examiner, the proposed changes will allow an examiner to "dig in" and sustain erroneous rejections, thereby improperly denying applicant(s) protection of his/her/their invention.

Proffered Reasons for the Proposed Changes: A Critique

Delay in examining new applications; backlog

The PTO states that each continuing application requires the PTO to delay taking up the examination of a new application. One would imagine that simple mechanisms could be put in place to prioritize the docketing and examination of new applications, compared to continuing applications, if the PTO were concerned with a delay in taking up new applications. Moreover, it would seem that continuing applications would, in general, be both easier and less time-consuming to examine, because a totally new search and examination is not required, given the file history of the parent case(s).[9,10]

[9] This speculation has been confirmed by the author in conversations with former examiners.

[10] Were the PTO to attempt to rebut this argument by asserting that continuing applications are often assigned to a different examiner, the reply would be that: (1) the entire search and examination history of the parent application is already available to the new examiner and (2) this is an examiner retention problem, which should be solved by changes in internal PTO practices, rather than by penalizing applicants (see below)

The PTO's own statistics show that the proposed changes will not reverse the backlog, but simply maintain it at projected levels.[11] Therefore, alternative, more efficient solutions to the backlog problem should be explored.

Alleged abuses of continuing application practice

The Office additionally points to abuses by a small minority of applicants, which can best be summarized as prosecution laches. However, recent changes, including institution of a patent term based on effective filing date, and publication of applications, have addressed the majority of this small category of abusers. It would seem inequitable to place limits on all applicants in an attempt to police the even smaller fraction of postulated abusers that remains. Rather, the PTO should provide incentive for applicants to avoid deliberate delay of prosecution, as recently exemplified by the *Symbol Technologies* and *Bogese II* cases.

Notice Function

Related to the foregoing issue is the assertion, by the PTO, that the issuance of multiple patents resulting from continuing application practice tends to defeat the public notice function of patent claims in the initial application. However, although the public notice function of claims in an issued patent has long been recognized, claims in a published application should not be required to fulfill the same function. Moreover, unpatented published claims clearly place the public on notice of the scope of protection that an applicant is trying to obtain, and evaluation of the published specification as a whole places the public on notice as to what an applicant can legitimately claim.

Thus, it is difficult to understand the PTO's reason for asserting that continuing application practice somehow defeats any type of notice function.[12]

Improved patent quality

The Office asserts that the proposed changes should improve the quality of issued patents, making them easier to evaluate, enforce and litigate; but does not say how the processes of evaluation, enforcement and litigation will become easier as a result of

[11] *See*, for example, presentation by Commissioner Doll on Feb. 1, 2006 at slides 52-54

[12] Were it to be asserted that the notice function is not served because not all applications are published, it is noted that any such lack of notice is not a result of continuing application practice.

requiring a petition and showing for second and subsequent continuing applications. Nor does it explain how the quality of issued patents will improve.

Patentably indistinct claims

The Office proposes that "patentably indistinct" claims in multiple applications with the same filing date, overlapping disclosure, a common inventor and a common assignee be placed in a single application absent good and sufficient reason. However, the Office provides no criteria for determining whether different claims are "patentably indistinct." Indeed, Office practice in this area has been inconsistent[13] and in conflict with the statute, and therefore does not provide any guidance.

Magnitude of effect of continuing applications

The Office states that, because the number of second or subsequent continuing applications is low (11,800 out of 44,500 CONs and CIPs, and *ca.* 10,000 out of 52,000 RCEs), the proposed changes will not have an effect on the vast majority of patent applications. If this is true, it is difficult to understand how the proposed changes will have a significant impact on reducing the current and projected application backlog, which is the primary reason used to support the proposed changes.

Summary and conclusions

When the reasons that have been advanced to support the proposed changes are critically evaluated, it does not appear that the proposed changes will provide solutions to the stated problems. Although it is true that a backlog of applications exists, and that this backlog leads to delay in examination of new applications, it is not seen how reducing the number of total applications by 20-25% will contribute significantly to alleviating such a backlog. Indeed, the PTO has provided figures showing that the proposed changes will not eliminate the backlog and will reduce it only slightly, if at all. Moreover, it would not appear to be difficult to establish procedures which prioritize the examination of new applications, compared to continuing applications, if the PTO desired address a problem of delayed examination of new applications.

[13] *See* Green Paper: USPTO Study on Restriction Reforms at http://www.uspto.gov/web/patents/greenpaper.htm

With respect to its assertions that the proposed changes would improve the notice function of patents, improve patent quality, and facilitate evaluation, enforcement and litigation of patents; the Office has provided no evidence in support of any of these assertions.

Alternatives

As stated in the Introduction to these comments, the factors which necessitate the majority of continuing application filings by Sangamo are (1) the inability to obtain examination across the full scope of our claims in a single application and (2) examiner error. Sangamo therefore suggests that the focus of any reform efforts be placed on improving the quality of examination, before placing any limitations on applicants. The PTO has acknowledged its difficulties in attracting and retaining qualified examiners, and is taking steps to reduce the error rates, and these are valuable first steps in addressing the problems of pendency and backlog. To obtain further improvements, the following suggestions are offered.

Provide adequate time and reward for proper search and examination, based on complexity of subject matter

Two recent reports by the GAO[14] point out that the system of production quotas used to reward examiners is based on assumptions established in 1976. The field of biotechnology did not exist in 1976, yet examiners are evaluated for their examination of applications in this complicated and rapidly-advancing field using criteria which have not been updated in three decades.

It is suggested that examiners be given time and resources for search and examination that are commensurate with the complexity of the inventions they examine.[15]

[14] "INTELLECTUAL PROPERTY: USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain;" GAO-05-720 (June 17, 2005); and "INTELLECTUAL PROPERTY: Improvements Needed to Better Manage Patent Office Automation and Address Workforce Challenges," GAO-05-1008T (September 8, 2005)

[15] Anecdotal evidence suggests that this is not always the case; however, it has proven difficult for the author to obtain specific information on the amount of time provided to Examiners in TC1600 compared to that allotted for search and examination in other Technology Centers. Increased transparency by the PTO in this area would be appreciated.

Significantly more time should be allowed for the search and examination of a biotechnology invention than for simpler types of invention. It is also suggested that examiners be encouraged and enabled to search and examine applications across a reasonable scope. In this regard, full search and examination of independent claims should be encouraged, as opposed to current practices of limiting initial search and examination to alternative limitations of dependent claims.

Reduce error rate

Over half of appealed cases are found to contain an examiner error, and one in five Office Actions in TC 1600 contain an error. The legal errors encountered by Sangamo in our applications are often based on over-reliance by an examiner on a single case in a complicated area of case law. For example, as mentioned above, many current written description rejections in the biotechnology arts are based on *Regents of U.C. v. Eli Lilly & Co.*, in which this case is used as justification to require provision of a nucleotide or amino acid sequence for every biological molecule falling within the scope of a generic claim. These types of rejection ignore the clear traditions of both the CCPA and the Federal Circuit that compliance with written description is fact-specific and therefore very little precedential value can be accorded to prior cases, let alone to a single case such as *U.C. v. Lilly*. A more balanced treatment of the law would also include consideration of cases such as *Union Oil of California v. Atlantic Richfield Co.*, standing for the proposition that a composition can be adequately described by its properties, and *Capon v. Eshhar v. Dudas*, which re-states the long-established rule that what is well-known in the art need not be disclosed explicitly in the specification (with respect to sequences of chimeric immune system receptors).

By providing examiners with balanced training in case law, rather than over-emphasizing particular cases, the frequency of erroneous rejections in Office Actions could be reduced, leading to more expeditious prosecution and less need for applicants to file continuing applications to correct examiner errors.

Conclusions

Having attended multiple presentations by PTO personnel and reviewed the data put forth by the PTO to support the proposed changes,[16] the author does not believe that problems with pendency and backlog are due to the filing of continuing applications, nor does he believe that the proposed changes will address the problems which have been put forth to justify them, for the reasons presented above. Pendency and backlog problems more likely result from (1) the piecemeal fashion in which search and examination are often conducted in the PTO and (2) errors in examination. If examiner accuracy were improved and if applications were searched and examined across a reasonable claim scope, problems with application pendency and backlog would be reduced and, in addition, the necessity for applicants to file continuing applications would decrease.

The proposed changes place most, if not all, of the burden for solving backlog and pendency problems on applicants. This seems singularly inappropriate as a solution to a problem that is largely the result of PTO examination practice and internal personnel issues. Before taking steps that are, in effect, punitive to applicants by unduly restricting their ability to protect their intellectual property rights, it is respectfully suggested that the PTO improve its own practices relating to evaluation, retention and training of examiners, thereby improving the overall quality of examination, from which all will benefit.

Respectfully submitted,

/Sean Brennan/

Sean M. Brennan (Registration No. 39,917)
Senior Director, Intellectual Property
Sangamo BioSciences, Inc.
501 Canal Blvd., Suite A100
Richmond, California 94804

Telephone: (510) 970-6000 ext. 252
Facsimile: (510) 236-8951

[16] For example, presentation by Undersecretary Dudas, General Counsel Toupin and Deputy Commissioner Lucas at PTO Town Hall Meeting, Berkeley, CA, Feb. 28, 2006 and presentation by Solicitor Whealan at BIO IP Counsels' Committee Meeting, San Francisco, CA, March 9, 2006