Strategies For Operating Under The American Inventors' Protection Act: What's In It For Biotech Inventors?

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I. Introduction

In this paper we will discuss the impact that the American Inventors' Protection Act (AIPA) may have for biotech inventors and their employers. We will address four topics: Publication of U.S. patent applications; patent term guarantee; *inter partes* reexamination and compliance with requirements for information. For each of these we will follow a basic outline, first discussing the new or newly amended provisions, next addressing the general risks and benefits and finally the impact on the biotech community.

II. 18 Month Publication Of U.S. Patent Applications

A. Publication Of U.S. Patent Applications

1. The Amended Statute

Congress amended 35 U.S.C. ' 122 (new subsection (b)) to provide for publication of applications at eighteen months from the earliest filing date claimed under 35 U.S.C. '' 119(a)-(e), 120, 121 or 365. 37 C.F.R. '' 1.211 - 1.221 implement section 122(b) of the statute.

The amended statute applies to new patent applications filed on or after November 29, 2000, including continued prosecution applications under 37 C.F.R. ' 1.53(d), and divisional applications, continuation applications, and continuation-in-part applications under 37 C.F.R. ' 1.53(b) . The filing of a request for continued examination (RCE) under 37 C.F.R. ' 114 will *not* trigger publication.

Applications that will not be published are applications that are abandoned prior to the 18 month publication date, applications under secrecy order or whose disclosure would be detrimental to national security, design applications, and applications that are filed with a request not to publish.

An applicant may request that an application not be published if the invention has not been and will not be the subject of an application filed in another country (or under international agreement) that requires eighteen month publication. The statute requires that the request must be made upon filing. United States Patent and Trademark Office (USPTO) regulations require that the request have a signed certification and be conspicuous. The non-publication request may be rescinded at any time. If an application is subsequently filed in another country (or under an international agreement) that requires eighteen-month publication, the applicant must notify the USPTO within forty-five (45) days or the U.S. application will become abandoned.

If corresponding foreign applications have a less extensive description than the U.S. application, the applicant may submit a redacted copy of the application for publication that eliminates the subject matter not also contained in any of the corresponding foreign applications. Such a redacted copy must be submitted within sixteen months after the earliest filing date for which a benefit is sought under Title 35.

Published U.S. patent applications will be available on the USPTO's electronic search systems, but the USPTO will *not* maintain paper copy collections. In addition, an Official Gazette for published applications will *not* be available.

The content of a published application will be the content based on the application at the time of release to a USPTO Technology Center for examination. A preliminary amendment will not be a part of the published application, unless the application and the preliminary amendment are filed electronically. A CPA publication will reflect the prior application as filed.

The USPTO requires that each utility and plant application be in condition for publication when released to a Technology Center for examination. The specification must be of sufficient quality for optical character recognition conversion of the image to text. The title and abstract must be in compliance with 37 C.F.R. ' 1.72. The drawings must be of sufficient quality to readily use the patent application publication as a prior art document, under 37 C.F.R. ' 1.84. Finally, a sequence listing must be in compliance with 37 C.F.R. '' 1.821 *et seq.*

If an applicant wishes for a patent application to reflect the application as amended during examination or with preliminary amendments, the applicant must file a clean copy of the application, as amended, in compliance with the USPTO's electronic filing system. The application must be filed electronically before the later of one (1) month from the actual filing date, or fourteen (14) months from the filing date of the earliest application from which the application to be published claims priority benefit. An applicant must also file an electronic copy of an application if the applicant request voluntary publication of an application pending on November 29, 2000.

The USPTO will not honor a request (1) that publication occur on a specific date, (2) that two or more applications be published on the same day, or (3) that only a part of an application be published. If an applicant wishes for only part an application to be published, the applicant must electronically file a redacted version of the application.

2. General Risks and Benefits

Publication of U.S. patent applications will not have a major impact on whether an applicant files a patent application. Prior to the AIPA, most applicants typically filed foreign applications which published 18 months after the priority filing date. Generally, applicants filed

foreign applications unless the technology was of dubious value, or if the trade secret value of the application was high for the period of time during which the application was in prosecution. Most applicants had therefore already taken the risk of foreign publication into account for most of their filings. The fact that the US application will now also publish is not likely to change the decision too dramatically. The strategy of filing only in the U.S. in order to preserve possible patent rights without filing abroad so as to avoid publication altogether will still be available to applicants since, under such circumstances, the USPTO will not publish either. Such strategy is sometimes used the patentability of the invention is in doubt and the loss of trade secrecy due to publication without concomitant patent rights is too high.

The cases where a US application and a foreign application are filed and thus, the US application publishes do have one major difference from prior practice where only the foreign application published: Publication of U.S. applications halt secret U.S. prosecution. The adoption of the 20 year from filing patent term by the USPTO had already halted the proliferation of "submarine patents" but, prior to the AIPA, prosecution of all patent applications was still conducted in secret. This is no longer the case Under new rule 14(c)(2), the public can monitor when a continuing application is filed, and can monitor the prosecution of any published patent application.

Although the USPTO will not provide direct physical access to a pending published application, the Office will provide a copy of the file wrapper and contents of a published application, or a copy of any one or more specific papers in a file. *See* 37 C.F.R. ' 1.14(c)(2). Thus, under the AIPA, it is now possible to monitor a competitors' prosecution of a published patent application. This is a fundamental change in USPTO practice, and puts the U.S. on par with European Patent Office Practice. It is now possible, for the first time, to simultaneously monitor a competitor's patent prosecution in the two largest commercial markets in the world economy.

A drawback to publication for applicants but an advantage to potential infringers, is that the invention claimed in a continuing application is made public shortly after the continuing application is filed. An applicant may not wish for an infringer to know that a continuation application has been filed with claims that will cover the infringer's activity. Since the continuation application will be published, the infringer will be able to detect the applicant's prosecution activity long before a patent issues.

Prior to the AIPA, under 35 U.S.C. ' 135(b), one had one year from patent issuance to copy claims, and could later request an interference. Under amended section 135(b), if a competitor=s application publishes, one must copy claims within one year of the publication date of the application. This increases the burden on applicants (or potential applicants) to actively monitor published applications and to act much earlier than was required under the old statute.

It will be interesting to see if the filing of a new application for purposes of copying claims after the publication of a competitor's application will be considered "spurring," in analogy with past interference case law in which the new filing and copying of claims occurred after the issuance of another's patent.

3. Relevance to Biotechnological Applicants

a. Designing around

In general, the later in the patenting process that a competitor becomes aware of a patented product, the more difficult and the more expensive it will be for the competitor to design a noninfringing product. For biotechnological products, design changes typically require months to years to effect, and can cost tens of millions of dollars. Clearly, the sooner a competitor becomes aware of a product for which patent protection is sought, the sooner the competitor can begin the redesign process, and the less expensive the process will be. Thus, publication will accelerate the rate at which design changes and "invent around" can be effected by competitors.

b. Biological Deposits

For some bio-technologies, a biological deposit is required to meet the written description and/or enablement requirements of 35 U.S.C. ' 112, first paragraph. For example, if the patented technology is an isolated naturally occurring bacterium, a sample of the bacterium is normally deposited with an authorized depository, such as the American Type Culture Collection.

Prior to the AIPA, if a deposit was required it could not have been accessed by the public until after a patent had issued. Under AIPA, the public can still not obtain access to the deposited material until after a patent has issued. *See* 60 Patent, Trademark & Copyright Journal 1495: 661 (2000), which describes a report by the U.S. General Accounting Office ("GAO"), in which the GAO concluded that the new requirement for publication of pending U.S. patent applications does not require the concurrent release of an associated biological deposit. Since the public cannot obtain access to a deposited material until a patent issues, competitors cannot exploit the claimed technology prior to the time when a patent right has been awarded. However, competitors are also prevented from testing the operability of the invention, or comparing it with their own.

The U.S. approach to deposited materials differs from the approach under the European Patent Convention (EPC). If a patent application is filed under the EPC, deposited biological material is available to the public when the European application publishes. Rule 28 EPC provides that if a member of the public requests access to deposited material, the depositor can

request that only an independent expert be allowed access to the material during the period between publication of the application and the grant of the patent. After the patent has been granted, the deposited material is available to the public. If the application is abandoned or refused, then the deposited material is available to the public at the time of the abandonment or refusal. It may be worthwhile to consider such "expert solution" in the U.S. in order to address the issues of operability and comparability we have mentioned.

B. Provisional Patent Rights

1. Basic Provision

Prior to the AIPA, no patent right attached until the issue date of a patent. Under 35 U.S.C. ' 154(d)(1), a patentee now has the right to obtain a reasonable royalty from any person who makes, uses or sells in the U.S. the invention claimed in a published patent application, and this right begins when the U.S. patent application is published.

2. General Risks and Benefits

For the accused infringer to be liable, he must have had actual notice of the published patent application. *See* 35 U.S.C. ' 154(d)(1)(B). In addition, for the patentee to be able to benefit from this provision, the invention claimed in the issued patent must be substantially the same as the invention claimed in the published application. *See* 35 U.S.C. ' 154(d)(2). Thus, for a patentee to recover damages for activity by an infringer during the period between the application publication date and the patent issue date, an issued claim covering the infringer=s activity must have published.

This is distinct from the situation in which an infringer=s activity is detected after a patent application has published, and in which the published claims do not cover the infringer=s activities. In this scenario, if the application contains support for claims that cover the infringer=s activities, a continuation application could be filed and published with claims that do cover the infringer=s activity. Assuming that a claim issues from the published continuation application that covers the infringer=s activity, the provisional patent right would begin upon publication of the continuation application.

For international applications that are published by the International Bureau, provisional rights are afforded as of the date that a copy of the publication (or a copy of an English translation of the application, if the publication is not in English) must be filed at the PTO.

A drawback to the provisional patent right scheme is that it encourages filing a large variety of claims, in the hope that at least one commercially relevant claim will issue in the same form that is published. This results in increase drafting, prosecution and claim costs.

3. Relevance To Biotechnological Applicants

Companies which patent research tools (such as drug receptors or drug design software) may find the provisional patent right particularly important. It is always a question whether to seek patent protection for a research tool because research tool patents can be difficult to police. For example, consider a receptor that is useful for drug screening. Prior to the AIPA, prosecution of claims in a U.S. patent application that cover the receptor would have been carried out in secret. Meanwhile, corresponding foreign applications that disclose the receptor would have published. Competitors could have used the receptor in secret to discover compounds that bind to the receptor without any liability. By the time a U.S. patent issued that covered the receptor, the competitor might be finished using the receptor and there would be no infringement. Thus, in the period of time between publication of the foreign application and the issuance of the U.S. application, the applicant had no patent protection and no trade secret protection.

Under the AIPA, provisional protection is afforded to applicants in the form of a reasonable royalty. There is now more incentive to file for protection on such trade secrets.

C. Time For Making Priority/Continuity Claims

1. Basic Provision

Prior to the amendments of Chapter 37 C.F.R. that implemented the AIPA, applicants could file a claim to domestic or foreign priority at any point during prosecution, or in a reissue application. However, 37 C.F.R. ' 1.78(a) has been amended to require that a priority claim be filed "within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is *not extendable*." (Emphasis added.)

Thus, under amended rule 78, in every new application, including any continuing application or a continued prosecution application, if the applicant wishes to claim priority, he must claim priority within the time period specified in rule 78. An unintentional failure to claim priority in a timely fashion will require the applicant to petition the USPTO to accept an unintentionally delayed priority claim under 35 U.S.C. '' 120, 121 or 365(c). *See* 37 C.F.R. ' 1.78(a)(3).

Importantly, intentional failure to file a claim to priority *cannot* be cured. Thus, if a priority claim is not made in a timely manner, the ability to make a priority claim is waived.

2. General Risks and Benefits

Amended Rule 78 benefits the USPTO, and can operate to the detriment of an applicant who fails to file a claim to priority in a timely fashion, unless the applicant can show, in good faith, that failure to claim priority in a timely fashion was unintentional. Applicants and practitioners should be mindful that every new application, including a continued prosecution application falls under amended rule 78.

3. Relevance to Biotechnological Applicants

The amendment of Rule 98 forces an early decision on the risk/benefit of claiming priority to earlier applications. The claiming of priority back to earlier applications so as to overcome intervening prior art must be balanced by the loss of patent term. In biotech it is not always clear whether an earlier application may or may not inherently support a later claim, so early decisions will place an extra hurdle on applicants in our field.

The need to make an early decision about claiming priority back is also a disadvantage to any applicant who does not have a good understanding of the prior art. If an applicant discovers prior art after filing and it is too late to file a request for priority the consequences may be loss of patent protection. This requirement then will impose a new burden on applicants to carry out thorough prior art searches before filing so as to understand whether priority claiming will become an issue during prosecution. This need to search the prior art is compounded by the recent *Festo* decision where any amendment related to patentability – especially amendments to overcome prior art – results in an estoppel with no range of equivalents. Carefully drafting claims to overcome the prior art before filing has become a critical issue in the preparation and prosecution of applications.

D. Creation of ' 102(e) Prior Art By Publication

1. Basic Provision

Prior to the AIPA, only patents, not published applications, qualified as prior art under 35 U.S.C. ' 102(e). Under that section of the patent statute, the date on which an issued patent qualified as prior art was the earliest effective U.S. filing date.

Under the AIPA, published U.S. patent applications are afforded prior art status. A published U.S. patent application qualifies as prior art under 35 U.S.C. ' 102(e) as of its U.S. filing date. Thus, the ' 102(e) date of a U.S. patent that issues from a U.S. application filed after May 29, 2000 will be the same as the ' 102(e) date of the corresponding published U.S. application.

Unfortunately the statute is quite muddy with respect to the prior art effect of international applications that designate the U.S. We refer the reader to recent publications by commentators[1], and we note that both branches of the U.S. Congress are endeavoring to clarify section ' 102(e), with respect to international applications.

2. General Risks and Benefits

A clear benefit to an applicant is that, by publishing a patent application, she can create prior art against competitors, even if a U.S. patent never issues from that application. Creation of prior art by the publication mechanism can have significant strategic value. Naturally, a drawback for the applicant is that publication also creates prior art against the applicant.

3. Relevance to Biotechnological Applicants

Often in biotechnology a party wishes to prevent others from obtaining blocking patents. Such an applicant only wishes to assure her freedom to use an assay, or a drug screen, especially in the area of research tools. She does not need patent protection; all she needs is freedom to operate. Creating ' 102(e) prior to 18 months from filing is a good mechanism to create such "unblocking" prior art.

III. Patent Term Guarantee

A. Basic Provision

Prior to the AIPA, the patent term for an application filed after June 8, 1995 was calculated as twenty years from the earliest effective filing date to which the application claims priority. The twenty year term was not affected by prosecution delays caused by applicants or the USPTO.

[1] For example, see Eliseeva, M. Ariadne=s Thread in the AIPA Labyrinth,@ Intellectual Property Today, December, 2000, pp. 20-24.

Under new section 154(b)(3) of the patent statute, patent term can be adjusted, to take into account prosecution delays caused by the USPTO. The implementing USPTO rules are found at 37 C.F.R. ' 1.701 *et seq.*

B. General Risks And Benefits

Under this new rule, the USPTO is obligated to issue allowable claims within three years of the application filing date, providing that the applicant does not slow the process down during prosecution. In addition, the USPTO is obligated to accomplish certain examination tasks within defined periods of time. If the USPTO is late at accomplishing those tasks, the applicant is afforded an adjusted, extended patent term. For example, the USPTO must act on a new application within 14 months of the application filing date, must respond to an amendment within four months of the amendment filing date, and must issue a patent within four months of the date on which the issue fee is paid.

However, if the applicant is late at accomplishing certain tasks, he cannot recover any patent term. For example, any extensions of time for replying to USPTO communications that are taken by an applicant cannot be recovered. Thus, an applicant who habitually fails to reply to USPTO communications within the shortened periods for reply set by the USPTO will lose any term he may have gained from the USPTO's slowness.

C. Relevance To Biotechnological Applicants

Compared to other technologies, biotechnology is relatively unpredictable. If experimental data must be generated to overcome rejections by an examiner for lack of enablement or obviousness, it can take a great deal of time (sometimes longer than the statutory period of 6 months for responding to an office action) to generate the data and prepare a suitable declaration. Thus, biotechnological applicants are liable to suffer disproportionately more than applicants in other technologies by the shortened response periods.

IV. *Inter Partes* Reexamination

A. Basic Provision

Prior to the AIPA, a third party who requested reexamination of a patent could file a request for reexamination, but could not participate in the reexamination proceeding. The AIPA established an optional *inter partes* reexamination mechanism for patents that issue from applications filed after May 29, 2000. *See* 35 U.S.C. ' 311 *et seq*. The implementing USPTO

rules are found at 37 C.F.R. ' 1.903 *et seq*. In an *inter partes* reexamination proceeding, the third party can file written comments each time the patent owner files a response on the merits. *See* 37 C.F.R. ' 1.947.

B. General Risks And Benefits

1. Benefits To Third Party Requestor

The primary benefit to the third party requestor is that he can participate in the reexamination proceeding.

The reexamination mechanism is probably more helpful for third parties who find a previously unconsidered reference that clearly anticipates the patent claims. Such a reference could invalidate the claims or force the patentee to narrow its claims.

2. Risks To Third Party Requestor

One risk to the requestor is that the USPTO may not grant a request for reexamination. In that case, the patentee becomes aware of the third party, and the third party has gained nothing but the attention of the patentee.

Since the only ground for reexamination is new art that raises a substantial question of patentability, the third party cannot request reexamination based on art already considered by the USPTO, even if claims are invalid over that art. In addition, the third party cannot request reexamination based on section 112, first or second paragraphs.

If the third party requestor disagrees with the outcome of the reexamination proceeding, the requestor can appeal the decision to the USPTO Board of Patent Appeals and Interferences, but the requestor cannot appeal an adverse decision by the Board to a district court or to the Court of Appeals for the Federal Circuit. Since the third party requestor is bound by the outcome of the reexamination proceeding, in the request for reexamination, the requestor must raise each argument that can be raised.

C. Relevance To Biotechnological Applicants

Invalidity arguments based on section 112, first paragraph violations are very common in suits involving biotechnology patents. Under the *inter partes* reexamination rules, however, section 112 arguments cannot be raised. Thus, third parties who wish to request reexamination

of biotechnology patents will be disproportionately affected by the *inter partes* reexamination rules.

Another ground of invalidity that is often argued in suits involving biotechnology patents is inherent anticipation. Under the *inter partes* examination rules, if a prior art reference was considered by the examiner during prosecution in the context of novelty, a third party cannot raise the issue of inherent anticipation in a request for reexamination. It is therefore not clear whether the increased participation afforded under the AIPA will make reexamination by third parties in biotechnology more frequent than it has been in the past. Such requestors will still be prevented from raising some of the most common defenses to biotech patents, such as lack of enablement or of written description, and thus will continue waiting to raise these defenses as invalidity challenges in district court litigation.

V. Compliance With Requirements For Information

37 C.F.R. ' 1.56 sets forth the duty to disclose information that is material to patentability. 37 C.F.R. ' 1.97 relates to the timing of the filing of an information disclosure statement, and 37 C.F.R. ' 1.98 relates to the content of an information disclosure statement.

A. Citation Of Co-Pending Applications

1. Basic Provision

In order to make an Examiner aware of copending, commonly owned applications that may claim subject matter that would form the basis for an obviousness-type double patenting rejection, Applicants are well advised to cite copending, commonly owned patent applications that contain potentially relevant claims. An amendment of rule 98 is relevant to this. Old rule 98(a)(2)(iii) provided that "no copy of a U.S. patent application need be included . . . "However, amended rule 98(a)(2)(iii) requires that "[f]or each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion . . ." shall be included in an information statement filed under 37 C.F.R. ' 1.97.

2. General Risks and Benefits

The new provision of rule 98 benefits the USPTO because it reduces the amount of work an Examiner has to do. Instead of having to find the cited copending application, an Examiner is provided with the application by the applicant.

A potential risk for applicants is that failure to cite copending applications that contain claims that might support an obviousness-type double patenting rejection could create an opportunity for an infringement defendant to assert that the claims in an issued patent are invalid for obviousness-type double patenting and/or unenforceable for failure to cite material art.

3. Relevance to Biotechnological Applicants

Eventually, all prosecution and all filings (except as noted earlier those not filed abroad for strategic purposes) will be publicly accessible in the U.S. However, even those cases which are purposely not filed abroad so they will not publish anywhere, may find their way into the public domain via the copies submitted into the published prosecution of another application. Biotech applicants need to take this into account when following a strategy of filing only in the U.S. with the expectation of secrecy.

B. Third-Party Submissions In A Published Application

1. Basic Provision

Section 1 of Chapter 37 of the C.F.R. was amended to include new rule 99. Under 37 C.F.R. ' 1.99, a third party my submit patents and printed publications to the USPTO, but the USPTO will not allow any activity that amounts to a protest or an opposition by the third party. Thus, no discussion of the claimed invention is permitted. However, rule 99 does not prohibit the third party from marking a reference to highlight the most relevant portions of a reference.

Rule 99 provides that the third party must serve the applicant, that no more than ten references can be submitted at a time, and that the third party may not submit any references later than two months after publication of the application or the mailing of a notice of allowance.

2. General Risks and Benefits

Rule 99 can theoretically benefit a third party who submits references to the USPTO. However, rule 99 uses permissive language such that submitted information A*may be* entered in the application file." Thus, an examiner is not obligated to enter the submitted references into the application file.

In addition, there is risk that an Examiner may not be inclined to review the submitted references thoroughly, and thus may not recognize the relevance of the references.

If the examiner does consider the submitted references, but allows the claims anyway, a later attempt by the third party to invalidate the patent over the submitted references might not be

successful. An issued patent is presumed valid, and attempts to invalidate a patent over art that was previously considered by an examiner can be particularly difficult.

Finally, rule 99 requires that the third party make himself known to the applicant. Rule 99(c) requires that the third party serve the applicant with a copy of the submission. Thus, a competitor that might otherwise go unnoticed by the applicant risks having the applicant=s attention focused upon the competitor when the competitor files the submission under rule 99.

3. Relevance To Biotechnological Applicants

Biotechnological competitors stand to benefit less from rule 99 than persons in other areas of technology. Rule 99(b)(2) limits the type of information that can be submitted to Apatents or publications.@ In patent litigation accused infringers often challenge the validity of asserted patents on the basis of 35 U.S.C. ' 112, first paragraph, for lack of written description, lack of enablement, and/or failure to disclose the best mode. Arguments for unpatentability based on failure to comply with section 112, first paragraph, cannot be made under rule 99.

C. Requirements For Information

1. Basic Provision

37 C.F.R. ' 1.105 establishes that certain information must be provided to the USTPO upon request by an examiner. Under 37 C.F.R. ' 1.105(a), such information includes (1) relevant commercial databases known to an inventor that could be searched, (2) whether a search of the prior art was made, and if so, what was searched, (3) a copy of any document, by any of the inventors, that relates to the claimed invention, (4) a copy of any document that was used to draft the application, (5) a copy of any document that was used in the invention process, (6) where the invention is an improvement, identification of what is being improved, (7) and identification of any use of the claimed invention known to any of the inventors at the time the application was filed.

Failure to reply to an examiner=s request for such information can result in the abandonment of the patent application. *See* 37 C.F.R. ' 1.105(c).

2. General Risks And Benefits

Clearly, new rule 105 creates an additional layer of administrative burden for patent applicants and practitioners. If information that falls within one of the enumerated categories of

rule 105 is retained by applicants or practitioners, that information must be provided to the examiner upon request.

3. Relevance To Biotechnological Applicants

Rule 105 is neither more nor less relevant to biotechnological applicants than to other types of applicants. A risk for every applicant is that potentially damaging comments by inventors or practitioners may become part of the public record when the application is published. Inventors and practitioners should take care not to annotate documents that are generated during the preparation of an application.