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IP Strategies

Highlights on the Latest Patent Reform Bill

In the 1960s, there was a saying, "If the opposite of 'pro' is 'con' then the opposite of 'Progress' is 'Congress'!" However, when it comes to the recently advanced patent reform bill, nothing could be further from the truth.

In March 2011, by a nearly unanimous vote, the U.S. Senate passed a patent reform bill—"The America Invents Act." In that same month, a similar patent reform bill was introduced into the U.S. House of Representatives. Some of the key provisions of these bills—which for ease will be referred to as "the patent reform bill"—include:

- Transitioning the United States to a first-to-file system.
- Fee-setting authority for the United States Patent and Trademark Office ("USPTO").
- Significant improvements in pre-grant and post-grant third-party submissions.

Unlike most of the world, the United States is a "first-to-invent" jurisdiction. That is, in the United States patents are to be granted to the party who is first to invent the subject matter claimed in a patent. Thus, the United States has been somewhat out of step because it is not a "first-to-file" jurisdiction.

Further, there are proceedings before either the USPTO or the U.S. Courts known as "Interferences." The main issue in Interferences is who is the first to invent. In Interferences, the first to file is presumed to be the first to invent and accorded senior party status, with the other party, the junior party, bearing the burden of proving earlier invention. Typically the senior party prevails. Interference proceedings have been costly and a burden to patentees because they add an element of uncertainty.

By eliminating "first-to-invent," the patent reform bill seeks to put the United States in step with the rest of the world, as well as do away with a costly proceeding that provided uncertainty to patentees. However, a key feature of the patent reform bill is that a new administrative "derivation proceeding" is created to ensure that the first-to-file is a true inventor, and not merely a copier.

On fees, the current law does not enable the USPTO to have sufficient flexibility to assure that its revenues are commensurate with costs and that it can further modernize its operations. As a result, the USPTO suffers a serious backlog in examinations. The U.S. Commerce Department has reported that the fee-setting authority in the patent reform bill will contribute significantly to reducing patent pendency and hence reducing the backlog in examinations.

Most significantly, the patent reform bill proposes to allow third parties to weigh in on patent applications, akin to amicus briefs before U.S. Courts. In other countries or jurisdictions, such as before the European Patent Office, during prosecution, third parties may submit observations.

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Presently, in the United States, a third party has only a three-month period after publication to submit art, and not comment on it—at most, the third party may quote from the art, to demonstrate its relevance. As a result, there is really no effective pre-grant mechanism for the public to assist the USPTO. The patent reform bill seeks to bring the United States more in line with other countries that allow for pre-grant observations.

Currently, after a patent is granted, a third party may initiate reexamination proceedings before the USPTO. But, there have been some significant disadvantages to reexaminations, including the limited involvement of the Requester in ex parte reexaminations and limitations on the Requester in *inter partes* reexaminations. Most other jurisdictions allow for post-grant oppositions before the patent office, within a period of time after the grant (such as nine months).

Like the current law in other jurisdictions, the patent reform bill creates a "first window" post-grant opposition proceeding to help weed out patents that should not have been issued. The patent reform bill seeks to create a meaningful alternative to the very costly patent litigation option by establishing an adversarial *inter partes* review of granted patents by Administrative Patent Judges. It is believed that if enacted, the patent reform bill, especially by its post-grant opposition proceeding, will provide a faster, less costly alternative to civil litigation to challenge patents, and it will improve patent quality by reducing abusive challenges and eliminate invalid patents. The post-grant opposition proceedings proposed by the patent reform bill will bring the United States more in line with patent offices throughout the world.

When the patent reform bill is reviewed in comparison with patent laws in most major jurisdictions, the patent reform bill seems to primarily seek to bring the United States into line with the laws of most major jurisdictions. Hence the patent reform bill represents Congress making Progress, despite the slogan of the 1960s, and it is hoped that at least the key provisions discussed herein become law while this Congress is in session. ■

IP Experience in the Due Diligence Process More Important than Ever

The Federal Circuit has recently denied Abraxis Bioscience, Inc.'s ("Abraxis") bid for panel rehearing and rehearing *en banc* in its dispute with Navinta LLC ("Navinta").[1] The decision of the Court to deny rehearing in any form is important because the denial leaves unchanged the Court's decision from November 2010 regarding patent assignments.

The Federal Circuit's decision in *Abraxis Bioscience, Inc. v. Navinta LLC* in November 2010 dismissed Abraxis' claim for lack of standing after Navinta appealed a district court's judgment of direct and indirect infringement of Abraxis patents directed toward pain management drug products.[2] On appeal, the Federal Circuit dismissed the case without prejudice and vacated the district court's decision based on Abraxis' lack of standing. The Federal Circuit held that, as a matter of federal law, Abraxis lacked standing because it did not have legal title to the patents at the time the suit was brought.

Abraxis acquired title to the patents through a multitiered trail of assignments that began with an Asset Purchase Agreement between Abraxis and AstraZeneca. The two parties ultimately assembled and executed the assignments properly to convey the rights in the asserted patents from the original inventor and assignee to Abraxis, but this did not occur, said the Federal Circuit, until after the patent infringement suit had been filed.

The Federal Circuit carefully analyzed the specific language of the assignment documents and stated that, despite state law allowing transactions to be given legally binding retroactive effect, the after-suit assignment did not give Abraxis the legal title required for standing to bring a patent infringement suit. The opinion stated, "[A]lthough state law governs the interpretation of contracts generally…the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is

[1] *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 2009-1539, 2011 LEXIS 5006 (Fed. Cir. Mar. 14, 2011).

[2] *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359 (Fed. Cir. 2010).

intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law."[3]

The Federal Court's decision hinged on the language of the Asset Purchase Agreement, which stated that AstraZeneca "shall, or shall cause" the transfer of the patent rights to Abraxis. This language created only an expectancy interest and not an actual transfer until the subsequent assignment documents were executed. The Federal Circuit's decision is reminiscent of parts of the chain-of-title dispute that is currently under review by the U.S. Supreme Court in *Bd. of Trs. of Leland Standford Junior Univ. v. Roche Molecular Sys., Inc.*[4]

The bottom line considering this and previous Federal Circuit holdings is that there are unique situations to the transfer of patents that are governed by the law of the Federal Circuit and not state law. For this reason, an experienced IP attorney should be intimately involved in transactions that involve the transfer of patent rights. ■

[3] *Id*. at 1364.

[4] 583 F.3d 832 (Fed. Cir. 2009); *see* Vedder Price IP Strategies, December 2010.

Patent Application Drafting for International Prosecution: Practice Tips

Oral proceedings before the European Patent Office ("EPO") provide insight on patent application drafting for global prosecution.

There are several parts to a patent application: Title, Field of Invention, Background, Objects and/or Summary of Invention, Brief Description of Drawings, Detailed Description, Examples, Claims and Abstract. The Background sets up a problem previously existing in the art and provides a "sales pitch" for why the invention is patentable. The Objects and/or Summary of Invention should parallel the claims.

Ideally, the invention is presented as an advance and/or a solution, but it should not be stated that the invention must achieve a specific object (but rather that it is only advantageous to achieve the object). During a litigation, everything written in a patent application will be scrutinized and subject to interpretation.

A patent application can be compared to a funnel. The broadest part of the funnel is the broadest area of disclosure and includes the Background. Just as liquid flows down a funnel from the broadest part to an area slightly narrower, in a patent application, where prior art leaves off is the point at which claims may be granted. The tip of the funnel includes the actual experimentation and Examples. The goal is to have claims as filed and granted to have a scope that extends from the broad part of the funnel, i.e., just outside the prior art, to the narrow part, i.e., the Examples.

In the United States, a detailed description is a written description that enables the skilled artisan to make and use the claimed invention, and it sets forth the best mode known to inventors at the time of the invention.[1] It is advantageous to avoid statements that imply or state that something is a necessity in every instance of practicing the invention; this may then need to be recited in the claims to meet the written-description requirement.[2] For example, instead of reciting "the chemical formulation requires a heterocyclic amine," it is better to recite "the chemical formulation may include a heterocyclic amine."

The Examples describe how an invention was worked or can be worked. Any actual work that was done is written in past tense, and hypothetical work is written in present tense. A patent application does not need to have examples.[3] Enough examples should be included to comply with utility, written-description and enablement requirements, especially in an unpredictable art. If the art is "unpredictable" (for example, the treatment of cancer), then more examples endeavor to demonstrate in specification that both description and exemplification remove "unpredictability" as to the subject matter claimed.

In the United States, the Examples may be generalized from support claims; however, in Europe, the Examples may not be generalized from claim language. However, drawings and a Brief Description of Drawings may be relied upon as a

[1] 35 U.S.C. § 112, first paragraph.

[2] *Tronzo v. Biomet*, 156 F.3d 1158 (Fed. Cir. 1998).

[3] *In Re Meir Strahilevitz*, 668 F.2d 1229 (Fed. Cir. 1982).

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basis for claims. The recommended approach is to include any pertinent data from the examples in the Detailed Description, and to generalize in the Detailed Description from the Examples. For instance, if a specific vector is claimed, broader examples of vectors (such as plasmid or viral) may be disclosed in the Detailed Description and, then narrowed to more specific vectors (such as bacterial, yeast or adenoviral vectors), before being further narrowed to a specific vector in the Examples.

Sometimes a detailed disclosure may become repetitive; however, for countries with strict disclosure requirements (including many countries in Europe), various iterations of preferred embodiments may be helpful. For example, for an invention directed to diagnosing a disease via a qualitative and quantitative method, it may be advantageous to present both methods separately and repeat similarities to avoid any confusion.

For patent prosecution in China, Korea and Japan, data is required at the time of filing. A practitioner should consider such data prior to pursuing applications in these countries.

The Claims set forth the invention. Claims should be commensurate in scope with the disclosure. For each claim, there must be a description in the application that enables the skilled artisan to make and use the invention. The claims should be clear and concise, and consistent with the disclosure; they should also be consistent with that which the inventor believes to be his or her invention. Any claimed use (such as a method of treatment) should have evidence to support such use in the application.

When the patent application is sent to the client and inventors, the application should be marked as confidential and attorney-client and work product privileged. It may also be a good idea to remind the client and inventors that the application is provided only for purposes of discussion and that it is not for distribution or intended as a publication or offer for sale. This will prevent the triggering of any publication or on-sale bars. ■

Practice Tips:

1. Present the invention as a solution to a problem, but avoid admitting that anything in the invention is absolutely required.
2. Draft the application with a funnel in mind—broadly and narrowly—and claim from what is believed to be outside the prior art to the Examples.
3. Include examples with data in an unpredictable art or if prosecution is planned in countries in which data is required.
4. Include recitations from examples in the Detailed Disclosure in countries in which examples are not relied upon to generalize.
5. Remind the client and inventors that the patent application is confidential and privileged until filing.

NEWS FLASH—Implementation of Track I of Enhanced Examination Timing Control Initiative by the USPTO Postponed

The United States Patent and Trademark Office has postponed the start date of the Track I prioritized patent examination program. The program was scheduled for implementation on May 4, 2011. The postponement is a result of the current federal budget issues and due to the reduced spending authority in the Full-Year Continuing Appropriations Act, 2011. David Kappos, Under Secretary of Commerce for Intellectual Property and Director of the USPTO, stated, "Without the resources to hire a sufficient number of examiners to implement Track One, we must postpone the effective date of the program until we are in a position to implement it successfully while ensuring there will be no adverse impact on non-prioritized examination applications."[1] A new start date for the program will be announced as soon as circumstances permit.

The Track I portion of the Enhanced Examination Timing Control Initiative was planned to take effect

[1] *USPTO Postpones Effective Date of "Track One" Fast-Track Patent Processing*, Press Release 11-30, Apr. 27, 2011, *available at* http://www.uspto.gov/news/pr/2011/11-30.jsp.

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on May 4, 2011. The program will be available for any original utility or plant application. The proposed changes to the Code of Federal Regulations were published in the Federal Register on February 4, 2011,[2] and comments by the public were solicited. On April 4, 2011, the USPTO published the final rule regarding the program.[3] The Track I portion provides for expedited examination to be conducted within 12 months for certain patent applications for an additional fee of US $4,000. The current wait time from the filing of a patent application to the first Office Action is 24.5 months.[4]

The original Initiative proposed a three-track system through which an applicant could either (Track I) submit a fee and receive prioritized examination, (Track II) obtain examination under the current procedure or (Track III), for non-continuing applications, request a delay lasting up to 30 months before examination. With the release of the final rule, the USPTO will implement the Track I portion of the Initiative.

The final rule outlines the procedure for obtaining prioritized examination of electronically filed original utility or plant nonprovisional applications filed under 35 U.S.C. § 111(a). For a fee of $4,000, an applicant would obtain prioritized examination of a patent application, with the USPTO's goal being to reach final disposition of the application within 12 months from the grant of prioritized status. Final disposition under the program is considered to be:

1. Mailing of a notice of allowance,
2. Mailing of a final Office Action,
3. Filing of a notice of appeal,
4. Declaration of an interference by the Board of Patent Appeals and Interferences (the "BPAI"),
5. Filing of a Request for Continued Examination ("RCE"), or
6. Abandonment of the application.

The program has other limitations and aspects that an applicant should consider before reaching a decision to participate in the program. The program is limited to applications containing no more than four independent claims, no more than 30 total claims, and no multiple dependent claims. An applicant is not prevented from using extensions of time or restricted to a period for reply when in the program; however, the prioritized examination of the application will be terminated if such a petition for extension of time is filed by the applicant. Further, prioritized examination will only be available for applications filed on or after the date of implementation of the program and will not be available for reissue applications.

The USPTO has also stressed that the 12-month goal for final disposition of an application is only just that: a goal. The Office has specifically stated that if a particular application does not meet the 12-month goal, the applicant will not receive a refund of the fee for requesting prioritized examination. Similarly, no refund will be made to an applicant that decides to change the status of an application or to an applicant that has its prioritized status terminated due to the filing of a petition for extension of time, for example.

In the first year of the program, the USPTO will accept only the first 10,000 requests for prioritized applications in order to gain experience with the program. ■

Practice Tips:

1. Review your patent portfolio to determine if this program can be used to reach your business goals, given the shortened time frame and added cost.
2. If you are planning on filing an application, determine if it is worth waiting until the program is implemented.
3. Possible reasons to use prioritized examination: (i) known infringement, (ii) licensing opportunities and (iii) competitive advantages.
4. Consider the scope of the claims of the patent application at issue. The program terminates upon the filing of an RCE, so the scope of the claims should lend itself to shortened prosecution.

[2] Changes to Implement the Prioritized Examination Track, 76 Fed. Reg. 6,369 (Feb. 4, 2011).

[3] Changes to Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures, 76 Fed. Reg. 18,399 (Apr. 4, 2011).

[4] *See* USPTO Data Visualization Center, *available at http://www.uspto.gov/dashboards/patents/main.dashxml*.

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