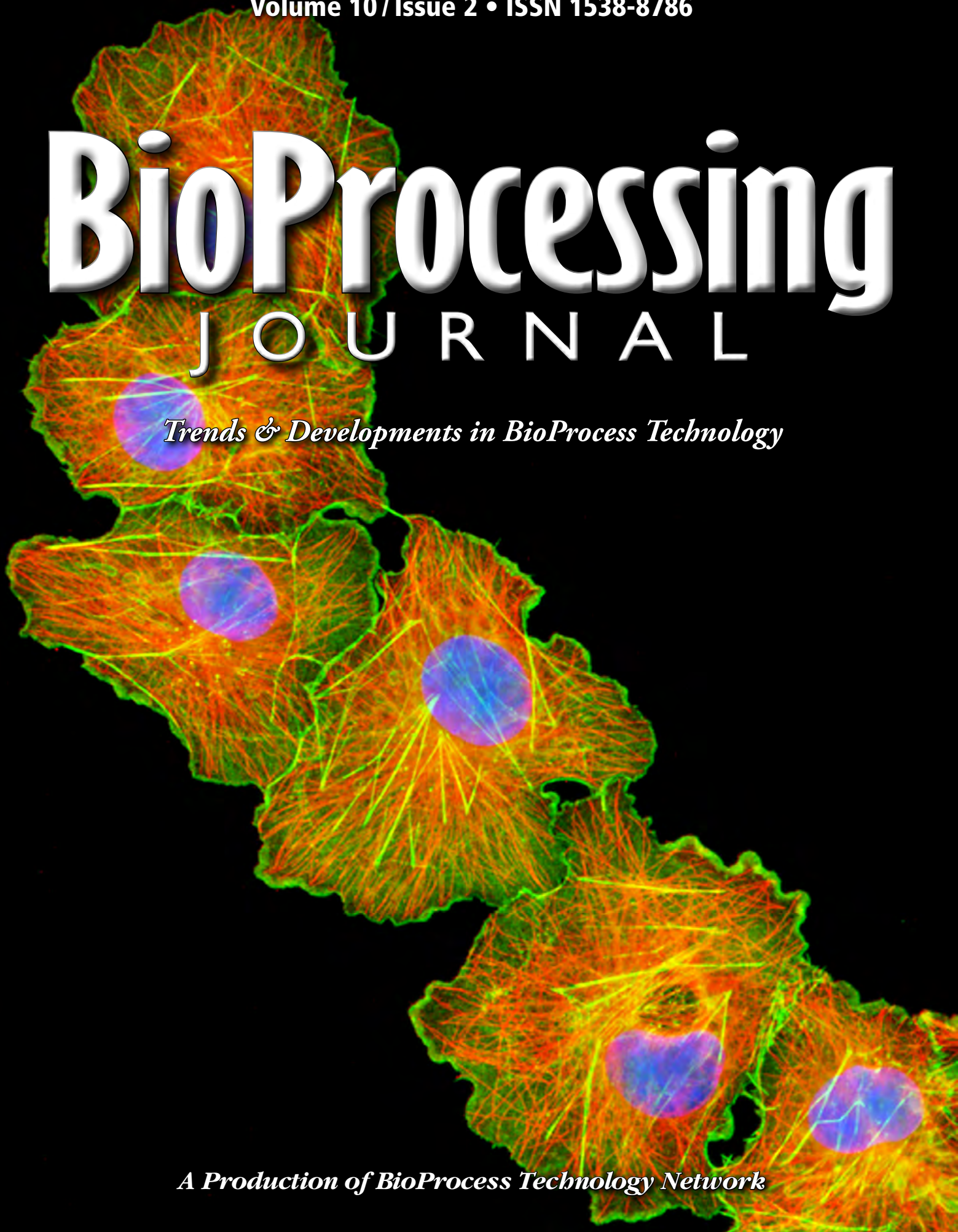
Volume 10 / Issue 2 • ISSN 1538-8786

BioProcessing JOURNAL

Trends & Developments in BioProcess Technology



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BioProcessing JOURNAL
TRENDS & DEVELOPMENTS IN BIOPROCESS TECHNOLOGY

Recent Statutes, Regulations, and Court Cases Affecting Intellectual Property Rights of Life Sciences Institutions:

Key Provisions of the Leahy-Smith America Invents Act and the Biologics Price Competition and Innovation Act

The First of a Three-Part Series

Analysis of the Leahy-Smith America Invents Act

By VERNE A. LUCKOW

Government policies affecting intellectual property rights and the review of food and health care products dramatically influence investments in research leading to the development and sale of products that serve unmet medical needs or provide consumers with safe sources of food and drug products at a low cost. When statutes that affect several regulatory agencies are revised within a short time period, institutions that rely on exclusive rights offered by those agencies in exchange for obligations of disclosure and compliance must alter their business plans to adjust to new rules leading to the benefit conferred by the government. In 2011, the Leahy-Smith America Invents Act (AIA) was passed, changing many aspects of the federal statutes relating to the United States Patent and Trademark Office (PTO), and in 2010, the Patient Protection and Affordable Care Act (PPACA) was passed, which included the Biologics Price Competition and Innovation Act (BPCIA), requiring the United States Food and Drug Administration (FDA) to establish an abbreviated regulatory approval pathway for complex macromolecules produced in living cells or organisms. This series of articles briefly reviews key aspects of the AIA and the BPCIA, plus recent court cases relating to complementary periods of exclusivity offered by the FDA and the PTO, which should be of great interest to academic and corporate institutions having an interest in the life sciences. Important aspects of the AIA will be discussed in the first article in this series.

Introduction

New statutes, regulations, and court cases often change the economic incentives driving investments by companies, universities, and research foundations in technologies leading to the discovery and development of pharmaceutical products, medical devices, diagnostics, and agricultural products. As a result, many business strategies, which are based on expectations of stable markets and regulatory policies, are often in flux as provisions of new laws become effective on different dates after a statute is signed, and regulations interpreting the statute are implemented by the appropriate regulatory agency.

Two recently-enacted statutes will fundamentally alter the business strategies and investment patterns of many institutions involved in projects relating to the life sciences for many years. The Leahy-Smith America Invents Act of 2011 provides a transition from a "First-to-Invent" (FTI) system to a "First-Inventor-to-File" (FITF) system, and significantly alters United States Patent and Trademark Office policies relating to the filing, prosecution, and review of patents.[1] The Biologics Price Competition and Innovation Act of 2009 established an abbreviated regulatory approval pathway through the Food and Drug Administration for macromolecules (*e.g.*, biologics) produced in living cells or organisms.[2]

The AIA will force many institutions to review and revise their technical, legal, and business plans. Intellectual property strategies based on patent statutes last revised in

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a major way in 1952, for example, will need to be altered to accommodate new provisions linking inventorship priority with the filing date of an application, accelerated examination, adjustments to the term of a patent for delays which occur during prosecution, and procedures for post-grant review of patents. It also allowed the PTO to raise fees for many services.

The BPCIA implements many new provisions relating to the abbreviated review and approval of applications for biopharmaceutical products. Three major issues are addressed in the BPCIA:

1) instructing the FDA to establish formal guidelines for evaluating the similarity, bioequivalence, and immunogenicity of reference and follow-on macromolecules, commonly called follow-on biologics (FOBs);

2) establishing procedures for the sponsor of a reference macromolecule and the sponsor of an FOB to use in exchanging patent and regulatory information between each other, the FDA, and federal court systems; and

3) establishing periods of data and market exclusivity for reference macromolecules, regardless of patent protection, that reflect more complex methods needed to discover, characterize, and manufacture macromolecules compared to small chemicals.

While some aspects of this abbreviated review process are similar to the well-established schemes used to regulate the review and approval of small molecule drug products under statutes and regulations commonly known as the Hatch-Waxman Act,[3] many provisions are different, requiring new strategies for the sponsors of reference molecules and the sponsors of FOBs to be developed. Litigation strategies, in particular, will require creative solutions, as several terms used in provisions of the BPCIA appear to be undefined or ambiguous, or otherwise left up to the FDA to clarify and publish in guidelines for the pharmaceutical and biotechnology industries, which are expected to be released for review in early 2012.

Court decisions can also have a dramatic effect, particularly when an agency like the PTO or the FDA is ordered to revise or put into effect new procedures regarding the acceptance, review, and approval of patent applications or new drug applications. Decisions affecting the term of a utility patent, which protect products and processes in many technology areas, are often of great interest. Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010),[4] for example, forced the PTO to respond to over 30,000 requests for larger patent term adjustments (PTAs) due to an error in interpreting a provision in a statute relating to the calculation of adjustments involving overlapping periods of agency delay. A comprehensive evaluation of court cases relating to patent term adjustments was published recently by Luckow and Balsarotti.[5]

Requests to adjust or extend the term of a patent, and requests to alter periods of regulatory exclusivity which complement the term of a patent, in view of new regulations or court decisions, are always examined carefully for their impact on the perceived value and the investment required to support intellectual property portfolios protecting a new product or process. These issues drive not only the strategies of innovative reference products sponsors, but also the strategies of sponsors of generic or follow-on products that are introduced into the market after the expiration of a patent or the regulatory exclusivity period protecting a reference product.
In this three-part series, I will briefly describe provisions of the AIA and the BPCIA, and several recent court cases that will have a dramatic effect on academic and corporate institutions having a strong interest in the life sciences. This first article will address key provisions of the AIA affecting life sciences institutions. The second and third articles will address: a) issues in the BPCIA relating to evaluation of similarity, bioequivalence, and immunogenicity of reference and follow-on macromolecules; plus b) several related legal topics: i) legal issues relating to the exchange of information between the sponsors of reference and follow-on molecules, regulatory agencies, and the courts; ii) issues relating to data and market exclusivity periods for small molecules and macromolecules; and iii) recent court cases relating to patent term adjustments and patent term extensions that are often viewed with great interest by the sponsors of small molecule and FOB drug products.

Major Provisions of the AIA Affecting Institutions with an Interest in the Life Sciences

Like many statutes, the patent reform measures included in the AIA represent a compromise between many competing interests. Large corporations, academic institutions, and professional organizations representing many small and large entities all lobbied for provisions linking the cost of filing and maintaining a patent to entity size. Organizations representing industries with products having a long economic life, like pharmaceuticals, and those representing industries with products having a short economic life, like hardware and software, all had their influence in lobbying Congress to include or exclude provisions which affect their interests. The AIA also has provisions giving the PTO greater control over the setting of fees, offering flexibility in implementing new programs designed to facilitate the filing and accelerate the examination of new patent applications. Many of the reforms are quite dramatic, and while a complete analysis is beyond the scope of this article, several provisions of the AIA will certainly influence the technical, legal, and business strategies of institutions having an interest in the life sciences.

President Barack Obama signing the America Invents Act on September 16, 2011 at Thomas Jefferson High School for Science and Technology in Alexandria, Virginia.
(Photo is posted on the PTO website, http://www.uspto.gov/aia_implementation/index.jsp.)

Conversion from a First-to-Invent to a First-Inventor-to-File System

Section 3 of the AIA sets forth provisions amending a variety of sections in the patent statute relating to conditions for patentability of an invention, particularly 35 USC § 102 relating to novelty. Inquiries on inventorship shift away from determining the earliest conception date, followed by diligence in reducing the concept to practice, to an inquiry based primarily on the filing date of an application filed by an inventor of the claimed subject matter. Congress provided two reasons for the transition to a First-Inventor-to-File system:

1) It would provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

2) The FITF system will improve the United States patent system and promote harmonization with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.[6]

While these reasons are still being debated by many patent practitioners and economists, the practical effect of the AIA is to change many well-established policies and practices before the PTO.

The new FITF system, which is not the same as the First-to-File system used in the rest of the world, will never-the-less stimulate the filing of patent applications, and eventually reduce the number of rare, but typically complex and expensive priority contests known as interference proceedings. Under the new FITF system, the scope of prior art is expanded such that there is now no distinction between acts that occur in the United States and acts that occur in a foreign country.

Under the new 35 USC § 102(a)(1), the "claimed invention," which is defined as being the subject matter defined by a claim in a patent or an application, must not be patented, described in a printed publication, in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.[7]

Under the new 35 USC § 102(a)(2), a person will not be entitled to a patent if the "claimed invention" was described in a patent issued under 35 USC § 151 or in an application for a patent published or deemed published under 35 USC § 122(b) in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention. This second provision will likely be interpreted as a patent document that has a different list of inventors and will be considered as prior art as of its effective filing date (defined in 35 USC § 100(i)(1) as (a) the actual filing date of the patent or the application for the patent containing a claim to the invention; or (b) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under § 119, 365(a), or 365(b)), if it is before the effective filing date of the claimed invention. Many foreign patent documents, therefore, will be considered prior art back to the earliest effective filing date of such applications, and not just their actual filing date. For a PCT application, its international filing date is considered as the actual filing date.

Several important exceptions to these provisions are provided under the new 35 USC § 102(b). Disclosures made one year or less before the effective filing date of a claimed invention will not be prior art if the disclosure was made by the inventor or a joint inventor or by another who obtained the subject matter directly or indirectly

from the inventor or a joint inventor.[8] Other exceptions creating a one year grace period also apply. These include disclosures described in an issued patent or published application which names another that was effectively filed before the effective filing date of the claimed invention, and disclosures where the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.[9] These provisions mean that an applicant can no longer antedate prior art (argue earlier conception and reduction to practice) that was published by a third party prior to the effective filing date for an application claiming the invention. One way to overcome this, however, is to argue that the third party derived their subject matter from the applicant. The new provisions also provide an incentive to file applications early in the grace period to eliminate as many other public disclosures or patent documents that occur after the first public disclosure by the inventor or joint inventors of a claimed invention.

The new challenge for institutions having a strong interest in the life sciences is deciding when and how often to file new applications. Filing early in the development of a new technology will help preserve rights if other parties have an active program and are likely to file patents in the same technology area. Early filing, however, often limits a disclosure with respect to the identification and characterization of preferred compounds that are worthy of preclinical development, for example, that under the FTI scheme would be included in large applications that also disclose optimal methods of synthesis, proposed methods of use, and perhaps preferred formulations and modes of administration in clinical settings. Under the FITF scheme, a continuous series of applications may be needed, larger in number than used in the FTI scheme, to ensure that an applicant has adequate, enabling support for the claimed invention before the effective filing date of an application filed by a competitor.

The effective date of the new FITF provisions is 18 months after the date of the enactment of the AIA. As a result, many applicants will need to assess whether they will be better off by filing applications before this effective date, that will provide benefits based on priority of inventorship offered under the FTI scheme, or filing after the effective date, that will provide benefits based on priority of filing by inventors offered under the FITF scheme. Other amended or new provisions offered under the AIA which take effect on different dates will also need to be considered before filing applications under the FTI or FITF schemes. The exact boundaries of the FITF provisions may take years to appreciate and resolve, however, through litigation and new regulations.

Inter Partes Review and Post-Grant Review Proceedings

Another key aspect of the AIA revises provisions relating to proceedings before the PTO that are initiated by a party seeking to challenge the validity of a granted patent. Under the old scheme, a third party can request a reexamination proceeding and assert that a patent is invalid over one or more prior art publications or patents. Assertions that a patent does not meet the written description or enablement requirements, or that one or more claims are indefinite, are not permitted in reexamination proceedings. Requests can be filed in two ways, as an *inter partes* proceeding, with the challenger playing an active role, or as an *ex parte* proceeding, with the challenger not playing a formal, active role after the request is filed. The AIA does not change provisions relating to *ex parte* proceedings, but alters the provisions relating to *inter partes* proceedings, and introduces new, complementary provisions relating to post-grant review proceedings, which are similar in many respects to opposition proceedings used by many foreign countries and regional patent authorities.

Section 6 of the AIA amends 35 USC §§ 311–319 to *revise* provisions relating to *inter partes* review of a patent. Under the new scheme, *inter partes* review (IPR), which replaces *inter partes* reexamination proceedings (IPRP), will be limited to patents that have been issued for at least nine months with the review completed in less than a year (extendible by six months for good cause). IPR is not available if more than a year has passed since a challenger has been served with a complaint alleging infringement, or if the challenger filed a lawsuit contesting validity of the patent. Many of the altered provisions relate to conduct of the parties and the PTO including the content, timing, and exchange of documents, and issues relating to civil actions before a federal court or the International Trade Commission. In an *inter partes* review, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence, compared to a looser standard of whether an examiner would merely consider an assertion to be important in determining whether at least one claim is patentable. The effective date of the amended IPR provisions is one year after the date of the enactment of the AIA.

Section 6 of the AIA amends 35 USC §§ 321–329 to *add* provisions relating to post-grant review (PGR) which parallel many of the provisions that relate to IPR. Unlike IPR, PGR allows any party other than the owner of the patent to challenge the validity of a patent for any reason, including issues relating to enablement, written description, and definiteness of the claims. The PGR process is limited to newly-issued patents, and petitions for a PGR must be

filed no later than the date that is nine months after the date of the grant of the patent or the issuance of a reissue patent. The petition must identify all of the real parties in interest, identify in writing and with particularly each claim challenged, the grounds on which the challenge to each claim is based, and evidence that supports the grounds for the challenge to each claim. Documents relied upon in the petition, such as patent documents and affidavits, other information required by the PTO, and the appropriate fee, must be included with the petition.

Many of the new PGR provisions, like IPR provisions, relate to the conduct of the parties and the PTO, including the content, timing, and exchange of documents, and issues relating to civil actions before a federal court or the International Trade Commission. The PTO will bar PGR requests, however, if a petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent. If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for a post grant review of the patent, the civil action shall be automatically stayed, until either: a) the patent owner moves the court to lift the stay; b) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or c) the petitioner or real party in interest moves the court to dismiss the civil action. A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent in a PGR proceeding. In a post-grant review, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence. The effective date of the new PGR provisions is one year after the date of the enactment of the AIA.

Prioritized Examination

The AIA provides applicants with a new option to elect accelerated examination as part of an initiative designed to offer applicants greater control over the timing and speed with which their applications are examined, and to provide the PTO with flexibility to apply its resources to better meet the needs of innovators. The original proposal, published in June 2010, offered a multi-track examination process which would have provided applicants with the ability to elect: 1) accelerated; 2) default; or 3) deferred examination of applications. By deferring, an applicant would better balance the timing and budget needs with resources available in the PTO to search, examine, and issue high quality patents. Budget cuts in April 2011, and concerns about the deferred examination process, forced the PTO to suspend aspects of the initiative until sufficient funding for the initiative was provided by the AIA.

On September 23, 2011, the PTO published a notice in the Federal Register entitled "Changes To Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures Under the Leahy-Smith America Invents Act" (final rule) stating that PTO would begin to accept requests for prioritized examination on September 26, 2011. Track I provides two major pendency goals: 1) first office action on the merits within four months; and 2) final disposition within 12 months of prioritized status being granted. Under Track II (traditional examination), pendency varies by technology center and the complexity of subject matter being examined. In 2009, pendency to first office action varied between 21–33 months, and 30–48 months to final disposition. Under the initiative, the goal is to reduce these amounts to ten months to first office action and 20 months to final disposition. Key aspects of the new procedures are summarized below:

1) The application must be a new original utility or plant nonprovisional application filed under 35 USC § 111(a) on or after September 26, 2011, is complete, and must be filed via the PTO's electronic filing system (EFS-Web) if it is a utility application.

2) A compliant certification and request form and an executed oath or declaration under 37 CFR 1.63 must be filed with the application.

3) The application must contain no more than four independent claims, no more than 30 total claims, and not contain any multiple dependent claims.

4) The following fees in amounts consistent with the current fee schedule are filed with the application: a) basic filing fee; b) search fee; c) examination fee; d) any required excess claims fees; e) any required application size fee; f) publication fee set forth in 37 CFR 1.18(d); g) processing fee (Track I) set forth in 37 CFR 1.17(i); and h) prioritized examination fee (Track I) set forth in 37 CFR 1.17(c).

Typical PTO fees for filing a utility examination for a large entity would be $6,480, which also includes filing fees of $1,250, a $130 processing fee, a $300 publication fee, and a $4,800 prioritized examination fee. Typical PTO fees for filing a utility examination for a small entity would be $3,360, which also includes filing fees of $530, a $130 processing fee, a $300 publication fee, and a $2,400 prioritized examination fee.

Under prioritized examination, the application will be placed on a special docket until a final disposition is reached, with an aggregate goal of disposition within 12 months of prioritized status being granted. Final disposition means: 1) mailing of a notice of allowance; 2) mailing of a final office action; 3) declaration of an interference by the Board of Patent Appeals and Interferences (renamed under the AIA as the Patent Trial

and Appeal Board); 4) filing a request for continued examination (RCE); or 5) abandonment of the application within 12 months of the date prioritized status has been granted. Shortened statutory periods for responding to office actions will apply, but: 1) filing of a petition to request an extension of time; 2) a suspension of action; 3) an amendment which results in more than four independent claims or 30 total claims; or 4) a multiple dependent claim will terminate prioritized examination.

Institutions with interests in the life sciences should consider accelerated examination under the new rules described above to facilitate the rapid evaluation and examination of new utility and plant applications. The opportunity to have an enforceable patent in about a year, as compared to three or more using the traditional examination queue, is a *valuable right*, that will often far exceed the higher initial cost of prioritized examination after taking into account filing fees and legal services that can be recovered from licensees, investors, and competitors, where the enforceable term of patent is much longer, and its perceived value of a patent is much larger.

Required Study on Genetic Testing

Section 27 of the AIA orders the Director of the PTO to conduct a study and deliver a report not later than nine months after the effective date of the AIA on "effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist." The study is required to address the following issues:

1) the impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;

2) the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

3) the impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine including but not limited to the interpretation of testing results and performance of testing procedures; and

4) the role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

The report should be of great interest to many pharmaceutical and biotechnology companies with an interest in clinical testing. Many universities and reagent supply companies that develop and optimize protocols for genetic testing in research settings should also be interested, as they often provide core technologies that are licensed to, or provide inspiration for, companies that provide diagnostic testing services as a commercial service.

Conclusions

The Leahy-Smith America Invents Act alters many provisions of the patent statute that were, for the most part, unchanged in over 50 years. As a result, many inventors, their employers, and legal counsel will face new challenges as they interpret amended or new provisions of the statute and regulations put in place by the PTO when developing business plans to protect and enforce patents relating to new products and services. Key aspects of the AIA that will dramatically influence patent filing and litigation strategies for institutions having an interest in the life sciences include: 1) the transition to a First-Inventor-to-File system; 2) amended procedures with respect to *inter partes* reexamination proceedings; 3) new procedures for post-grant review of newly-issued patents; and 4) the ability to request prioritized examination of a new application upon payment of a large fee, which should result in disposition, preferably issuance, in about a year. Many other provisions of the AIA influence administrative aspects of the PTO, and require the agency to participate in studies concerning the consequences of litigation by non-practicing entities, the diversity of applicants, and diagnostic testing using genetic material. It will take years to implement and understand all aspects of the AIA that will influence technical, legal, and business strategies leading to the discovery, development and sale of new products and services.

Parts 2 and 3 of this series will address how provisions of the AIA and the BPCIA interact, particularly with respect to intellectual property and regulatory strategies used by the sponsors of reference macromolecules and those used by the sponsors of follow-on-biologics.

REFERENCES (PART 1 OF THE SERIES)

[1] Biologics Price Competition and Innovation Act (BPCIA) of 2009, incorporated into the Patient Protection and Affordable Care Act (PPACA), Public Law No: 111–148, signed on March 23, 2010, available at http://www.govtrack.us/congress/bill.xpd?bill=h111-3590.

[2] Leahy-Smith America Invents Act (AIA), commonly known as the "Patent Reform Act" of 2011 (Pub.L. 112–29, H.R. 1249), signed on September 16, 2011, available at http://www.govtrack.us/congress/billtext.xpd?bill=h112-1249.

[3] Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98–417, 98 Stat 1585 (the "Hatch-Waxman Act", Title II of which is codified in part at 35 USC § 156).

[4] Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010), affirming the decision in Wyeth v. Dudas (580 F. Supp. 2d 138 (D.D.C. 2008).

[5] Luckow VA and Balsarotti SC. Statistical analysis of federal district court cases seeking longer patent term adjustments in the wake of Wyeth v. Kappos. *J Marshall Rev Intell Prop L*, 2010, 10: 1–94, available at http://www.jmripl.com.

[6] AIA § 3. First Inventor to File, §§ 3(o) and 3(p), Sense of Congress.

[7] 35 USC § 102(a)(1) under the AIA, where FITF provisions are effective 18 months from effective date of the AIA.

[8] 35 USC § 102(b)(1) (A) and (B) under the AIA.

[9] 35 USC § 102(b)(2) (A), (B) and (C) under the AIA.