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Navigating the Sea Changes in Patent Law to Successfully Build Value

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Abstract: Major changes in U.S. patent law are having an impact on the value of patents. The Leahy-Smith America Invents Act (AIA) introduced numerous changes to U.S. patent law including the switch to a first to file patent system from a first to invent patent system. New proceedings at the U.S. Patent and Trademark Office to challenge the grant of issued patents have produced quick results and emerging trends. Recent U.S. Supreme Court decisions have changed the threshold determination of patentability under 35 U.S.C. § 101, altering the patentability standards for biotech/pharma inventions, as well as computer/business method inventions. In Europe, the framework for an emerging unitary patent system, expected to be implemented by mid-2016, will add complexity to strategic patent planning for that region. This article will review these changes, discuss trends and provide strategies to build a patent portfolio with valid and enforceable patent claims as a foundation to withstand patentability and validity challenges.

Keywords: America Invents Act (AIA), Biotech/pharma, European unitary patent, Intellectual property (IP), Inventions, patents, Patent trial and appeal board (PTAB), Patentability.

INTRODUCTION

In recent years, there have been major changes in U.S. and European patent law, impacting the ability to obtain, defend, and enforce patents. The Leahy-Smith America Invents Act (AIA), enacted on September 16, 2011, introduced numerous changes to U.S. patent law [1]. One major aspect, implemented on March 16, 2013, changed the U.S. to a first to file system from a first to invent system, with the first inventor to file an application at the U.S. Patent and Trademark Office (USPTO) being awarded the patent. Another major change was the creation of new proceedings at the USPTO to challenge the grant of issued patents. Now that these changes have been in effect for a few years, emerging trends and results provide the basis for practical tips to build value and strong patent portfolios. On the near-term horizon in Europe, the framework for a new unitary patent system [2] is being created that will add complexity to strategic patent planning for that region for at least the next decade. These developing patent law issues provide an opportunity to evaluate the effects of key changes, highlight recent outcomes, and discuss options for protecting your business interests. First, we provide an overview of intellectual property.

WHY DOES INTELLECTUAL PROPERTY MATTER?

Intellectual property (IP) is an important contributor to the value of a company in the biotechnology, pharmaceutical and health care industries. IP comprises the knowledge, products, processes, innovations and brands that give individuals and companies a competitive advantage. The types of intellectual property include patents, trademarks, copyrights, trade secrets and trade dress. IP rights are valuable assets that can be monetized through their sale, licensing exclusively or non-exclusively to generate income streams, or as collateral to secure financing.

Start up and early stage companies, universities and technology transfer centers tend to focus first on developing a patent portfolio, but the other types of IP may become relevant as the invention is developed and marketed. When a product is going to be sold, it is important to register the trademark in the countries where the product will be marketed. Trademarks are identifiers of brands and their sources, giving the owner the right to prevent others from using a word, name, symbol or device, or combination thereof, that is likely to cause confusion in the marketplace as to the source of a product or service and damage the trademark owner's goodwill in his business. The look and feel of products, packaging or places of business are considered trade dress and can be protected. Copyrights give their owners the right to prevent copying original works of authorship, which can include computer software, source codes, product manuals and company websites. Since patents are published, there may be competitive reasons to keep, for example, a manufacturing process secret as a trade secret. Trade secrets must have commercial value and must be kept secret from third parties. Once a trade secret is disclosed, it is lost forever.

WHY FOCUS FIRST ON PATENTS?

Patents protect new and useful inventions by giving their owners the right to exclude others from making, using, selling or offering to sell the patented invention for a limited period of time. In the United States and in most countries, the term of a patent is twenty years from the date of filing of the patent application. This limited period of exclusivity gives the owners of the invention an opportunity to recoup their investment and financially benefit from their invention if it is successful in the marketplace. In exchange for being given these patent rights, inventors and owners of the invention disclose the information necessary to educate the

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public about the invention, thereby facilitating further innovation, all of which benefits society.

Patent rights are important for early stage companies on several levels:

- Face Value Level of Patents
  - Create a competitive edge with new and improved technological innovations
  - Prevent competitors from unauthorized use/sale of your innovations
  - Generate licensing revenue from others who wish to use your technology
- Strategic Level of Patents
  - Dissuade potential competitors from attempting to enter your market
  - Use defensively if faced with threat of infringement of another's patent
- Business Level of Patents
  - Patents are an asset of the company and can have value beyond the company's core business
  - IP is an important factor in the valuation of a company
  - For some technologies, patents are key to the deal
- Public Relations Level of Patents
  - Can promote products as being "*patented*" (independent recognition of innovation)
  - Being named as an inventor on a patent is a significant achievement

WHY ARE ASSIGNMENTS OF PATENTS IMPORTANT?

Proper assignments of the invention from the inventors to the company or university are needed to ensure all transferred IP rights can be sold or used as collateral to secure financing. If the invention was acquired from another party, any purchaser or lender will insist on verifying the ownership of the IP rights in that invention by reviewing assignments, contracts of sale, and licenses pertaining to the purchased invention, and verifying such transfers were properly made and recorded throughout the chain of title of ownership. A purchaser or lender will also check for claims of creditors against the IP rights being sold or used as collateral, including determining if there are any security interest agreements or any other type of lien. Assignments are important for securing full priority rights, discussed more fully in the next section. Assignments also play a role in whether or not the applicant will obtain a reduction in U.S. official fees at the USPTO with small entity status or the newly created micro entity status, discussed in more detail below. Not obtaining assignments from inventors to the company or university can create a variety of legal headaches in the future.

Assignment Best Practice For Securing Full Priority Rights

It is typical for a U.S. provisional application of a company or university to be filed in the name of the employee inventors. Patent and Cooperation Treaty (PCT) applications or other foreign applications claiming priority to the US provisional application are often subsequently filed in the name of the employer. This creates a situation where the entity filing the priority provisional application differs from the entity filing the final application claiming priority—a situation that in best practice should be avoided.

The risk in this situation is that according to case law from the United Kingdom (UK) and European Patent Office (EPO), a priority claim is only valid if the applicant was in the possession of the priority right at the time of filing the European application (*e.g.*, the PCT application designating the EP application) [3]. Thus, a best practice regarding assignments (*e.g.*, the transfer of rights, including the priority rights) is the following:

Before any foreign filings claiming priority to a US provisional application (*e.g.*, filing the PCT application designating the EP), execute an assignment expressly including the transfer of the priority right from the entity having filed the priority application(s) (*e.g.*, the inventors) to the entity filing the PCT application [4].

1. Identify the priority application(s), preferably by application number;
2. Include an applicable law clause;
3. In case of uncertainty over which law may govern the assignment, a best practice is to have the assignment executed by **both parties**, *i.e.*, by the assignees and assignors.

We note that the assignment does not need to be recorded at the USPTO to fulfill the priority rights, but must be executed by the relevant parties prior to filing the PCT application in order to have confidence that all steps have been taken to preserve priority rights [5].

Similarly, when acquiring or evaluating an IP portfolio, reviewing the applicants and assignment specifics of the patents should be a part of the overall IP audit and valuation/risk.

THE NEW MICRO ENTITY STATUS

If you qualify as a "*small entity*" (small business, independent inventor or nonprofit organization), the official fees you pay to the USPTO continue to be reduced 50% [6]. Additionally, Congress created a new "*micro entity*" status that gives you a 75% reduction in official fees if you qualify, which became effective on March 19, 2013 [7]. Micro entity status is available for all U.S. applications, whether they were filed before or after March 19, 2013, and for all granted U.S. patents. A micro entity certification may be filed in a pending patent application at any time during prosecution and in a granted patent prior to, or concurrent with, a

maintenance fee payment [8]. Qualifying for micro entity status can result in savings of at least $750 per application in average prosecution costs, and at least $3000 over the life of a patent including maintenance fees.

To qualify as a "*micro entity*" under the "*gross income*" basis, you have to:

1. qualify as a "*small entity*" under 37 CFR § 1.27;
2. not be a named inventor named on more than four previously filed US utility applications;
3. your gross income is 3 times or less than the Census Bureau reported median household income for the preceding calendar year (currently $50,022); and
4. you have not assigned or licensed your invention to a non-micro entity [9].

To qualify as a "*micro entity*" under the "*institution of higher education*" basis, you have to:

1. qualify as a "*small entity*" under 37 CFR § 1.27, and
2. earn the majority of your income from an institution of higher education; or
3. have assigned, granted, conveyed, or be under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in your particular application to such an institution of higher education [10].

An institution of higher education is a public or non-profit accredited institution that admits post-secondary students for programs of not less than 2 years [11]. However, foreign universities do not qualify as institutions of higher education and are not eligible for micro entity status [12].

When there are multiple inventors for the patent application, micro entity status is determined by applying the rules individually to each joint inventor. Under the gross income basis, no joint inventor can be named as an inventor on more than four applications, and no joint inventor can have a gross income (as defined by the IRS) exceeding three times the median household income for the preceding calendar year [13]. Under the institution of higher education basis, each joint inventor must earn the majority of his/her income from an institution of higher education, or have assigned or be under an obligation to assign the patent application to an institution of higher education [14]. If just one joint inventor does not qualify for micro entity status, then micro entity status is not available for the application. However, you may still qualify for small entity status.

WHAT HAS CHANGED IN U.S. PATENT LAW?

In response to the numerous substantive changes to U.S. patent law instituted by the AIA, the U.S. Supreme Court (Supreme Court) has issued several decisions that are reshaping patent law in several important areas. The USPTO has issued numerous rules and examination guidelines for patent examiners in response to these legislative and court mandated changes. What is a patent applicant to do?

AMERICA INVENTS ACT – WHAT HAS CHANGED?

First to File

The AIA made the U.S. a first to file system effective March 16, 2013, with the first inventor to file an application at the USPTO being awarded the patent [15]. It no longer matters if you were the first to think of and make the invention before a second inventor who invents the same or substantially similar invention. You will not get the patent if your patent application is filed second. There is one exception. If you can show the USPTO that the inventor of the first filed application derived that invention from you or one of your co-inventors in a newly created derivation proceeding, then the patent should be awarded to you [16].

Applications filed prior to March 16, 2013 were filed under the first to invent system, with the first inventor to invent the claimed invention being awarded the patent, even if the second inventor filed the application before the first inventor. For the next few years, there will be a dual patent system with applications filed before March 16, 2013, examined under pre-AIA law and applications filed on or after March 16, 2013 examined under AIA law. This can complicate decision making and strategic planning for a patent portfolio containing both pre-AIA and post-AIA patent applications.

One Year Grace Period

Before March 16, 2013, you had a grace period of one year to file your patent application in the U.S. from the date you or any other party disclosed the invention to the public, provided you were able to show the USPTO that you conceived of the invention before that publication. Now, that one year grace period only applies if you are the one who disclosed the information [17]. If a third party discloses the invention at any time before you file your application, then you will not get a patent. This means that it is more important than ever to file applications quickly, and a best practice is to file an application before you publish your data.

Third Party Submissions

When you file your patent application at the USPTO, it will be published 18 months from the earliest effective filing date. For the first time ever in the U.S., Congress is permitting any third party to submit prior art to your application file at the USPTO for consideration by the patent examiner before issuance of a first rejection of one or more of your claims [18]. This new practice, known as preissuance submission, took effect on September 16, 2012. This provides a third party an inexpensive way to try to block the granting of a patent to you.

Accelerated Examination

In a hurry to get that patent granted? If you are willing to pay $4,000 in addition to all the regular application filing

fees, you can request prioritized examination from the USPTO [19]. The USPTO's goal for prioritized examination is to provide a final disposition within twelve months of prioritized status being granted. Prioritized examination of newly filed applications is also known as "*Track One*" or "*Track I*". Only 10,000 requests per year will be accepted. Another caveat: your application is limited to 4 independent claims, no multiple dependent claims, and 30 claims total [20]. While the majority of Track One requests have been filed in computer and software arts, over 2,000 Track One requests have been filed in the pharma/biotech areas since September 26, 2011 [21].

Supplemental Examination

The AIA has created a new proceeding, known as supplemental examination, for a patent owner to request the USPTO to consider, reconsider, or correct information believed to be relevant to the patent in accordance with requirements which have been established by the USPTO [22]. The information that may be presented is not limited to patents and printed publications. The purpose of the supplemental examination proceeding is to immunize the patent against the defense of inequitable conduct in a lawsuit for the information considered, reconsidered, or corrected during a supplemental examination. For example, if prior art was overlooked during prosecution of the application that led to the patent, or if prior art was received in prosecution of foreign counterpart application after the U.S. patent was granted, it might be appropriate to request supplemental examination. It is important to note that the supplemental examination request must provide a detailed explanation of each item of information to be considered and why consideration of the item is requested [23]. Claims cannot be amended or added in a supplemental examination request [24]. If the supplemental examination certificate is issued and states that a substantial new question of patentability is raised by one or more items of information in the request, then ex parte reexamination of the patent will be ordered [25]. The total fees for the supplemental examination request are high at $16,500 for a large entity ($8,250 for a small entity) because the $12,100 fee for reexamination that could be ordered as a result of supplemental examination must be paid at the time the supplemental examination request is filed [26]. Alternatives, such as filing a reissue application, should be carefully explored with patent counsel before filing a request for supplemental examination.

False Patent Marking

35 U.S.C. § 287(a) provides that a patent owner and its authorized agents may give notice to the public that an article made, offered for sale, or sold within the United States by the patent owner and its authorized agents is patented. This notice, known as patent marking, is done by placing on the patented article the word "*patent*" or the abbreviation "*pat.*" together with the patent number or an internet address that provides the patent number, or if the patent number cannot be placed on the article, then providing the notice on a label attached to the article or on the package for the article. The failure to provide such patent marking means that no damages can be recovered by the patent owner in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe after receiving notice, in which event damages can only be recovered for infringement occurring after such notice [27].

To prevent fraud on the public and competitive injury arising from false patent marking, 35 U.S.C. § 292(a) provides a civil fine of $500 for every offense, i.e., for every article on which the false patent marking appears, with a focus on counterfeiters, imitators, and those seeking to deceive the public [28]. Before the AIA was enacted on September 16, 2011, any private person could sue and get one-half of this civil fine, with the other half of the civil fine going to the United States [29].

One of the provisions in 35 U.S.C. § 292(a) states that whoever marked, affixed to, or used in advertising with any unpatented article, the word "*patent*" or any word or number importing that the article is patented for the purpose of deceiving the public shall be fined for false marking [30]. In recent years, many lawsuits were filed by private plaintiffs exploiting this provision to sue a patent owner whose patent markings on the product are claimed to be unexpired when they have, in fact, expired, in order to be given one half of the civil penalties awarded by the court. For example, if a particular patent had expired but was still listed in patent markings on a product, its label or its packaging, the patent owner could be sued for false marking. This scenario occurred with some frequency in the pharmaceutical sector where strict regulatory processes governing labeling changes and manufacturing procedures often slowed or complicated the removal of expired patent numbers from a product's label or packaging. For a consumer product where thousands of products are sold, a $500 fine multiplied by the number of products sold could amount to a huge fine for the patent owner who typically was not acting with deceptive intent. These nuisance lawsuits diverted companies' resources to oppose these false marking claims, with the resulting costs ultimately being passed along to consumers.

Effective immediately on September 16, 2011, the AIA provided that marking a product with a patent number covering the product that subsequently expired will not give rise to liability for false marking [31]. Importantly, only the US government will be able to sue for civil penalties [32]. Private parties can only sue for damages for false marking if they can show they suffered competitive injury as a result of the false marking [33]. No civil fines can be collected by private parties. The false marking provisions of the AIA applied to all lawsuits that were pending on September 16, 2011, as well as to lawsuits begun on or after September 16, 2011, eliminating many private plaintiff lawsuits.

WHY IS PATENTABLE SUBJECT MATTER IMPORTANT?

Another area of significant change in U.S. patent law has been in the standards for the threshold determination of patentability of the subject matter of the invention under 35 U.S.C. § 101, also known as subject matter eligibility. The Supreme Court has issued several decisions that have altered the patentability standards for biotech/pharma inventions, as well as computer/business method inventions.

1. Traditional View of Subject Matter Eligibility

Historically, the bar for subject matter eligibility in the U.S. has been very low. For the last 30 years, the memorable assertion that "anything under the sun that is made by man," from the Supreme Court's *Diamond v. Chakrabarty* decision [34] has dominated the US landscape of patent eligible subject matter, contributing to the concurrent biotech boom. However, in the last several years, the *exclusions* from patent protection under 35 U.S.C. § 101, namely:

- Laws of nature
- Physical phenomena
- Scientific principles/mathematical formulas
- Abstract ideas
- Mental processes

have gained prominence in the eyes of the Supreme Court, resulting in a narrowing range of inventions that are subject matter eligible in the United States. This shift has particularly impacted the computer software and financial systems industry, as well as the biotech industry, at a time when these fields are experiencing economic booms.

2. Biotech/Pharma Patent Numbers

Biotech/pharma patent applications dominate USPTO filings with 23% of overall filings at the USPTO. Additionally, worldwide sales of biologics have increased 353% from 2001 to 2012 to over $163 billion [35]. The shift from small molecule development to biologics development is also reflected in the 907 biologics clinical trials conducted in 2012, a 155% increase over the 355 trials conducted in 2001 [36]. With this landscape in mind, it is helpful to analyze several of the Supreme Court decisions that have formed the basis for the narrowing scope of subject matter eligibility, culminating in the recently promulgated Subject Matter Eligibility Guidelines at the USPTO.

3. Impact of *Prometheus, Myriad* and *Alice* Decisions on Subject Matter Eligibility

a. Mayo v. Prometheus

The Supreme Court in *Mayo v. Prometheus* (*Prometheus)* held that **claims reciting nothing more than natural phenomena with no additional steps were not patent eligible** [37]. The claims at issue were directed to methods of optimizing the dosing regimen of a thiopurine drug (previously known and used) for certain gastric disorders. The claims included determining levels of a metabolite (previously known and used) that resulted naturally from the administration of drug in a patient. In the Supreme Court's analysis, the claims at issue recited nothing more than the natural phenomena with no additional steps (*i.e*., the correlation between the dose level of a naturally occurring metabolite and the therapeutic efficacy/toxicity).

The *Prometheus* case has arisen at a time when medical treatments and reimbursements increasingly rely on diagnostic assays and genetic analyses in order to establish the appropriate treatment regimen. Patients, consumers, and industry all benefit greatly from quicker FDA approval of new pharmaceuticals and biologics, as well as decreased side effects and spending when non-responsive patients are excluded from treatments [38].

Importantly, *Prometheus* does not preclude patent eligibility of diagnostic and monitoring methods *per se*. Successful arguments can be made by including evidence supporting the assertions that the ***method claims are not drawn to a natural principle***, ***recite more than a natural phenomenon***, ***provide a practical application*** **and** ***do not preempt all uses.*** To support such arguments, applicants should keep in mind that including as much specific data in the specification will be important. When possible, the following claim elements will be beneficial:

- Recite actual boundaries on the compound administered– both dosage and means of administration of a specific compound.
- Include meaningful limits on the type of sample; when the sample is obtained; type(s) of analysis performed.
- Do not foreclose use of data in all types of patients, e.g., include specific types of cancer that apply to the test - (prostate, lung, or brain, etc.).

b. Association for Molecular Pathology v. Myriad Genetics

In another seminal case relating to patent eligible subject matter, the Supreme Court held in *Association for Molecular Pathology v. Myriad Genetics* (*Myriad)* that a naturally occurring DNA segment is a product of nature and not patent eligible, and mere isolation does nothing to change this premise [39]. However, the Supreme Court found that complementary DNA (cDNA) is patent eligible because it is not naturally occurring (lacks introns and exons). Importantly, the Supreme Court stated that it was **not expressing** any opinion on the patent eligibility of ***novel method claims*****,** ***applications of knowledge about genes or altered DNA*****.**

The *Myriad* decision was applied in a recent case, *In re Roslin Institute* (Edinburgh), where the Federal Circuit Court of Appeals (Federal Circuit) held that product claims directed to Dolly, the cloned sheep, are not directed to patent eligible subject matter [40]. In this case, product claims to cloned mammals were determined to be ineligible subject matter because there were no differences *recited in the claims* between the cloned mammal and the genetic parent. It is noted that methods for generating the clone itself comply with 35 U.S.C. § 101.

To overcome this issue with respect to a naturally occurring nucleic acid segment, it will be beneficial to include cDNA and vector claims in order to capture some aspect of nucleic acid fragments/segments. Consider the following options for nucleic acid or protein fragments:

- Include any structural differences in the compound – mutations, synthetic residues or bases, altered or optimized glycosylation or other modifications (*differentiate from the native compound*).
- For a fragment or combination of fragments without any sequence changes, correlate and emphasize any

gained function that is not present for the individual fragments in nature.

c. USPTO Guidelines For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products

In response to the Myriad and Prometheus Supreme Court decisions, and what it viewed as a major shift in the law relating to subject matter eligibility, the USPTO issued new guidelines on March 4, 2014, that were roundly criticized by patent practitioners and applicants (See USPTO guidance memorandum entitled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products) [41].*

The guidelines set out a new procedure for U.S. patent examiners to evaluate whether a claim reciting or involving a naturally occurring product reflects a significant difference from what exists in nature. The guidelines applied to all types of claims– machine, composition, manufacture and process claims that recite or involve:

- Laws of nature/natural principles
- Natural phenomena, and/or
- Natural products

The guidelines defined "*natural product*" broadly, with the scope and breadth of the USPTO's interpretation viewed by many in the field as fairly narrow in its specific holdings relating to subject matter eligibility and unduly restrictive.

d. Alice Corp. Pty. Ltd. v. CLS Bank Int'l

After the USPTO issued new examining guidelines in March 2014, the Supreme Court decided a seminal case that has heavily impacted the software and business method arena, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (*Alice*) [42]. The Supreme Court held that "the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention." At issue were claims to a computerized method, computer-readable medium containing computer instructions, and a computer system that implements those instructions, for reducing settlement risk by effecting trades through a third party intermediary empowered to verify that both parties can fulfill their obligations before allowing the exchange to be completed.

In analyzing the *Alice* claims, the Supreme Court utilized the two part test of its *Prometheus* decision, *i.e.*, (1) to determine whether the claims at issue are directed to one of the patent-ineligible concepts (law of nature, natural phenomena or abstract idea), and (2) if so, to determine the presence of an element or combination of elements that would be "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself" [43].

In response to this decision, on June 25, 2014, the USPTO issued additional examination guidelines entitled: Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Ply. Ltd. v. CLS Bank International, et al.* [44]. Numerous decisions have since resulted in the invalidation of many software related patents. There have been rejections of pending applications, as well as withdrawal from allowance of cases in this technology area.

The *Alice* decision has been applied to numerous diagnostic applications and those involving steps reciting any type of correlation of values—placing the claims in the "*abstract idea*" patent-ineligible concept category.

e. New USPTO Guidelines—December 16, 2014

In response to the widespread criticism, the USPTO issued new guidelines on December 16, 2014, entitled 2014 Interim Guidance on Patent Subject Matter Eligibility (Guidelines), discussed below, that were published in the Federal Register [45]. These Guidelines supplement the June 25, 2014 Preliminary Examination Instructions in view of the Supreme Court Decision in Alice Corporation Ply. Ltd. v. CLS Bank International, *et al*. and supersede the March 4, 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature. Included with the new Guidelines are seventeen pages of examples that relate to nature-based products. The USPTO has requested comments on these new Guidelines by March 16, 2015 and is expecting to issue at a future date additional explanatory example sets relating to claims that do and do not amount to significantly more than a judicial exception, taking into account the public comments.

An important change from the March 2014 guidelines is that the test for determining whether a claim is directed to a "*product of nature*" exception is now separated from the analysis of whether the claim includes "*significantly more*" than the exception [46]. Under the previous March 2014 guidelines, the USPTO used a "*markedly different*" analysis which focused primarily on the claimed product's structure as compared to its naturally occurring counterpart [47]. Starting December 16, 2014, however, the "*markedly different*" analysis will focus on a number of characteristics that can include a product's structure, function, and/or other properties as compared to its naturally occurring counterpart in its natural state [48]. This is an important change from the previous guidelines because changes in functional characteristics and other non-structural properties can now be used to evidence markedly different characteristics from the naturally occurring counterpart in its natural state. Importantly, if a claim includes a nature-based product that has markedly different characteristics, the claim does not recite a "*product of nature*" exception and is patent eligible, unless it recites another exception [49]. Thus, claims can be found patent eligible based solely on a showing that the nature-based product in the claim has markedly different characteristics from the naturally occurring counterpart in its natural state, when no other exception is recited in the claim. Similarly, when a nature-based product is produced by combining multiple elements, the "*markedly different*" characteristics analysis should be applied to the resultant nature-based combination, rather than to its component parts [50]. Process claims that merely use a nature-based product should not be subject to an analysis for "*markedly different*" characteristics [51].

Additionally, with regard to patent claims that include software/business methods, the December 2014 Guidelines stress that there is no *per se* excluded category of subject matter, such as software or business methods, nor are there any special requirements for eligibility of software or business methods [52]. As such, applicants should not be daunted by the many case examples provided in Part IV in which the claims fall within the judicial exceptions and, thus, are not patent-eligible, because some patent eligibility rejections can be overcome, as will be evidenced by future examples to be provided by the USPTO.

4. Strategies for Supporting Patent Eligibility

At a time when diagnostic and treatment responsiveness and regimen based applications are gaining in both numbers and importance, U.S. patent applicants are being increasingly subjected to rejections based on the *Alice/Prometheus* framework of patent eligibility. It is estimated that approximately 70% of medical decisions by physicians rely on diagnostic assay results [53]. Such methods allow for quicker FDA approval of new pharmaceuticals, decreased side effects when non-responsive patients are excluded from treatments, and decreased spending on ineffective pharmaceuticals. In order to overcome or avoid such patent eligibility rejections, emphasize that the claimed method does not "*preempt*" all uses of the natural phenomenon. Factors that support such arguments include:

- Reciting actual boundaries on the compound administered – both dosage and means of administration of a specific compound.
- Reciting meaningful limits to the type of sample; when sample is obtained; type of analysis performed; if it is for a specific disease/specific cancer, etc.
- Reciting treating the disorder with altered dosage if appropriate.

Even with the changes in the updated December 2014 Guidelines, it is important to include as much helpful data in the specification to distinguish inventions from natural products, to include claims of varying scope, and to keep cases pending in the U.S. in anticipation that the criteria for patent eligibility determinations will continue to change over the next few months or years.

An area particularly impacted by the changes in USPTO examination practices for subject matter eligibility is that of vaccine development. Many vaccine compositions are made up of a combination of several protein fragments which often do not differ in sequence from what is found in nature. It will be especially important to include the following elements in the specification:

- Include any structural differences in the compound – mutations, altered or optimized glycosylation or other modifications (*differentiate from native compound*). If the claim is directed to a deletion mutation—highlight any structural difference from the intact polypeptide, including any improved or unpredictably maintained functions.
- For a fragment or combination of fragments without any sequence changes, emphasize any gained function that is not present for individual fragments in nature.
- Include any data about the synergistic activities of antigens; explanation that when isolated and combined together *in a new formulation that does not occur in nature,* they present something new and improved to the immune system; difference in epitopes or some structure compared with the natural state (*e.g*. vaccine antigens).
- Consider formulation and other modifications for compound eligibility.

A pending case to watch with respect to this issue is U.S. Application No. 13/382,906, which has been finally rejected by the USPTO applying the March 4, 2014 Guidelines. In rejecting the claims, the Examiner concluded: "the polypeptides of the claims are isolated from nature and although reflect the 'hand of man' in their isolation, the isolation or fragmentation does not confer a marked structural difference from the naturally occurring product" [54]. It remains to be seen how the claims in this application will be treated under the revised Guidelines issued on December 16, 2014. However, it would appear that the new December 16, 2014 Guidelines, which include features such as structure, function, or other activities compared to the naturally occurring counterpart, as well as a more flexible analysis of a "*product of nature*," will provide a window of hope for such claims directed to protein fragments, deletions, or new combinations of so-called naturally occurring immunogens [55]. For difficulties encountered during U.S. patent examination, consider consulting the USPTO Ombudsman program to address improper application of the Guidelines, which has a response time of one to two days, and is anonymous with respect to the applicant [56].

Even though we are in the midst of navigating the ongoing changes that are narrowing the scope of patentable subject matter in the U.S., it is important to remember to continue to include broader scope claims and supporting examples for other jurisdictions such as Europe and Japan, which have not narrowed subject matter eligibility in this manner. Additionally, it is recommended to keep applications pending in the U.S., as the criteria for subject matter eligibility could change again in the next several years.

NEW WAYS TO CHALLENGE PATENTS IN THE U.S. AND IN EUROPE

U.S. Patent Challenges

You finally get your U.S. patent granted, but you cannot breathe a sigh of relief. The AIA created new post-grant trial proceedings to review the patentability of claims in a granted patent, namely post-grant review, inter partes review, and a transitional post-grant review for covered business method patents, shown in Table **1**. The USPTO Patent Trial and Appeal Board (PTAB) is charged with conducting these trial proceedings, as well as derivation proceedings to determine whether (i) an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application, and (ii) the earlier application claiming such invention was filed without authorization.

Table 1. Summary of proceedings at USPTO to challenge validity of pre-issuance and post-grant patents.

Patent Invalidity Challenges at the USPTO Throughout a Patent's Entire Life			
Original Examination	**Within 9 Months of Patent Grant**	**After 9 Months, Until Expiration of Patent**	
Preissuance Submissions			
	Post-Grant Review		
		Inter Partes Review	
	Ex Parte Reexamination		
	Covered Business Method Post-Grant Review (Transitional Program)		

Any third party can challenge your patent in a new post-grant review proceeding at the USPTO created by the AIA, but they must file the petition within 9 months from the date your patent is granted [57]. If the USPTO accepts the petition to institute the post-grant review, then the USPTO must make a decision on the challenge to the patent within one year of the request [58]. This new post-grant review came into effect on September 16, 2012, but can only be filed against patents with an effective filing date on or after March 16, 2013.

Nine months have passed. Are you home free yet? Not necessarily. A third party could challenge the validity of your patent through an inter partes review regardless of when it was issued [59]. The inter partes review replaced the former inter partes reexamination on September 16, 2012. No longer will the alleged basis of unpatentability have to be "*new*," *i.e.*, not previously considered by the USPTO. The earliest that a petition for inter partes review can be filed is nine months after the date of grant of your patent, or if a post-grant review is filed, then after the post-grant review is completed [60]. If the USPTO accepts the petition to institute the inter partes review, then the USPTO must make a decision on the challenge within one year of the request [61].

The AIA also created a new post-grant review proceeding at the USPTO under a transitional program to challenge covered business method (CBM) patents, which will end on September 16, 2020 [62]. A person may only file a petition for a CBM post-grant review proceeding against a covered business method patent if the person or the person's real party in interest or privy has been sued for infringement of the patent or charged with infringement under the patent [63].

The PTAB is obligated by the AIA to reach a final determination in these new post-grant proceedings no later than one year from the Board's decision to grant a petition to institute a post-grant review, an inter partes review or a covered business method review [64]. The proceeding can be extended up to 6 months for good cause, which will not be routinely granted. Fig. (**1**) illustrates the timetable for these post-grant trial proceedings [65].

It is possible for the parties to enter into a settlement to end a post-grant proceeding, which can be filed at any stage of the proceeding, even before a decision to institute the proceeding is issued [66]. However, the PTAB is not a party to the settlement and may still independently determine any question of jurisdiction, patentability, or Office practice [67]. If the settlement is filed at an advanced stage of the proceeding, especially after all briefs are filed, the PTAB could still proceed to issue a final written decision. To avoid having that happen, a motion to terminate should be filed in the early stages.

The different post-grant proceedings at the USPTO are summarized in Table **2** [68].

Initially slow to be embraced when post-grant trial proceedings first became available in 2012, the USPTO has seen a rapid growth in the number of petitions filed to institute post-grant trial proceedings to challenge the validity of patents. Table **3** provides the PTAB's official statistics, as of January 1, 2015, from September 2012 through the first quarter of the USPTO's 2015 fiscal year [71].

While the majority of the petitions have been filed in the electrical/computer technology areas, there has been a steady increase in the number of petitions filed in the

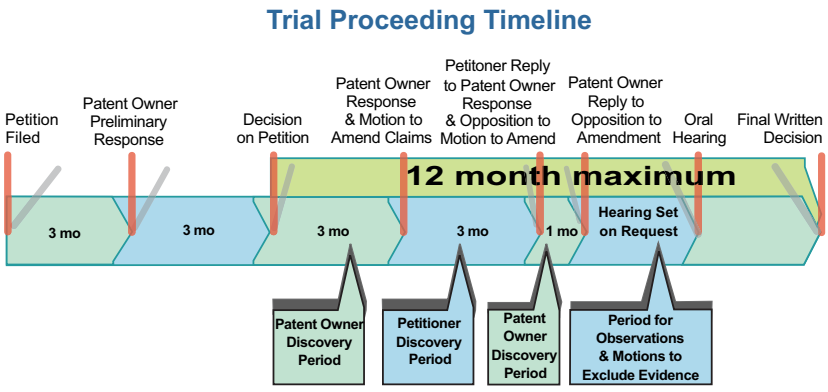

Fig. (1). Trial proceeding timeline.

Table 2. Summary analysis of USPTO post-grant proceedings.

Reexamination	Post-Grant Review	Inter Partes Review	Covered Business Method
Patent owner the only party	Both petitioner (patent challenger) and patent owner are parties		
No time limit; can take years to complete	Must be completed within one year of decision to institute proceeding		
Any patent can be reexamined	Any first-inventor-to-file patent (application filed on or after March 16, 2013)	Any patent can be petitioned for an inter partes review	Any Covered Business Method patent, but not Technological Inventions
Can challenge under 35 U.S.C. §§ 102, 103 (based on patents or printed publications only)	Can challenge under 35 U.S.C. §§ 101,102, 103, 112 (but not best mode), double patenting	Can challenge under 35 U.S.C. §§ 102, 103 (based on patents or printed publications only)	Can challenge under 35 U.S.C. §§ 101, 102, 103 (with restriction on prior art for first-to-invent), 112 (but not best mode)
Can file after issue of patent	Must file within 9 months of issue of patent or reissue of patent and before any invalidity action is filed in court by petitioner	*First-to-invent patents*: can file after issue of patent or reissue of patent *First-inventor-to-file patents*: can file after 9 months from date of issue of patent or reissue of patent and, if a post-grant review was instituted, after the post-grant review is complete Petition must be filed within one year after service of a complaint of infringement on petitioner and before any invalidity action is filed in court by petitioner	Can file after petitioner has been charged with infringement or has been sued for infringement.
Petition must raise substantial new question of patentability	Petition must demonstrate that it is more likely than not that at least one claim being challenged is unpatentable, or raises a novel or unsettled legal question important to other patents/applications	Petition must demonstrate a reasonable likelihood that petitioner would prevail on at least one of the claims being challenged	Petition must demonstrate that it is more likely than not that at least one claim being challenged is unpatentable, or raises a novel or unsettled legal question important to other patents/applications
Standard for claim construction is the broadest reasonable interpretation consistent with the patent's specification [69]			
Evidentiary standard for invalidation of patent is a preponderance of the evidence [70]			

Table 3. USPTO official statistics on petitions filed to institute post-grant trial proceedings.

Petitions Filed By Fiscal Year	Total	Inter Partes Review	Covered Business Methods	Post-Grant Review	Derivation
2012	25	17	8	-	-
2013	563	514	48	-	1
2014	1,494	1,310	177	2	5
2015	505	458	44	1	2
Cumulative	2,587	2,299	277	3	8

biotech/pharma technologies. In Fiscal Year 2014, sixty-seven petitions were filed in the biotech/pharma technologies at the midpoint of that year. In Fiscal Year 2015, as of January 1, 2015, forty petitions have been filed in the biotech pharma technologies, shown in Table **4**, and there are still nine months left in this fiscal year [72].

ROUNDUP OF BIOTECH/PHARMA INTER PARTES REVIEW DECISIONS

Even though a significant number of inter partes review petitions are now being filed involving biotech/pharma technologies, very few decisions have been issued. The first pharma inter partes review opinions were issued on June 20, 2014 for four related proceedings initiated by Gnosis, S.P.A., Gnosis Bioresearch S.A., and Gnosis U.S.A., Inc. to challenge patents owned by Merck & Cie in one proceeding and patents owned by South Alabama Medical Science Foundation (SAMSF) in the other three proceedings [73]. These proceedings involved compositions of natural folate used in the treatment of vitamin deficiencies. In all four proceedings, the PTAB held that the challenged claims were invalid as obvious over the art cited by petitioners.

Eli Lilly and Company (Eli Lilly), a major pharmaceutical company, was sued for inducing patent infringement of U.S. Patent No. 8,133,903, a fibrosis

Table 4. USPTO official statistics on fiscal year 2015 petitions filed grouped by technology centers.

Petitions Filed FY15 Based on Technology Center (TC)	Number of Petitions	Percentage
Electrical/Computer – TCs 2100, 2400, 2600, 2800	323	64.0%
Mechanical/Business Methods – TCs 3600, 3700	118	23.3%
Chemical – TC 1700	22	4.3%
Bio/Pharma – TC 1600	40	8.0%
Design – TC 2900	2	0.4%

treatment patent, owned by Los Angeles Biomedical Research Institute at Harbour-UCLA Medical Center (LA BioMed) [74]. A few months later, Eli Lilly submitted two petitions to institute inter partes review of all five claims of U.S. Patent No. 8,133,903 as unpatentable. In two separate decisions issued on October 23, 2014, the PTAB granted both petitions, ruling that Eli Lilly had established that it was more likely than not that all five claims are either obvious or anticipated by prior art [75]. Because of the statutory requirement of completing an inter partes review within twelve months from the date of the decision instituting the proceeding, decisions on these two inter partes review proceedings should be issued in October 2015.

In a victory celebrated by branded pharmaceutical companies, the PTAB, on December 9, 2014, affirmed the validity of claims from three patents relating to the rosacea treatment Oracea [76]. The inter partes review proceedings were instituted in June 2013 from a petition for inter partes review filed by Amneal Pharmaceuticals based on obviousness. The three patents at issue, U.S. Patent Nos. 8,394,406; 8,206,740; and 8,394,405, are the first Orange Book listed patents to be reviewed to a final decision under inter partes review, as well as to survive the challenge.

One trend is clear from the statistics provided by the PTAB. If an inter partes review petition is granted, a trial is instituted, and a final written decision is issued, the majority of the decisions will find some or all of the claims reviewed to be unpatentable. For a patent owner, it is important to file a full and complete preliminary response to convince the PTAB to decide not to institute a trial, so that the patent remains valid and enforceable. An insufficient response or no response could result in a decision to invalidate the patent.

European Patent Challenges

The European patent system has not sat quietly on the sidelines. After decades of discussion and debate, in December 2012, the European Parliament and the Council of the European Union agreed on two regulations laying the foundation for unitary patent protection (UPP) in the European Union (EU) [77]. EU Regulation No. 1257/2012 finally establishes the framework for the unitary patent under the Unitary Patent Regulation. Additionally, in June 2013, the EU issued an Agreement on a Unified Patent Court (UPC) that created a pan-European court structure [78]. EU Regulation No. 1257/2012 is expected to take effect by early to mid-2016, and will involve a complex transition period. The new Unitary patent granted under this regulation (which will be examined under the current EPC system) will be effective in those EU member states which ratify the UPC Agreement. To date, countries ratifying the UPC Agreement include at least Great Britain, Germany, France and 10 additional member states, with up to 24 total states involved. At this stage, it is of note that Spain, Italy, Poland and Croatia will not participate in the UPC.

The goals for the UPP and UPC include providing streamlined, simplified alternatives that provide cost effective options for businesses. The UPC will have its effect on post-grant proceedings which are viewed as costly and piecemeal by many patent applicants and defendants. Although intended to provide streamlined and cost effective options, the developing rules and procedures are already complex, and fee structures have not been provided. As noted above, EU Regulation No. 1257/2012 will involve a complex transition period, which will increase uncertainty in decision making for applicants and patent owners. The UPC Agreement provides that in the first seven years, an EP claim can be brought in either a national court, or in the UPC [79]. Importantly, the UPC will have jurisdiction across UPC Agreement states, and the national court will only have jurisdiction nationally [80]. However, the UPC is required to cooperate with the Court of Justice of the European Union (CJEU) to ensure the correct application and uniform interpretation of EU law by requesting preliminary rulings from the CJEU, with CJEU decisions binding on the UPC [81]. At present, there are uncertainties related to how the UPC Agreement may be viewed by the CJEU.

Once the UPC is implemented, there will be three different systems for challenging patents in Europe, which depend on whether or not you have a traditional European patent that is validated in the individual countries in Europe, a traditional EPO patent with national validations, or the new UPP patent (*i.e.*, a European patent with unitary effect). These three systems are outlined in Table **5**.

While there are many details and procedures for the UPC system that remain to be developed, it will be helpful to at least be aware of some of the key provisions for patent portfolio planning. The first is that there will be a seven year opt in/opt out period, which may have an extension of another seven years. A driving factor that will motivate patent owners' inclination to opt out of the UPC is the uncertainty associated with the lack of any prior decisions and the unpredictability of the panels that will be deciding the cases, in addition to the risk of a one shot "knock out" of the patent, which will be effective across many jurisdictions. One useful option for a patent applicant or owner to consider includes filing national applications in individual countries for "*crown jewels*" to protect them from a central, winner

Table 5. Summary analysis of European post-grant trial proceedings [82].

EPO Opposition	Central Revocation (UPC)	National Revocation (If Opted Out)
9 months after grant	Any time	Any time
Central effect	Central effect	National effect
No counterclaim for infringement possible	Counterclaim for infringement possible	Counterclaim for infringement possible
No expert evidence	Expert evidence possible	Expert evidence possible
Fact witnesses possible	Fact witnesses possible	Fact witnesses possible
Experiments possible	Experiments possible	Experiments possible
No discovery	No discovery	No discovery (except in UK and Ireland)
Panel of technical judges	One technical judge on panel	Technical judges depending on jurisdiction
Duration: 2 years for first instance, plus 3-4 for appeal	Duration: 1 year for first instance, plus 1-2 for appeal	Duration: a lot of variation

takes all, validity attack. Another option is a blended approach that leaves some existing European Patents in the UPC, while strategically filing national divisional applications that opt out of the UPC, to hedge the risks, costs and uncertainties of this new UPC system over the course of the transition period.

A development to watch for is a "sunrise provision" in which patents can be proactively opted out of the UPC. This provision may be very important for protecting "*crown jewel*" patents. Determining the timeframe and procedures for opting patents out of the UPC under any "sunrise provision" will be important for many patent owners.

On the competitive surveillance front, it may be useful to identify key competitor patents to challenge as soon as possible under the UPC, which would effectively lock such patents into the UPC to the surprise of the patent owner. Under this scenario, one would have a chance in theory to broadly knock out a competitor's patent.

This very brief overview is just the tip of the iceberg of this exciting development in Europe. The UPP/UPC is creating a dynamic and evolving situation in which European patent attorneys will prove essential for ongoing advice, enforcement and filing strategies.

RECENT COURT CASES AND LEGISLATION TO WATCH

U.S. Supreme Court Cases

Teva v. Sandoz

The Supreme Court issued its decision on January 20, 2015 in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.* in which Teva appealed a Federal Circuit decision invalidating its patents on the multiple sclerosis drug Copaxone after a district court (trial court) had found them valid [83]. The Federal Circuit's rule has been that district court claim construction rulings are a question of law that may be reviewed anew ("*de novo*") on appeal without deference to the district court's decision. The impact of this standard of review has been that over the years, the Federal Circuit has frequently reversed the claim construction decisions of trial courts. Teva argued that claim construction, which is often dispositive in patent cases, involves factual findings that should be reviewed with deference on appeal. This is in part due to the rationale that the district court spends the most time and has direct contact with witnesses, issues relating to claim construction, extrinsic evidence and Markman hearings. The Supreme Court decided that the Federal Circuit's rule that a district court's claim construction may be reviewed *de novo* in its entirety as a question of law, including the district court's determination of subsidiary facts pertaining to the claim construction, is incorrect [84]. The Supreme Court held that the Federal Circuit is required under Rule 52(a)(6) of the Federal Rules of Civil Procedure to review the district court's resolution of any underlying factual dispute made in the course of the district court's construction of a patent claim involving extrinsic evidence under the clearly erroneous standard [85]. The practical impact of this holding is that the district court's fact finding is treated as correct unless its fact finding is shown to be clearly erroneous on appeal.

The Supreme Court's opinion also provided guidance on how the clear error review rule should be applied when reviewing subsidiary fact finding in patent claim construction [86]. The Supreme Court first confirmed that if the district court only reviews evidence *intrinsic* to the patent, namely the patent claims, patent specification and the patent's prosecution history, then the district court's claim construction will amount solely to a determination of law, which the Federal Circuit may review under the *de novo* standard of review [87]. Should the district court also consult *extrinsic* evidence, such as testimony from experts, to understand, for example, the meaning of a technical term in the relevant technical field or to understand the background science, and such subsidiary facts are in dispute by the patentee and the alleged infringing party, then the district court will make subsidiary factual findings about this extrinsic evidence [88]. After making the factual findings, the district court will then interpret the patent claim in light of these factual findings to arrive at the legal conclusion about what is the proper interpretation of the written patent claim [89]. The subsidiary factual findings must be reviewed under the clear error standard by the Federal Circuit [90]. In contrast, the district court's legal conclusion on the proper interpretation of the patent claim may be reviewed by the Federal Circuit under the *de novo* standard of review [91].

What does this decision mean for future patent litigation? Litigants will have to pour their efforts into the Markman hearing in which the district court determines how the patent claims will be construed, and into the district court trial. It can be expected that there will be more expert testimony presented to the court as each party jockeys to obtain a favorable factual finding on the meaning of claim terms and other technical terms to support a legal interpretation of the patent claim that the party argues is correct. This will mean increased costs for the litigants for expert witness preparation and involvement in the Markman hearing and trial, which will be necessary as the battle of experts over claim term meanings will be even more critical to a successful outcome for the prevailing party on appeal. The losing party can no longer assume that there will be a strong probability of reversal on appeal under a *de novo* standard of review. For Teva and Sandoz, this Supreme Court decision does not settle their dispute. The Federal Circuit's judgment has been vacated and the matter sent back to the Federal Circuit to review the record, apply the correct standards for review of factual findings and legal conclusions and reissue its decision [92]. It remains to be seen how the Federal Circuit applies the Supreme Court's Teva decision to the Teva appeal and to future appeals.

Commil USA LLC v. Cisco Systems Inc.

On December 5, 2014, the Supreme Court granted the petition of Commil USA, LLC to review a Federal Circuit decision that a defendant's good faith belief that a patent is invalid can serve as a defense to induced patent infringement [93]. The Federal Circuit decision reversed the $74 million damages awarded by a jury that had found Cisco infringed a Commil wireless networking patent. The Federal Circuit created a new defense to induced infringement by holding that evidence of an accused inducer's good faith belief of invalidity of the patent may negate the requisite intent for induced infringement, whereas previously, an accused inducer had to provide evidence of a good faith belief of non-infringement [94]. This new defense sharply divided the judges of the Federal Circuit, which voted 6-5 not to review the case by all of the judges of the Federal Circuit ("*en banc*"), with the dissenting judges saying the ruling created an "improper escape hatch from liability." The Supreme Court's decision will determine whether or not this new defense can be used against a claim of induced infringement.

Kimble v. Marvel Enterprises Inc.

On December 5, 2014, the Supreme Court granted the petition of Stephen Kimble, the inventor of a Spider Man toy, to review a decision of the Ninth Circuit U.S. Court of Appeals [95]. The Ninth Circuit Court of Appeals held that a license agreement from Kimble to Marvel Enterprise, which had a single royalty rate for intellectual property rights that included patents as part of those rights, as well as trade secret and other intellectual property rights, could not be allowed to extend the royalty payments beyond the expiration of the patents, which had expired [96]. The Ninth Circuit Court of Appeals relied on the Supreme Court decision in *Brullote v. Thys Co.,* 379 U.S. 29 (1964). The question is whether the Supreme Court will continue to uphold the *Brullote* holding that charging patent royalties beyond a patent's expiration date is unlawful, or will it overrule the *Brullote* opinion and allow parties to agree to have royalty payments extend beyond the expiration of patent rights that are a part of the licensing agreement.

Federal Circuit Court Cases

In re Cuozzo Speed Technologies LLC

The Federal Circuit issued its decision on February 3, 2014 in *In re Cuozzo Speed Technologies LLC* in which Cuozzo Speed Technologies appealed the decision of the first PTAB inter partes review invalidating one of its patent claims as obvious [97]. When making its determination that the patent claim was obvious, the PTAB used the broadest reasonable interpretation standard for its claim construction [98]. In its appeal, Cuozzo Speed Technologies argued that the PTAB was using a claim construction standard that is different from the ordinary and customary meaning claim construction standard used by federal district courts, which Cuozzo Speed Technologies argued could lead to different results in how the same claims are construed. The other main issue on appeal was whether certain jurisdictional requirements of inter partes review proceedings, including the PTAB's decision to institute an inter partes review, may be appealed.

The Federal Circuit first decided that it does not have jurisdiction to review the PTAB's decision to institute an inter partes decision, even after the PTAB issues a final decision [99]. The basis for this part of the decision was 35 U.S.C. § 314(d), entitled "*No appeal*," which provides that "[t]he determination by the Director [of the USPTO] whether to institute an inter partes review under this section shall be final and nonappealable" [100]. The Federal Circuit stated that mandamus may be available to challenge the PTAB's decision to grant a petition to institute an inter partes review after issuance of the PTAB's final decision in those situations where the PTAB has clearly and indisputably exceeded its authority [101]. As a practical matter, most respondents will not be able to meet the high standards for mandamus to challenge the PTAB's decision to institute an inter partes review.

The Federal Circuit then proceeded to decide that it was appropriate for the PTAB to use the broadest reasonable interpretation standard for claim construction in inter partes review proceedings, concluding that Congress implicitly adopted the broadest reasonable interpretation standard when enacting the AIA [102]. The PTAB's specific claim construction was determined by the Federal Circuit to be proper and the PTAB's obviousness determination was upheld [103].

The decision of the Federal Circuit was not unanimous. Judge Newman dissented from the majority, arguing that the intent of the AIA was to have PTAB proceedings serve as less costly surrogates for district court litigation and therefore the PTAB should apply the same legal and evidentiary standards as a district court [104]. Judge Newman's arguments could ultimately prevail. On February 5, 2015, the Innovation Act (H.R. 9) was introduced to the House of Representatives and referred to the House Committee on the Judiciary for further action [105]. If enacted into law, Section 9 of the Innovation Act will amend

the AIA to require the use of the ordinary and customary meaning claim construction standard used by federal district courts in inter partes review and post-grant reviews [106]. Until such time that legislation is enacted, patent owners will be faced with conflicts arising from the disparate claim construction results that are determined by which forum is construing the patent claims, the courts or the PTAB. For patent challengers, there is now certainty about the claim construction standard to be applied in proceedings before the PTAB.

University of Utah Research Foundation v. Ambry Genetics Corp.

In another recently decided case relating to product claims reciting primers and methods of comparing and analyzing DNA, the Federal Circuit held that synthetic single-stranded DNA molecules known as primers are not patent eligible when they contain the identical sequence to naturally occurring DNA [107]. The patents at issue on this appeal are owned by Myriad Genetics, Inc. and covered compositions of matter and methods relating to the BRCA1 and BRCA2 genes [108]. The plaintiffs appealed the U.S. District Court's denial of a preliminary injunction to enjoin Ambry Genetics Corp. from selling medical kits designed to test for the presence of gene mutations linked to breast and ovarian cancer [109].

The Federal Circuit reasoned that primers, even though they are synthetic, are not distinguishable from the isolated, natural DNA that the Supreme Court found patent-ineligible. Additionally, the Federal Circuit applied the Supreme Court's *Alice* decision to assert that the method claims are also unpatentable as being directed to merely an "*abstract idea*" of comparing cancerous and non-cancerous genes. This Federal Circuit decision is important because it expands the Supreme Court's holding from the *Myriad* decision by intuiting that the primer product claims that were not challenged in *Myriad* have the same deficiency as the isolated DNA product claims.

Ariosa Diagnostics v. Sequenom

In a closely watched case, the Federal Circuit heard oral arguments on November 7, 2014 in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* relating to methods of detecting paternal DNA in a sample of maternal serum [110]. Applications of this technology have resulted in non-invasive maternal tests performed as early as ten weeks into pregnancy for detecting certain chromosomal anomalies such a trisomy 21 (Down Syndrome). In 2013, the U.S. District Court applied the Myriad/Prometheus framework of patent eligibility and found all of the claims at issue in U.S. Patent No. 6,258,540, which was exclusively licensed to Sequenom, Inc., were not patent eligible. The District Court reasoned that diagnostic claims containing only conventional and existing detection steps do not make the use of a natural phenomenon patent eligible [111].

In the meantime, an inter partes review of U.S. Patent No. 6,258,540 has been decided by the PTAB on September 2, 2014 [112]. In a mixed outcome, the PTAB interestingly found a number of the claims unpatentable under 35 U.S.C. § 102(b) as anticipated by certain prior art references. However, the Board also found that claims 3, 12, 13, 15, 18, 21, and 22 of this patent withstood an obviousness challenge under 35 US.C. § 103(a). This outcome raises a number of interesting issues, namely that this patent could have been challenged on the traditional and straightforward grounds of anticipation and/or obviousness, without adding to the § 101 patent eligibility quagmire.

Regardless of the Federal Circuit's upcoming decision, the issues in this case will remain a hot topic and likely result in further actions that impact obtaining patents in the field of diagnostics and genetic testing [113]. It is expected that a decision will be issued later in 2015.

Legislation to Watch

The Innovation Act (H.R. 3309), a patent reform bill designed to curb abusive litigation, overwhelmingly passed the Republican-controlled U.S. House of Representatives in 2013, but did not move forward in the Democratic Senate in 2014. On February 5, 2015, the Innovation Act (now numbered as H.R. 9) was reintroduced to the House of Representatives and referred to the House Committee on the Judiciary for further action [114]. If the Innovation Act is passed by Congress as written, there will be a number of changes to patent litigation. The party bringing suit, the plaintiff, must disclose the owner of the patent to the court, the USPTO and each defendant in order to prevent a patent owner from hiding behind a shell company to avoid accountability for bringing frivolous litigation under Section 4 of the Innovation Act [115]. Section 3 of the Innovation Act will require the plaintiff to provide more detailed information in the complaint that starts the lawsuit, including, *e.g.*, identifying each patent and each patent claim that is being infringed, identifying and describing each accused process, machine, manufacture or composition of matter that infringes the patent claim [116]. Both sides would be limited from obtaining discovery from each other until after the court has issued a claim construction ruling, which would be a significant change from how litigation is currently conducted [117]. One of the most significant changes under the Innovation Act will be the requirement that the losing party must pay the legal fees and expenses of the prevailing party, unless the court finds that the position and conduct of the losing party was reasonably justified in law and fact or that special circumstances make an award unjust [118]. Currently, each party pays its own costs in litigation unless the court finds that the losing party's conduct was exceptional, meriting an award of attorney fees and expenses to the prevailing party. It is expected that the U.S. House of Representatives will pass H.R. 9. It remains to be seen if this bill will ultimately be enacted into law.

On December 11, 2014, Senator Orrin Hatch, R-Utah, and Senator Michael Bennet, D-Colo., introduced the Dormant Therapies Act of 2014, a bill that, if passed and signed into law, would establish a new class of pharmaceuticals known as "*dormant therapies*" eligible for 15 years of data protection [119]. In his press release, Senator Hatch stated, "This provision will remove the "*ticking patent clock*" conundrum that forces companies to prioritize research based on which compounds can be brought quickly to market" [120]. The draft bill provides that a "*dormant therapy*" is a medicine, drug or biologic, that will address one or more unmet medical needs. The Senators

intend for this bill to encourage companies to invest in the research and development of new treatments that could help people with complex medical conditions resulting from long-term diseases or disabilities, such Alpha-1, ALS, Alzheimer's, epilepsy, lupus, mesothelioma, and multiple sclerosis. The bill was not acted on by the 113th Congress and Senator Hatch has not yet reintroduced this bill to the 114th Congress for consideration.

Senators Hatch and Bennett did reintroduce a bill on January 16, 2015, the ''Promise for Antibiotics and Therapeutics for Health Act'' or the ''PATH Act'' to create a limited population pathway for approval of certain antibacterial drugs [121]. In his press release, Senator Hatch explained that the PATH act would help address the increasingly urgent public health threat from antibiotic-resistant bacteria by permitting the Food and Drug Administration (FDA) to accelerate an antibacterial drug's approval for an identifiable, limited patient population upon determining that the drug treats a serious or life-threatening condition and addresses an unmet need. In addition, the bill would require a drug's label to include special designation from FDA indicating their intended use in limited, high-risk populations approved under this pathway [122]. This bill has been referred to the Committee on Health, Education, Labor, and Pensions for further action [123].

CONCLUSION

It is a foregone conclusion that we can expect more changes in patent law that will affect the ability of applicants to obtain patents, and the ability of patent owners to enforce patents. In the biotech/pharma arena, trends indicate that there will be an increasing number of post issuance challenges to the validity of patents filed at the USPTO by generic companies against pharma and biotech companies, as well as by pharma companies against other pharma and biotech companies. These new USPTO trial proceedings provide an alternative tool to challenge a patent under a lower standard of proof, compared to a trial in federal district court where there is a higher standard of proof. Readying budgets and strategies for attacks on multiple fronts, with potential inter partes review challenges concurrent with Hatch-Waxman proceedings will undoubtedly keep in-house counsel busy.

In Europe, the creation and future implementation of the unitary patent and the Unified Patent Court presents patent applicants and patent owners with new strategic planning questions. Decisions will have to be made on whether to obtain a traditional European patent that is validated in the individual countries in Europe, a traditional EPO patent with national validations, or the new UPP patent. Those decisions will determine under which of the three revocation systems that patent can be challenged. Applicants will have to weigh the benefits of a UPP patent that can be enforced in a single court proceeding against the risk of having it invalidated across many jurisdictions. For important inventions, consider filing national applications in individual countries to protect them from a winner takes all validity attack. Alternatively, obtain some UPP patents, while strategically filing national divisional applications that opt out of the UPC, to hedge the risks, costs and uncertainties of this new UPC system over the course of the transition period.

The creation of these additional venues in the U.S. and Europe for challenging patents can be expected to affect the commercial value of the patent and potentially place downward pricing pressure on valuations and royalty rates. On the flip side, monitoring and challenging a competitors' patent(s) under these frameworks may provide an important defensive tool or bargaining chip in especially crowded or contentious patent landscapes.

What are some steps that you can take to safeguard your invention? The goal is to obtain valid and enforceable patent claims that will adequately protect the inventors and any investors in the patented invention and withstand patentability challenges. The detailed description in the application provides the basis for claim construction. When your patent application is being written, provide as much detail as possible on how to make and use the invention to support a claim construction that protects your invention. Important terms for understanding the invention should be clearly defined and consistently used throughout the description and the patent claims. Building flexibility into your patent portfolio by including a variety of claim scopes supported by concrete examples is a recommended practice. Consider pursuing the claims that are narrow in scope in one application and the claims having a broader scope in a separate application to mitigate the impact on the value of your patent portfolio if one of the patents is invalidated. File continuation applications for your important inventions to have applications pending to enable you to pursue claims that are responsive to future changes in the law.

By paying attention to ongoing changes in patent law and working with your patent attorneys to develop strategies to build flexible patent portfolios, you can build value during these turbulent times for cutting edge innovations.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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Declared none.

DISCLAIMER

The opinions expressed are those of the author(s) and do not necessarily reflect the views of Leason Ellis LLP or the firm's clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

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