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Patent News

Important Recent Patent Law Developments

The America Invents Act

The Leahy-Smith ***America Invents Act*** (AIA) was enacted on September 16, 2011, and makes the most significant changes to the U.S. patent system since 1952.

New First-Inventor-to-File System	Unlike the current "first-to-invent" system, dates of invention will not be relevant in establishing novelty. (effective March 16, 2013)
New Derivation Proceeding	If an applicant believes that another person "stole" his/her invention and filed an application claiming the stolen invention, the applicant may petition the U.S. Patent & Trademark Office ("Patent Office") to determine who is the actual inventor. (effective March 16, 2013)
U.S. Application May be Filed in Name of Assignee	An assignee of rights, such as an employer, or an entity to whom there is an obligation to assign rights in an invention, may file the application. The patent will issue to the real party in interest. (effective September 16, 2012)

Interference Proceeding is Abolished	An interference proceeding to determine which of two entities first invented an invention no longer will be necessary for applications filed under the first-inventor-to-file system. (effective March 16, 2013)
Post-Grant Supplemental Examination	Patent owners can prevent third party attacks on enforceability of a patent by submitting information not previously considered by the Patent Office. (effective September 16, 2012)
Inventions Directed to Tax Strategies or Human Organisms Prohibited	Patent protection cannot be obtained for tax strategies or human organisms. (effective September 16, 2011)
Micro-Entity Established for Fee Purposes	A "micro-entity" will be entitled to a 75% reduction in Patent Office fees. (implementation date to be determined by the Patent Office)
Prioritized Examination of Applications	Applicants may request expedited handling of applications at a cost of $4,800 ($2,400 for "small entities"). (effective September 26, 2011)
"Transitional" Post-Grant Review for Business Method Patents	Entities charged with infringement of a "business method patent"(that relates to a *financial* product or service) can request the Patent Office to review the validity of the asserted patent. "Transitional" post-grant review phases out for patents that are subject to the first-inventor-to-file provisions. (effective September 16, 2012)
Post-Grant Review for any Patent (Opposition Proceeding)	Any entity can request the Patent Office to review, on nearly any ground, the validity of a patent with an effective filing date on or after March 16, 2013.
Inter Partes Review to Replace Inter Partes Reexamination	After the period in which Post-Grant Review can be requested, a third party may request the Patent Office to review the validity of a patent based solely on prior art patents and printed publications. (effective September 16, 2012)
False Patent Marking Cases Eliminated	An entity may bring an action for false marking only if it can show that it has been competitively injured by the false patent marking of another. (effective September 16, 2011 – applicable to pending litigations)
Prior Commercial Use Defense Expanded	Prior *bona fide* commercial use is now a defense to infringement of nearly all types of patents. (effective September 16, 2011)
Failure to Satisfy "Best Mode" Requirement – Not a Defense to Infringement	Patent infringement defendants no longer may challenge the validity of a patent on the ground that the patent does not disclose the best mode for practicing the invention. (effective September 16, 2011)
Failure to Seek Advice of Counsel - No Impact on Willful Infringement Assessment	Failure to seek advice of counsel, or to disclose such advice, cannot be used to prove willful or induced infringement. (effective September 16, 2011)

The New First-Inventor-to-File System

In an effort to bring the U.S. patent system in line with the rest of the world, the America Invents Act switches the U.S. to a first-inventor-to-file system from a first-to-invent system. The new system will apply to all applications that are filed on or after March 16, 2013, and that are not a continuation or division of an application filed before that date.

Under the current first-to-invent system, the date of invention establishes what prior art may be cited against an application, and also is relevant to deciding who is entitled to a patent when two entities separately invent the same invention around the same time.

Under the new first-inventor-to-file system, only the filing date is used to determine what may be cited against an application. There is one exception to this. The new system retains the existing one-year grace period for the inventor's own public disclosures of the invention. However, the new law leaves unclear whether the one-year grace period applies to the inventor's own non-public sale of the invention prior to filing. But, prior disclosure of an invention may affect foreign patent rights since many foreign countries have an "absolute" novelty requirement.

If an inventor discloses an invention within one year prior to filing the patent application, the subsequent disclosures by other entities cannot be cited against the application. Currently, it is unclear exactly how much of the invention needs to be disclosed in order for subsequent disclosures by others to be not citable.

Also under the new system, the interference proceeding, which establishes who invents first, no longer is necessary. The new system replaces the interference proceeding with a new derivation proceeding, which will be held before the new Patent Trial and Appeal Board at the Patent Office. This proceeding will determine whether an inventor named in an earlier-filed application actually derived (*i.e.*, obtained) the invention from an inventor who filed an application later.

Under the new system, it is likely that there will be a fundamental shift in advice patent counsel give about when patent applications should be filed, as well as whether inventions should be disclosed prior to filing. Applicants no longer will be able to use their laboratory notebooks and other non-public records to establish dates of invention in order to predate references cited by the Patent Office. Only the date of prior public disclosure of the invention by the inventor, if applicable, and the filing date of the application itself, will be used in the novelty determination. Hence, the dates of these activities will become even more important than before.

Novelty Requirements under the America Invents Act

Most of the novelty requirements in the U.S. patent laws change on March 16, 2013. For example, it no longer will be necessary, or even relevant, to consider whether an invention to be patented was *invented* prior to certain activities.

Under the new system, there will be only two relevant dates of an invention to be patented:

> (1) the *filing date* of the application or, if the application claims the priority of a previously filed application, the application's "priority" filing date; and
>
> (2) the *public disclosure date* of the invention by the inventor (but only if the public disclosure date occurs no more than one year before the filing of the application).

The new law provides that the novelty requirement is satisfied *unless:*

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public [anywhere in the world] before the … filing date of the claimed invention; or
>
> (2) the claimed invention was described in a [U.S.] patent …, or in [a U.S. or Patent Cooperation Treaty (PCT) published application] … [that] names another inventor and was … filed before the … filing date of the claimed invention.

Hence, the new law seemingly sets out an absolute novelty requirement for U.S. applications; that is, novelty is satisfied if the invention is not publicly disclosed in any manner, or on sale, by anyone before the filing date. The new law also provides that U.S. patents and published U.S. or PCT applications (regardless of when published or issued) can be cited against an application (*i.e.*, to defeat novelty) so long as such patents/published applications were filed before the *filing date* of the application under examination and have an inventorship different from the application under examination. But, the "Exceptions" section of the new law modifies this absolute novelty requirement if the inventor discloses the invention prior to filing.

The "Exceptions" section provides that the inventor's own public disclosures, if made within the one-year grace period before filing, do not impact the novelty of the invention. In addition, disclosures of others, including patent filings of others, that occur after the inventor's own public disclosure do not impact the novelty of the invention. Finally, a prior patent filing does not impact novelty if such prior filed application and the application under examination are commonly owned.

Under the new system, the one-year grace period exists only in the event of prior disclosure by the inventor himself (or by his employer or by someone else who derives information from the inventor). Should the invention be maintained in confidence until the application is filed, there is *no grace period* and, thus, public activity that occurs *anywhere in the world* prior to filing and prior filings of others, if relevant, are citable against the application.

Importantly, not disclosing an invention before filing an application is a strategy that is strongly encouraged, if not absolutely required, in Europe and in many countries in other parts of the world. Applicants therefore should be strongly advised that there is no grace period with respect to third party prior art if they do not disclose the invention before filing. However, prior disclosure may, as indicated above, jeopardize foreign patent rights.

There is no grace period if the invention is maintained in confidence.

The new system also redefines the term "prior art" to include prior offers for sale and public use *anywhere in the world,* as well as anything that is *"otherwise available to the public,"* before the filing date of the application. Interestingly, until the courts identify examples of conduct that are "otherwise available to the public," it will remain unclear what that phrase is intended to cover that is not already covered by the Act. It also will remain unclear whether offers for sale, particularly non-public offers for sale, by the inventor would constitute prior art against the inventor's own application. Moreover, U.S. patents and published U.S. and PCT applications with an inventorship different from the application under examination and that are not jointly owned with the application under consideration are prior art as of their *priority* filing date inclusive of prior foreign filings, if applicable. Under the old system, the foreign priority of a potential reference was not relevant.

These changes will be better understood as time passes, and particularly as the Patent Office and the courts offer their guidance as to how certain terms and requirements of the new provisions are to be construed. While we expect to hear within the next year from the Patent Office, instructing patent examiners as to how to interpret the new novelty requirements, we will not be hearing from the courts for at least several years, since the new novelty provisions do not come into effect for new applications until March 16, 2013.

Post-Grant Proceedings in the Patent Office

In an effort to improve the quality of issued U.S. patents, the America Invents Act creates several new proceedings that may be brought in the Patent Office after patent applications issue as patents.

Post-Grant Review (Opposition Proceeding)

A third party may request post-grant review of a patent that has an effective filing date after March 15, 2013. Post-grant review must be requested within nine months of the issuance of the patent whose validity is being questioned. The grounds on which post-grant review may be requested include non-statutory subject matter, lack of novelty, obviousness, or a lack of definiteness, enablement, or written description. Currently, it is not clear whether failure to describe the best mode of the invention is a sufficient ground on which the request may be brought, since a patent may no longer be invalidated on this ground in a federal court.

The threshold for granting post-grant review will be that "it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or "if the petition raises a novel or unsettled legal question that is important to other patents or patent applications."

Once the Patent Office makes a final decision, the third party requestor will be precluded from asserting or reasserting before the Patent Office or in a court or an International Trade Commission (ITC) proceeding the unpatentability or invalidity of a claim on any ground that was raised or that reasonably could have been raised during the post-grant review. Currently, it is unclear whether post-grant review in the United States will become as popular as opposition practice has been in Europe.

Transitional Post-Grant Review for Asserted Business Method Patents

A third party may request, after September 15, 2012, a "transitional" post-grant review by the Patent Office of a business method patent (that issued on any date) if that third party is sued for infringement or charged with infringement under that patent.

However, if a general post-grant review is available for a particular patent (*i.e.*, the patent has an effective filing date after March 15, 2013), then this "transitional" program is not available for that patent.

As defined in the statute, a business method patent is one that "claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a *financial* product or service" (emphasis added). "Technological inventions" are expressly excluded. Hence, in accordance with this definition of business method patents, business-related method patents that do not pertain to a financial product or service, such as a non-technological manner of delivering goods or a non-technological manner of compiling information, are not eligible for "transitional" post-grant review.

Review by the Patent Office under this transitional program will be limited to issues actually raised by the third party requestor. If the Patent Office renders a final decision, the third party requestor is precluded from re-asserting in a court or ITC proceeding the unpatentability or invalidity of a claim on any ground raised during the transitional post-grant review. The transitional proceeding is available for eight years and will be replaced by general post-grant review as that process becomes available for all patents.

Inter Partes Review

Inter partes review, which replaces inter partes reexamination on September 16, 2012, is intended to be a relatively quick and inexpensive proceeding for challenging a patent's validity in the Patent Office. A third party may request inter partes review of any patent (that issued on any date) that challenges the patentability of one or more claims based solely on prior art patents and printed publications.

The request must be filed after the later of (a) nine months after the grant of the patent (or reissue of the patent) (the period during which a post-grant review may be requested) or (b) the date of termination of a post-grant review of the patent, if one was initiated. The requestor must show "a reasonable likelihood" that the requestor "would prevail" with respect to at least one of the challenged claims. The burden of proving unpatentability is a preponderance of the evidence.

Inter partes review includes litigation-type proceedings, such as (limited) discovery, protective orders, filing of supplemental arguments, rebuttal arguments by the patent owner, etc. The patent owner is permitted to amend a claim to overcome a challenge, but without enlarging the scope of the claim or introducing new matter into the patent.

The proceeding must be completed within 12 to 18 months from its initiation. Upon a final determination, the third party requestor is precluded from asserting or reasserting before the Patent Office or in a court or ITC proceeding the unpatentability or invalidity of a claim on any ground that was raised or that reasonably could have been raised during the inter partes review.

Supplemental Examination

As of September 16, 2012, a patent owner may request a supplemental examination of any patent (that issued on any date) for the Patent Office to consider, reconsider, or correct information believed to be relevant to the patent. For example, a supplemental examination request may be made to consider a reference that was not considered during the original examination.

If the presented information raises a question of patentability of one or more claims, the Patent Office may initiate a reexamination of the patent. With limited exceptions, a court proceeding may not result in a finding of unenforceability of the patent based on information considered during a supplemental examination of that patent.

Expanded Prior Commercial Use Defense in Patent Infringment Actions

The America Invents Act expands the prior commercial use defense so it is now available as a defense to patent infringement of nearly any type of asserted patent. The effective date of this change was September 16, 2011, so the expanded defense is available now. Previously, the defense was limited only to asserted business method patents.

The party asserting the defense must prove, by clear and convincing evidence, that it commercially began to use a process, machine, manufacture, or composition of matter (*i.e.*, the alleged infringing conduct) in the U.S. at least one year before the earlier of: (a) the effective filing date of the application of the asserted patent; or (b) the date of public disclosure by the inventor of the invention claimed in the asserted patent (see discussion of "Exceptions" on page 4 in "Novelty Requirements under the America Invents Act"). The party asserting the defense also must not have subsequently abandoned such use. The defense is personal to the user and is not transferrable or assignable, except when the entire enterprise or line of business is transferred or assigned. The defense is not a general license to carry out the patent in any manner and to any extent, and may be unavailable for activity that extends beyond that which gave rise to the defense.

The statute provides that activities that qualify as "commercial use" in the defense include premarketing regulatory review of a product or service during which safety or efficacy is being established, and laboratory use by a nonprofit research laboratory or other nonprofit entity (*e.g.*, university, hospital) for which the public is the intended beneficiary (but only for continued and noncommercial exploitation). The statute further provides that the prior commercial use defense cannot be asserted against a U.S. institution of higher education that used federal funds to reduce the invention to practice.

Selected Patent Litigations

Inequitable Conduct Is Now Harder to Prove – the Therasense Decision

A patent applicant and others involved in the patent process have a duty of candor and good faith in dealing with the Patent Office, which includes a duty to disclose to the Patent Office all known information that is material to the patentability of the invention claimed in the application. A finding of inequitable conduct (*i.e.*, fraud on the Patent Office) usually will result if a patent applicant fails to disclose, during the examination of an application, a known, material reference with the intent to deceive the Patent Office.

In the past decade, inequitable conduct has been raised as a defense to patent infringement in most patent infringement actions. This defense has now become significantly harder to prove, as a result of the Court of Appeals for the Federal Circuit's opinion in *Therasense, Inc. v. Becton, Dickinson and Co.* (Fed. Cir., May 25, 2011). According to the Federal Circuit, a finding of inequitable conduct requires a showing, by clear and convincing evidence, that the patent applicant: (1) knew of a particular prior art reference; (2) knew that the reference was material; and (3) made a deliberate decision to withhold the reference. As the Court held, each of these requirements must be separately proven, and the Court clarified that "material" in the second requirement means that "but for" the failure to disclose the reference the Patent Office would not have issued the patent.

Prior to the *Therasense* decision, most courts applied a "sliding scale" test for inequitable conduct, in which a greater showing of materiality permitted a lesser showing of intent to deceive. The *Therasense* Court expressly rejected the "sliding scale" test. Hence, it is expected that district courts will now be reluctant to find inequitable conduct in cases where known, potentially relevant references (*e.g.*, references known to the patent attorney in other matters) were inadvertently not disclosed or where known, non-invalidating references were intentionally not disclosed.

Patent-Eligible Subject Matter: Supreme Court Revisits What Kinds of Discoveries Can Be Protected

Under long-standing U.S. Supreme Court precedent, abstract ideas, laws of nature, and natural phenomena are not patentable, regardless of how much effort was expended in their discovery or how useful such discoveries may be. These types of discoveries and ideas are free for all to use and cannot be monopolized by the first to identify them. The Supreme Court, on December 7, 2011, heard arguments in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* on the issue of whether naturally occurring biological correlations of the type that are often used in medical diagnostic tests are patent-eligible subject matter. The Supreme Court had been set to address this important issue in 2006, in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, but ultimately dismissed that case on procedural grounds, without reaching a decision on the merits of the issue.

The patents at issue in the *Mayo* case cover methods for determining whether a patient has received an efficacious, minimally toxic dose of a certain drug. The methods consist of the steps of administering the drug, measuring the levels of certain metabolites of the drug in the patient, and then comparing these metabolite levels to certain pre-determined levels. The trial court held that the patents were not valid because the correlations between the metabolite levels and drug efficacy/toxicity were natural phenomena resulting from a natural body process. The trial court's decision was reversed on appeal.

The outcome, which is expected no later than Spring 2012, will be of particular interest to pharmaceutical companies, which often seek to patent medical diagnostic tests that they have developed based on naturally occurring correlations, and to health care providers who want to use such correlations in making medical diagnoses without the extra cost of patent royalties.

Online Transactions & Divided Infringement – Federal Circuit Reconsiders Law

A patent on a method usually includes several steps. The patent is infringed when an accused infringer performs all of the steps. The issue of divided infringement arises when the various steps are performed by different entities. For example, in the case of a patented online purchasing method, on the front end, a consumer uses his personal computer to enter data into the retailer's website, while, at the back end, the retailer's computer system performs the other steps necessary to complete the purchase. To prove direct infringement in this situation, current case law requires the patent owner to establish that the consumer is acting as an agent of the retailer. But in most types of online transactions, there is no agency relationship between the front-end user and the back-end system provider.

The Court of Appeals for the Federal Circuit heard arguments for reconsidering this law on November 18, 2011, when it conducted a full court rehearing in two cases: *Akamai Techs., Inc. v. Limelight Networks, Inc., and McKesson Techs. Inc. v. Epic Sys. Corp.*

One question presented to the Federal Circuit is:

> If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?

The outcome will be of particular interest to online retailers, financial services providers and other businesses that enable on-line transactions.

For further information about the America Invents Act, the patent decisions discussed in this Newsletter, or other patent matters, please contact ***Mark Montague*** *(mxm@cll.com) (212) 790-9252 or* ***Anastasia Zhadina*** *(axz@cll.com) (212) 790-9286.*

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Recent Honors

CLL and its Partners have been named in several peer surveys, including:

- *U.S. News-Best Law Firms* ranked CLL as **National Law Firm of the Year 2012** in Trademark Law.
- *The Lawyers World* magazine selected CLL as **Intellectual Property Law Firm of the Year 2011.**
- The *New York Super Lawyers* survey named 16 of our partners in 2011 in the fields of Intellectual Property Counseling and Litigation, Business Litigation, Entertainment & Sports, and International Trade.
- Towergate Software announced that CLL filed the most trademark oppositions of any firm in the United States in 2010 and again in 2011.
- *Intellectual Property Today* will be announcing that CLL acquired 278 U.S. patents for its clients in 2011.

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