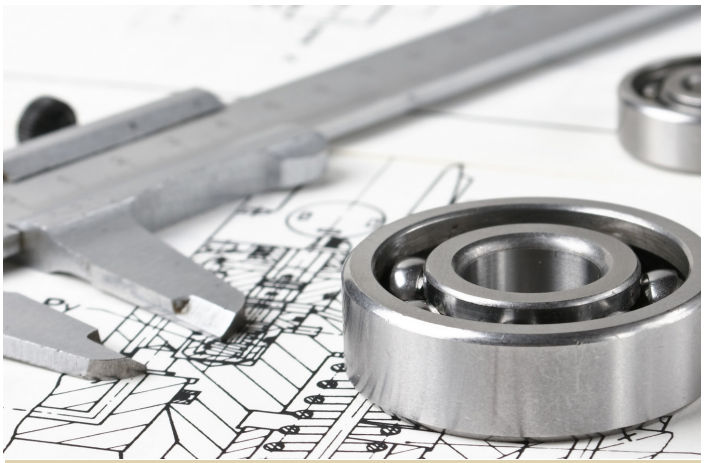

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AMERICA INVENTS ACT FINAL IMPLEMENTATION: FROM FIRST-TO-INVENT TO FIRST-TO-FILE

by Chris Mitchell, Esq., Ann Arbor Office

The America Invents Act ("AIA"), which went into effect September 16, 2011, introduces some of the most significant changes to the U.S. patent system since the first U.S. patent was issued in 1790. Under the AIA's rolling implementation, we've already seen new law go into effect repealing the "Best Mode" defense, changing the nature of "false patent marking" claims, incentivizing "virtual patent marking," and changing the way patent grants are challenged in the U.S. Patent and Trademark Office ("USPTO"). Now, as of last week, the last of these changes have been implemented and the U.S. has officially gone from a "first to invent" to a "first to file" jurisdiction.

Historically, patent grants in the U.S. have gone to the first party to invent the claimed subject matter. No longer. Like much of the rest of the world, patent rights in the U.S. will now go to the first inventor to file an application in the USPTO for the claimed invention.

As part and parcel of the U.S. move to "first-to-file," the novelty requirement is changing to create an absolute bar to patentability if the claimed invention of a patent application 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 patent application's effective filing date***. This is a major change. The law before the AIA recognized as a bar to patentability foreign patents and printed publications only; public use, sale or other "public availability" outside of the U.S. was not considered. In addition, the law before the change also permitted applicants in some situations to prove that they came up with their inventions before the effective date of a cited patent or printed publication. Now what matters is when the inventor ***filed*** his patent application, and not when he ***came up with*** the invention.

The guts of these changes are embodied in new Section 102(a), which states that "[a] person shall be entitled to a patent unless—

1. the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

2. the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application,

as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Exceptions are carved out in Section 102(b) for certain disclosures made before the effective filing date of the claimed invention, as well as certain disclosures made in patents and applications:

1. A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

   A. the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

   B. the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

2. A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if--

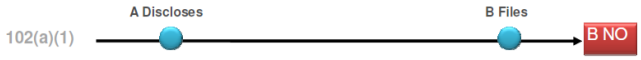
   A. the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

   B. the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

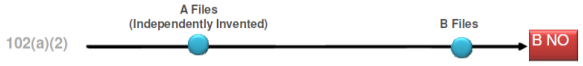
   C. the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

Let's look at a few practical examples of how these provisions will impact the ability to get a patent under the "first to file" system.

SECTION 102(a)(1): In this basic, Party A publicly discloses her invention and, within a year, Party B files an application to patent the same invention. Party B can't get a patent on the invention, ***even if*** he can show that he conceived of his invention before Party A's publication. What matters is when Party B filed, not ***when*** he invented.



SECTION 102(a)(2): In the next situation, Party A ***files*** an application for patent in the USPTO. ***Later***, Party B files an application to patent the same invention. Again, even if Party B could show prior conception of the invention, he would not be entitled to a patent. (As indicated, this situation presumes that Party A independently came up with the claimed invention rather than deriving it from Party B and then beating Party B to the USPTO.)



SECTION 102(b)(1)(A): In this situation, Party B publicly discloses his invention and then, ***less than a year later***, files an application claiming that invention. Because the filing was made within a year of the public disclosure date, Party B is still entitled to a patent.

SECTION 102(b)(1)(A): Where separate inventors work on similar inventions at the same time, the old "first-to-invent" system could result in proceedings at the USPTO to determine who was the first to come up with the claimed invention. What happens under the AIA's first-to-file system? "Can someone just steal my invention and file before I do?" is a fairly common question. Fortunately, the new laws guards against a party getting a patent on subject matter obtained from a later-filing inventor. In this situation, Party A discloses her invention and, less than a year later, Party B files an application in the USPTO claiming that invention. In this case, however, Party A obtained her invention from Party B. Accordingly, Party B is entitled to a patent for the claimed invention; provided, of course, that he can prove that Party A derived the disclosed invention from him. This requires the true inventor (Party B) to either institute a "derivation proceeding" in the USPTO or to file a case in federal court.

SECTION 102(b)(1)(B): In this situation – and perhaps the oddest circumstance possible under the new law – Party B publicly discloses his invention and then Party A, unaware of Party B's invention or disclosure, publicly discloses the same invention. Only ***after*** Party A's public disclosure does Party B file an application claiming the invention. Shouldn't Party A's public disclosure defeat Party B's ability to patent his invention in the "absolute novelty" environment created by the AIA? No. Under Section 102(b)(1)(B), Party B's even earlier public disclosure trumps any intervening, third party disclosures. However, Party B must have filed his application within a year of his public disclosure.

Clearly, the changes wrought by the AIA will take some getting used to, just as they will certainly require more deliberate strategic planning when it comes to inventions, both patentable and not, in order to create the strongest competitive position possible.

ARE HUMAN GENES PATENTABLE?

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The Supreme Court has long held that laws of nature, natural phenomenon, and abstract ideas are not patent eligible under 35 U.S.C. § 101. *See, e.g., Diamond v. Diehr*, 450 U.S. 175 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Since 2010, the Supreme Court has twice more considered this issue, both times reversing the Federal Circuit. *Mayo Collaborative Serv. v. Prometheus, Inc.* 132 S. Ct. 1289 (2012) (a method of optimizing the efficacy of a drug is an unpatentable law of nature); *Bilski v. Kappos* 130 S. Ct. 3218 (2010) (a method of hedging risk in trading commodities constitutes an unpatentable abstract idea). On April 15th, the Supreme Court will hear yet another case concerning patent eligible subject matter, this time on an issue of great importance to the biotechnology industry; namely, the patentability of human genes. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, U.S. No 12-398, (Nov. 30, 2012).

The claims at issue involve two genes known as BRCA1 and BRCA2. The *Myriad* inventors discovered that mutations in these genes are associated with a predisposition to breast and ovarian cancers. Women having BRCA mutations are said to have a cumulative risk of fifty (50%) to eighty (80%) percent of developing breast cancer and a cumulative risk of twenty (20%) to fifty (50%) percent of developing ovarian cancer. The discovery of these gene mutations and methods of diagnosing them are of paramount importance to millions of women.

The gene claims in the disputed patents are of two types: claims directed to "isolated" DNA encompassing full-length or genomic DNA sequences that are identical to the naturally-occurring BRCA1 and BRCA2 genes, and claims to shorter "isolated" DNA sequences including cDNA sequences as well as DNA fragments as small as fifteen (15) nucleotides.

In the District Court, Judge Sweet ruled that the "isolated" DNA sequences were unpatentable "products of nature." *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). Myriad appealed to the Federal Circuit, arguing, inter alia, that DNA isolated from the human body "differs markedly" from naturally-occurring DNA and that, unlike native DNA, the isolated BRCA DNA can be used for other purposes such as probes for diagnosing cancer. *Ass'n for Molecular Pathology v. U.S.P.T.O.* 653 F. 3d 1329 (Fed. Cir. 2011) (*Myriad I*).

Writing for the majority, Judge Lourie held that "isolated" BRCA1 and BRCA2 DNAs differ in chemical nature from BRCA DNA as it exists in the human body. Judge Lourie pointed out that in the natural state, the BRCA genes exist on chromosomes surrounded by other proteins such as histones. According to Judge Lourie, in order to isolate DNA from its native environment, covalent bonds between the DNA and the proteins which surround it, and the covalent bonds within the chromosomal backbone itself, must be broken. In his opinion, the cleavage of these covalent bonds constitute a chemical manipulation that require human intervention and result in a new, chemically distinct composition. Using this analysis, he found that both the full-length DNA sequences and the shorter 15 nucleotide fragments were not products of nature and thus patentable under §101.

With respect to the claims to cDNA sequences, Judge Lourie found that these were directed to non-naturally occurring man-made DNAs lacking the non-coding sequences (introns) present in the native BRCA genes. Accordingly, he concluded that they, too, were patent eligible.

Judge Lourie also noted that the USPTO has issued patents directed to human genes for over thirty (30) years. He argued that it was up to Congress, not the courts, to change the *status quo* by passing legislation to exempt DNA inventions as statutory subject matter under § 101.

Judge Lourie's fellow panel member, Judge Moore, concurred, but for different reasons.

Judge Bryson dissented, arguing that "breaking covalent bonds or isolating a gene from its natural setting does not turn DNA into a human-made invention any more than plucking a leaf from a tree would convert it [the leaf] into a man-made composition."

The ACLU filed a petition for *certiorari* which the Supreme Court granted. Rather than hearing the case, the Court vacated the Federal Circuit's decision and remanded for further consideration in light their concurrent decision in *Mayo Collaborative Serv. v. Prometheus Laboratories, Inc*. On remand, the Federal Circuit maintained its earlier position.

The Supreme Court has now twice granted *certiorari* for *Myriad*, and presumably is eager to weigh in on this issue. There is no end to the speculation on how it might rule. It is indisputable that the claims directed to full-length BRCA nucleotide sequences, and smaller fragments thereof, are identical to naturally-occurring DNA sequences. The question is whether the Court will agree with the Federal Circuit that DNA in its natural state differs chemically from "isolated" DNA.

Without doubt, a finding by the Court that human genes are products of nature and, therefore, not patent eligible, would have a devastating impact on the biotech community. The biotech industry was spawned with the advent of recombinant DNA technology in the early 1980s. As a result, treatments, diagnostic assays, and gene therapies have been developed for countless diseases and disorders. Absent patent protection, innovation in scientific fields that rely on the discovery and use of DNA would arguably come to a halt because there would be less incentive to invest in these areas.

Consequently, it may be that Court will punt and, like Judge Lourie, find that the USPTO has issued patents on human genes for so long that, absent Congressional action, this practice should not be disturbed by the courts.

However, should the Court decide that human genes are not patent eligible, patent prosecutors should not despair. Methods of using a known product in a novel manner would still be patentable, as are methods that incorporate a law of nature; provided the method does not preempt all uses of the law itself. While many commentators have argued that diagnostic methods are no longer patentable in view of

Prometheus, this is not necessarily the case. In *Prometheus*, the Court specifically reiterated its position that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." (*Citing Diamond v. Diehr*, 450 U.S. at 187.)

It is important to note that the *Myriad* patents include claims directed to methods of using the isolated DNA sequences to screen for potential therapeutic agents that the Federal Circuit held were patent eligible. The Supreme Court denied cert. on this issue. This would seem to send a strong signal that, if properly written, methods of using novel human DNA sequences will continue to be patent eligible even if the Court holds that sequences themselves are not.

APPLE RETAIL STORES RECEIVE TRADEMARK PROTECTION

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In Walter Issacson's 2011 biography of Steve Jobs, Issacson recounts how in 1999, after returning to Apple, Steve Jobs began to interview executives to develop a string of new Apple retail stores. At the time, Gateway Computers was on the verge of bankruptcy after opening its suburban stores, and Dell was succeeding by selling direct to customers without stores. Nonetheless, Jobs correctly predicted that if Window users, in particular, were passing by and found the Apple store inviting enough, Apple would win.

Jobs envisioned that the stores would be minimalistic and offer places for potential customers to try things out. "The stores would impute the ethos of Apple products: playful, easy, creative, and on the bright side of the line between hip and intimidating." When the final prototype retail store was completed in January 2001, the board approved going ahead so that Apple might take its brand to a new level and ensure that consumers did not come see Apple computers as commodity products like those of Dell or Compaq.

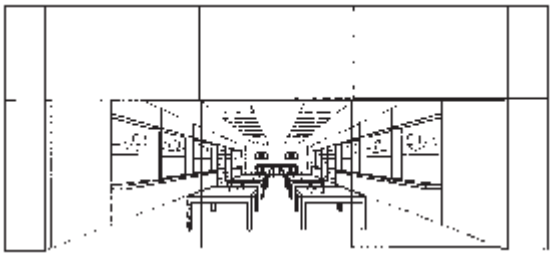
In May 19, 2001, the first Apple store opened in Tyson's Corner, Virginia with white counters, bleached wood floors, and a huge "Think Different" poster of John Lennon and Yoko in bed. Many outside experts at the time publically predicted that the stores would fail. But the skeptics could not have been more wrong. By 2004, three years before the introduction of the iPhone and six years before the introduction of the iPad, Apple stores had achieved $1.2 billion in revenue, setting a record in the retail industry for reaching the billion-dollar milestone.

A notable feature of the stores was the Genius Bar. The idea of the Genius Bar surfaced during a retreat in which Apple team members were asked to describe the best service they ever enjoyed. Almost all of the participants mentioned service they received at the Four Seasons or Ritz-Carton hotels. Apple's first five store managers were then sent through the Ritz-Carton training program, and it was there that the idea was born to create something new in the computer retail industry: a cross between a concierge desk and a bar. Staffed with the smartest Mac technical advisors, an oblong table with stools at the back of the store was named the GENIUS BAR.

There are now more than 326 Apple stores. The reported average annual revenue per store is $34 million and the total net sales in fiscal 2010 were reportedly $9.8 billion. By deliberately placing the stores in high traffic areas, the Apple stores were enormously influential in fueling Apple's brand awareness.

On January 22, 2012, following a lengthy and contested process, the United States Patent and Trademark Office granted registered trademark protection to the design and layout of Apple's retail stores. Initially, registration was refused because the claimed mark, a three dimensional configuration, commonly referred to as trade dress, was not -- according to the examiner -- perceived as a source identifier, but only as decoration or ornamentation. In its response, Apple argued that the law was well established by virtue of the Supreme Court holding in *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 765 (1992) that a retail establishment's trade dress can immediately be perceived as a source identifier and is thus capable of protection. In the alternative, Apple argued that if Apple's particular configuration was not immediately perceived as a source identifier, that because of its tremendous success, consumers had come to recognize the configuration as a source of Apple products. To support its claim, Apple submitted hundreds of pages of evidence showing the success of Apple's retail stores, consumer awareness of the configuration, and Apple's marketing efforts to increase consumer awareness of its store designs. After considering the evidence, the United States Patent and Trademark office granted the registration on the basis that the configuration has acquired distinctiveness and as such was recognized as a source identifier.

The mark covers the Apple store's clear glass storefront surrounded by a "panel façade consisting of large, rectangular horizontal panels over the top of the glass front, and two narrower panels stacked on either side of the storefront," and "cantilevered shelves below recessed display spaces along the side walls, and rectangular tables arranged in a line in the middle of the store parallel to the walls and extending from the storefront to the back of the store." See U.S. Trademark Registration No. 4,277,914.



Although Apple did not claim the walls, floors, lighting or other features of the store individually, the placement of the various items are nonetheless considered to be part of the overall mark including the GENIUS BAR described as an "oblong table with stools located at the back of the store."

The protection afforded Apple's retail store design and layout serves as a reminder that trademarks need not be limited to words or logos, but may, under the right circumstances, include any number of non-traditional identifiers of source, including appearance, shape, color, sound, and even the layout of an originally designed and successful retail store.

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