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Patents

Will Post-Grant Reviews Find a Place in the Molecular Diagnostic Industry?

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To date, less than 50 *inter partes* reviews (''IPRs'') related to molecular diagnostic patents have been filed with the U.S. Patent and Trademark Office (''PTO''). Of these, only 10 have completed trial before the PTO's Patent Trial and Appeal Board (''PTAB''). One reason for the low number of filings may be the limited grounds on which IPRs can be brought. IPRs only permit challenges for anticipation and obviousness. However, the most popular and recently fruitful invalidity challenge for diagnostic patents is the patent eligibility requirement under 35 U.S.C. § 101 (''Section 101'').

The Supreme Court's recent decisions in the *Alice, Prometheus* and *Myriad* cases[1] have vaulted Section 101 subject matter eligibility challenges to prominence. Under Section 101, laws of nature, natural phenomena and abstract ideas are not patentable. The Supreme Court has established a two-step approach to analyze subject matter eligibility: (1) are the claims directed to a patent-ineligible concept (*e.g.*, a naturally occurring product or law of nature), and (2) if yes, do the claims contain additional elements that transform the nature of the claim into a patent-eligible application. In other words, the court examines whether the patent contains an ''inventive concept''—an element or combination of elements that is sufficient to ensure that the claimed invention amounts to significantly more than a patent-ineligible concept.

In *Prometheus*, the court considered patents that claimed processes to determine the proper dosage of a drug based on the relationship between the administration of the drug and the amount of certain metabolites in a patient's bloodstream. In finding that the claims were not directed to patent-eligible subject matter, the court noted that the patents simply recited a correlation between naturally-occurring processes in the response to the drug—a relationship that existed apart from any human action. In the *Myriad* case, as well as the more recent U.S. Court of Appeals for the Federal Circuit *Myriad* decision[2], isolated gene sequences and primers were found to be naturally-occurring products that fell into the patent-ineligible realm. *Myriad* and its progeny, however, left the door open for other gene-related inventions: cDNA sequences, method claims related to the manipulation of genes and applications of knowledge based on identified genes remain patentable.

In the aftermath of *Prometheus*, *Myriad* and *Alice*, there has been an increase in the number of Section 101 challenges in district court proceedings. Defendants are using both Federal Rules of Civil Procedure Rule 12(b)(6) motions to dismiss and summary judgment motions to challenge asserted patents on subject matter

[1] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (''*Prometheus*''); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (''*Myriad*''); *Alice Corp. Pty Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (''*Alice*'').

[2] *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014) (''*Myriad II*'').

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eligibility grounds. Many courts will consider a motion to dismiss on Section 101 grounds early on in the litigation timeline, for example, prior to claim construction. These courts reason that if a patent is plainly directed to patent-ineligible subject matter, it is the type of deficiency that should be exposed at the early stages of litigation. These subject matter eligibility challenges have been largely successful. Reports suggest that post-*Alice*, district courts have found patents invalid under Section 101 in approximately 70 percent of cases.[3]

Recently, the Federal Circuit took another look at diagnostic methods claims in the *Ariosa* case.[4] The Federal Circuit applied the *Prometheus* test to invalidate a patent claiming methods for using cell-free fetal DNA (''cffDNA'') to detect and diagnose fetal genetic characteristics. The cffDNA is extracted from a blood sample taken from the mother. Part of the discovery was understanding that a maternal blood sample contains detectable levels of DNA from the fetus, so that a noninvasive diagnostic test could be applied. Though a concurring opinion characterized the invention as ''truly meritorious'' and distinguishable from the invalidated claims in *Prometheus*, the majority held the patent was invalid under Section 101. The court reasoned that the method started and ended with a naturally-occurring product, the cffDNA. It further reasoned that no genetic information was altered, and the location of the nucleic acids existed in nature prior to the inventor's discovery. Thus, for now, recent cases indicate that Section 101 remains a powerful ground for challenging molecular diagnostic patents.

Section 101 and Post-Grant Reviews

Given the success rate of these challenges, Section 101 could be a robust challenge to employ in post-grant procedures available at the PTO. These procedures have a reduced burden of proof as compared to the clear and convincing standard required in district court. They are intended to be quicker and less costly than traditional patent litigation. Most post-grant challenges also do not require a threat of infringement to initiate—any third party can file a petition. Thus, these procedures can be used, for example, by a new entrant or a competitor to ''clear a path'' for product development before its products reach the market and a competitor threatens suit.

But there is a catch—Section 101 claims cannot be brought in an IPR, only in post-grant review (''PGR'') challenges, and this procedure comes with some limitations. PGRs are only available for patents with an effective filing date on or after March 16, 2013. Patent eligibility for earlier patents is an issue reserved for district courts as a defense to infringement or in a declaratory action. This limitation takes out a large number of patents that are currently in force in the diagnostics space.

PGRs also must be filed within nine months of the patent's issuance. In contrast, IPRs may be brought at any time after the patent issues. This again removes a number of the patents that would be theoretically eligible based on filing date. It requires a challenger to be vigilant about monitoring patent applications and the likely evolution of their claims as they proceed to issuance. Additionally, this time limitation for filing a PGR brings with it a risk. By bringing a PGR, the challenger places itself on the patent owner's radar even before any threat of litigation may exist.

The proposed speed advantage of post-grant procedures also may be fading. It generally takes about six months after the petition is accepted for the PTAB to issue a decision whether or not to institute the PGR. The PTAB then has one year after institution to reach a final decision, subject to a six-month extension for good cause.[5] This puts the resolution of the PGR at approximately 18 months from filing. The recent success of motions to dismiss in district court based on Section 101 challenges, however, also offers a quick path to address subject matter eligibility. Moreover, the district court path allows a challenger to raise the issue before significant time and expense are expended in discovery, and at the same time, only face the time and cost of challenging the patent when and if litigation proceeds.

PGRs also come with the baggage of estoppel. A challenger is estopped from later raising any ground that was raised or reasonably could have been raised in the PGR.[6] This estoppel affects future proceedings in district courts and the International Trade Commission as well as additional PGR procedures before the PTO. Thus, having filed a PGR, the challenger may find itself estopped in a subsequent infringement action, not only from raising Section 101 issues, also from bringing additional invalidity defenses such as anticipation, obviousness, written description and enablement. This estoppel can present a fearsome picture for challengers when facing infringement allegations. Given the magnitude of the effect, a challenger raising Section 101 issues in a PGR should likely raise other invalidity grounds as well to the extent that they apply.

It should be kept in mind, however, that the estoppel only attaches if the PGR reaches a final written decision. The PTO's decision not to institute a PGR does not fall under the estoppel provisions. Thus, a failed attempt at invalidating claims through a PGR still leaves open challenges in court proceedings and future PTAB proceedings on both Section 101 and additional invalidity grounds. However, the decision not to institute a post-grant proceeding is public and discoverable. A number of patent owners have argued to include the PTAB's decision not to institute an IPR in their trial evidence to counteract parallel invalidity challenges in district court. The response of courts to the admission of this evidence has been mixed.[7]

PTAB Consideration of Section 101

A key question remains as to how Section 101 claims will fare in front of the PTAB. Will they have similar success rates as compared to the district courts? And will this rate differ between technology fields? Although diagnostic patents have not yet found their way into the PGR queue, the PTAB has recently instituted its first

[3] See http://cpip.gmu.edu/2015/08/10/alicestorm-in-june-a-deeper-dive-into-court-trends-and-new-data-on-alice-inside-the-uspto/.

[4] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (''*Ariosa*'').

[5] 37 C.F.R. § 42.200(c).

[6] 35 U.S.C. § 325(e).

[7] *See e.g., Stoneeagle Servs., Inc. v. Pay-Plus Solutions, Inc.*, 2015 BL 196583, 9 (M.D. Fla. June 19, 2015) (listing cases for exclusion but reaching an opposite decision).

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PGRs on Section 101 grounds in other technology areas.[8]

In the *American Sinmental* institution decision, the PTAB found that a patent claiming a method of determining an animal's relative economic value based on genetic and physical traits was directed to an abstract idea and that the use of a computer database was not something significantly more to transform the idea into patentable subject matter. Likewise, the panel in *Netsirv* found a patent directed to a containerized storage process was likely unpatentable. It reasoned that the process, which included steps for delivery and association of containers, receiving and storing an inventory, tracking containers and facilitating retrieval of container contents from storage, was a series of abstract steps that represented ''a fundamental economic practice long prevalent in our system of commerce.''[9] In the PTAB's view, the additional steps using a computer were ''routine, conventional, and/or well-known'' and did not convert the claims into patentable subject matter.

Although these patents are focused on other technologies, they demonstrate that the PTAB is willing to institute PGRs on subject matter eligibility grounds and generally follows the two-part *Prometheus* test for its analysis. How patents will fare in the full analysis remains to be seen. If these first few PGRs reach a final decision, it will provide the first basis to compare Section 101 challenges at the district court to those with the PTAB. Whether molecular diagnostic patent claims will see similar treatment awaits the entry of such patents into the PGR foray.

Overall, despite the unknowns and the potential constraints, PGRs offer a path to challenge patents under Section 101 as a defense that only formerly existed once patent litigation ensued. As more patents become eligible for PGR, time will tell if PGRs will become the avenue of choice for challenging molecular diagnostic patents on subject matter eligibility grounds.

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[8] *Netsirv v. Boxbee, Inc.*, PGR2015-00009 at Paper No. 10 (Aug. 4, 2015) (''*Netsirv*''); *American Sinmental Association v. Leachman Cattle of Colorado, LLC*, PGR2015-00003 at Paper No. 19 (June 19, 2015) (''*American Sinmental*'').

[9] *Netsirv v. Boxbee, Inc.*, PGR2015-00009 at Paper No. 10 (Aug. 4, 2015).