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Patent Eligibility in the Life Sciences

It's been six years since the Supreme Court's decision in *Mayo v. Prometheus*[1] and five years since the Court's decision in *Association for Molecular Pathology v. Myriad Genetics*[2]. How the standards for patent eligibility have been applied in the life sciences tends to vary based on the technology.

Healthcare IT/Telemedicine

- Healthcare IT patents cover methods and systems for selecting patient treatment – the heart of these methods is biostatistics. Telemedicine patents cover methods and systems for remote diagnosis and treatment of patients using telecommunication systems.
- Claims to these technologies have generally been analyzed as software claims under *Bilski*[3]. As such, most claims challenged in these areas have been found patent ineligible.
- <u>*Prosecution strategies for success*</u>: Patentability will rest on improvements in the function of computer technology (*Enfish*[4]) or a technological improvement (i.e. a technology based solution to a technical problem) (*Trading Technologies*[5]).

Personalized Medicine: Diagnostic/Prognostic Methods

- This field includes tools for genetic screening and methods of detecting, measuring, and correlating patient outcomes to biometrics.
- The analysis in *Mayo* is directly applied to these types of claims. The biological phenomenon at the heart of these claims is usually clearly apparent; thus, the patent eligibility analysis shifts to whether there is something more than the phenomenon in the claim that is innovative.
- Such claims are at issue in almost half of patent litigations in which patent eligibility has been assessed. The vast majority have been found patent ineligible, with the claims being considered as merely directed to implementation of a law or a product of nature using conventional lab techniques. Claims that were found to be patent eligible generally survived because the court considered them to be an improvement over existing technologies (*Exergen Corp.*[6]). However, as most of the challenged claims were broad in scope, it will be interesting to see if more narrowly focused claims (i.e. claims issuing post *Mayo*) will fare better.
- <u>*Prosecution strategies for success*</u>: When drafting claims, include new reagents and/or non-routine/unconventional steps or combinations of steps. Consider other ways to claim technology (e.g., components used, end products). Argue that the method provides significant improvement over existing technology.

Methods of Treatment

- This category involves methods of administering some form of treatment to a patient. In some instances, the claimed methods include diagnostic or prognostic elements to them.
- These claims are important for the pharmaceutical industry, providing protection around the identification of new dosing regimens and new conditions that a drug can be used to treat. These methods typically are follow-on innovations for existing drugs (i.e., the drug itself is not new).
- Dicta from the Supreme Court in *Myriad* and the Federal Circuit in *CellzDirect*[7] suggested that methods of treatment were patentable. Some district courts have found such claims patent ineligible, the Federal Circuit affirmed its position in *Vanda Pharma*[8] in April 2018. Because the decision in *Vanda Pharma* was split, the Federal Circuit may choose to rehear the case *en banc*, and an eventual petition for certiorari to the Supreme Court is possible.

Laboratory/Manufacturing Techniques

- Methods of performing laboratory techniques or for manufacturing products have had the strongest position relative to other methods with regards to patent eligibility.
- Considered to be useful innovations, courts have focused on the "desired outcome" and the "end result" achieved by these methods in finding patent eligibility (*CellzDirect*[9]).
- <u>*Prosecution strategies for success*</u>: When drafting claims, include the desired outcome/end result in the preamble and include, if possible, non-routine/unconventional steps or combinations of steps. Argue that the method is a significant improvements over the state of the art. Demonstrate real-world tangible applications for the method.

Compositions

- Technologies that fall within this category vary dramatically, including a diverse array of chemical and biological molecules that are claimed as compositions (e.g., small molecule drugs, proteins, peptides, nucleic acids, cells, formulations, and mixtures).
- The analysis for these types of claims generally rests on whether the claimed products are "markedly different" from the closest counterpart in nature.
- Product claims that have been found patent ineligible include cloned animals and DNA primers (isolated genomic DNA).[10] However, cDNA, combinations of DNA sequences that do not occur naturally together (e.g., combination of heterologous sequences), and sequences with non-natural substitutions are considered patent eligible.
- Nutraceutical compositions have recently been called into question at the district court level.[11] Composition claims to specific unit dosages of natural substance(s) or combinations of natural substances were found patent ineligible as directed to a natural product/phenomenon. Similarly, method of use claims were found patent ineligible as merely directed to the effect of the natural substance in the body (natural phenomenon). As all method of treatment claims rely to some extent on a law of nature or natural phenomenon, extension of similar reasoning to claims to other formulations would be problematic.
- Small molecule compositions and formulations are generally considered patent eligible. Aggressive litigants have challenged claims to compositions having particular pharmacokinetic effects, but these arguments were rejected.[12]
- Biologics, such as protein therapeutics, may be more vulnerable to challenge as their development often aims for them to be very similar to their natural counterparts.
- <u>*Prosecution strategies for success*</u>: In applications, emphasize novel or nonobvious characteristics different from the closest counterpart found in nature, such as biological or pharmacological functions or activities, chemical and physical properties, and structure and form (e.g., chemical, genetic, physical). Consider other ways to claim technology (e.g., kits, product in combination with other components during use).

Medical Devices

- Claims to medical devices – instruments, apparatus, implements, machines, or implants used alone, or in combination, for a medical purpose – have the strongest patent eligibility position of all the life science technologies.
- However, aggressive competitors have challenged such claims on patent eligibility grounds, illustrating the expansive use of Section 101 in challenging patent claims.

General Tips:

- The lines between Section 101 and Sections 102 and 103 are blurred, with a number of courts borrowing nonobviousness principles when assessing patent eligibility.
  - Draft applications to provide support for the inventive concept; identify problems in the art and improvements provided by invention.
- The Federal Circuit's recent decisions in *Berkheimer*[13] and *Aatrix Software*[14] establish that the patent eligibility analysis can include questions of fact.
  - Lay groundwork in the application for what is considered well-known, routine, and conventional in the art at the time of the invention, and distinguish invention from this prior art.
  - Identify distinguishing characteristics for compositions relative to counterparts in nature.

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1 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).
2 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).
3 *Bilski v. Kappos*, 561 U.S. 593 (2010).
4 *Enfish LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016).
5 *Trading Technologies Int'l, Inc. v. CQG, Inc.*, 675 Fed. App'x 1001 (Fed. Cir. 2017)(non-precedential).
6 *Exergen Corp. v. Kaz USA, Inc.*, Nos. 2016-2315, 2016-2341 (Fed. Cir. March 8, 2018); *see also Ameritox, Ltd. v. Millennium Health, LLC,* 88 F. Supp. 3d 885, 892 (W.D. Wis. 2015).
7 *Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).
8 *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*, Appeal No. 16-2707 (Fed. Cir. April 13, 2018)(precedential).
9 *CellzDirect, Inc.*, 827 F.3d at 1048-49, 1052; *see also Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, Civil Action No. 11-11681-NMG, 2017 WL 2623167 (D. Mass. June 16, 2017) (settled shortly after Federal Circuit decision in *CellzDirect*).
10 *In re Roslin Institute (Edinburgh),* 750 F.3d 1333 (Fed. Cir. 2014); In re BRCA1- and BRCA2- Hereditary Cancer Test Patent Litigation, 774 F.3d 755 (Fed. Cir. 2014).
11 *Natural Alternatives Int'l, Inc. v. Allmax Nutrition, Inc.*, 2017 U.S. Dist. LEXIS 99581 (S.D. Cal. June 26, 2017); *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC,* 2017 U.S. Dist. LEXIS 143434 (S.D. Cal. Sept. 5, 2017).
12 *Shire LLC v. Amneal Pharmaceutical, LLC*, 2014 U.S. Dist. LEXIS 85369 (June 23, 2014); *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 2015 U.S. Dist. LEXIS 114816 (S.D.N.Y. Aug. 14, 2015).
13 *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).
14 *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018).