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LIFE SCIENCES: LITIGATION UPDATE

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Overview

- Patent-Eligible Subject Matter (35 U.S.C. § 101):
 - *Myriad* discussion
 - *Alice Corp.* discussion
- Claim Definiteness (35 U.S.C. § 112):
 - *Nautilus* discussion
- Attorneys' Fee Awards (35 U.S.C. § 285):
 - *Highmark* discussion
 - *Octane Fitness* discussion
- Other Legal Developments:
 - Licensee DJ Actions – Burden of Proof (*Medtronic*)
 - Divided & Induced Infringement (*Limelight*)

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2

Patent-Eligible Subject Matter

35 U.S.C. § 101: “Whoever invents or discovers **any new and useful process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefore”

Patent-Eligible Subject Matter: *Myriad*

- *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, 689 F.3d 1303 (Fed. Cir. 2012)
 - Holding:
 - Isolated DNA = Patent-Eligible Subject Matter
 - Judge Lourie and Judge Moore agree but for different reasons; Judge Bryson dissents.
 - cDNA = Patent-Eligible Subject Matter:
 - All three Judges agree. *See id.* at 1329, 1340-41, 1356.

Patent-Eligible Subject Matter: *Myriad*

- Three DNA Molecule Claims:
 - 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
 - 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
 - 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.
- Two Types of DNA Molecules:
 - Isolated DNA: naturally occurring DNA sequences (e.g., claims 1 & 5)
 - Complementary DNA or cDNA: sequences of DNA that do not exist in nature and are synthesized from messenger RNA using complementary base pairing (e.g., claim 2)

Patent-Eligible Subject Matter: *Myriad*

- Isolated DNA (Judge Lourie):
 - “[T]he Supreme Court has drawn a line between compositions that . . . have similar characteristics as in nature, and compositions that human intervention has given ‘markedly different,’ or ‘distinctive,’ characteristics.” *Id.* at 1328.
 - “*BRCA1* and *BRCA2* in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.” *Id.* at 1328.

Patent-Eligible Subject Matter: *Myriad*

- Isolated DNA (Judge Moore):
 - Distinguished between “short” isolated DNA (e.g., primers and probes) and “long” isolated DNA (e.g., genes and gene fragments).
 - Short = Patent-Eligible Subject Matter: “The shorter isolated DNA sequences have a variety of applications and uses in isolation that are new and distinct as compared to the sequence as it occurs in nature.” *Id.* at 1341.
 - Long = Patent-Eligible Subject Matter: “If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter. . . . But we do not decide this case on a blank canvas.” *Id.* at 1343.

Patent-Eligible Subject Matter: *Myriad*

- Isolated DNA (Judge Bryson):
 - “The only material change made to th[e] genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are found in nature. While the process of extraction is no doubt difficult, and may itself be patentable, the isolated genes are not materially different from the native genes.” *Id.* at 1350.
 - “The use to which the genetic material can be put . . . is not a new use; it is only a consequence of possession.” *Id.* at 1354.

Patent-Eligible Subject Matter: *Myriad*

- Arguments to the Supreme Court:
 - **Petitioners:** “Myriad defends its claims on the grounds that a gene becomes a human invention when removed from the human body (‘isolated’). **Under this rationale, a kidney ‘isolated’ from the body would be patentable, gold ‘isolated’ from a stream would be patentable, and leaves ‘isolated’ from trees would be patentable.**”

Patent-Eligible Subject Matter: *Myriad*

- Arguments to the Supreme Court:
 - **United States:** “**Synthesized genetic materials such as cDNA are patent-eligible** subject matter because they do not occur in nature but instead are the product of significant human creativity. **By contrast, isolated but otherwise unmodified DNA is not patent-eligible** [because] while the process of isolating DNA entails physical changes, those changes do not significantly alter the structure or function of the relevant DNA segments.”

Patent-Eligible Subject Matter: *Myriad*

- Arguments to the Supreme Court:
 - **Respondents:** “No one would doubt the patent-eligibility of a newly created chemical composition that, when applied in a laboratory to a person’s blood or tissue sample, could detect a mutation genetically predisposing her to a risk of breast or ovarian cancer, thereby allowing her to take proactive measures to prolong her life even before cancer actually strikes. That is what Myriad’s patented molecules are—and they were never available to the world until Myriad’s scientists applied their inventive faculties to a previously undistinguished mass of genetic matter in order to identify, define, and create the isolated DNA molecules.”

Patent-Eligible Subject Matter: *Myriad*

- *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, 133 S.Ct. 2107, 186 L. Ed. 2d 124 (2013)
 - Decided: June 13, 2013
 - Holding:
 - Isolated DNA: “[A] naturally occurring DNA segment is a **product of nature and not patent eligible** merely because it has been isolated”
 - cDNA: “cDNA is patent eligible because it is **not naturally occurring**.”

Patent-Eligible Subject Matter: *Myriad*

- **Isolated DNA:** “Myriad **did not create anything**. To be sure it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.” *Id.* at 2117.
 - “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.” *Id.*
 - “[E]xtensive effort alone is insufficient to satisfy the demands of § 101.” *Id.* at 2118.
 - “Myriad’s claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the genetic information encoded in the BRCA1 and BRCA2 genes.” *Id.*

Patent-Eligible Subject Matter: *Myriad*

- **cDNA:** “cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. [Although] the nucleotide sequence of cDNA is dictated by nature, . . . **the lab technician unquestionably creates something new when cDNA is made**. cDNA retains the naturally occurring exons of DNA, but **it is distinct from the DNA from which it is derived**. As a result, cDNA is not a ‘product of nature’ and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.”

Patent-Eligible Subject Matter: Application of *Myriad*

- *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C 11-06391 SI, 2013 U.S. Dist. LEXIS 156554 (N.D. Cal. Oct. 30, 2013).
 - “On August 9, 2013, the Federal Circuit vacated this Court’s order denying [a] preliminary injunction and remanded the case . . . with directions that this Court examine subject matter eligibility of the asserted claims in the first instance in light of the Supreme Court’s recent decision in [*Myriad*].” *Id.* at *7-8.
 - Asserted Claims: methods of detecting a natural phenomenon—the presence of paternally inherited cffDNA in maternal plasma or serum.

Patent-Eligible Subject Matter: Application of *Myriad*

- Patentee argued “that the claims are patentable because although cffDNA is not patentable, the use of cffDNA is patent eligible.”
- The District Court disagreed:
 - “The Supreme Court has never stated that any use of a natural phenomenon is patentable. . . . **It is only an innovative or inventive use of a natural phenomenon that is afforded patent protection.** . . . [B]ased on the undisputed facts before the Court, the only inventive part of the patent is that the conventional techniques of DNA detection known at the time of the invention are applied to paternally inherited cffDNA as opposed to other types of DNA. Thus, the only inventive concept contained in the patent is the discovery of cffDNA, which is not patentable.

Patent-Eligible Subject Matter: Application of *Myriad*

- The District Court also considered “whether the claim poses a risk of preempting a law of nature, natural phenomenon, or abstract idea.”
- Patentee argued there were alternative methods for detecting cffDNA, even if they weren’t practical and commercially viable.

Patent-Eligible Subject Matter: Application of *Myriad*

The District Court rejected the patentee’s arguments:

“If the alternative methods are not commercially viable, then the effect of the patent in practice would be to preempt all uses of the natural phenomenon. It is important to note that the ‘540 patent does not merely claim uses or applications of cffDNA, it claims methods for detecting the natural phenomenon. **Because generally one must be able to find a natural phenomenon to use it and apply it, claims covering the only commercially viable way of detecting that phenomenon do carry a substantial risk of preempting all practical uses of it.**”

Patent-Eligible Subject Matter: Application of *Myriad*

- *In re BRCA1- & BRAC2-Based Hereditary Cancer Test Patent Litigation*, No. 2:14-MD-2510, 2014 U.S. Dist. LEXIS 31345 (D. Utah Mar. 10, 2014).
 - “On June 13, 2013, the Supreme Court issued a unanimous decision holding that ‘genes and the information they encode are not patent eligible simply because they have been isolated from the surrounding genetic material.’ This case arises in the aftermath of that decision.” *Id.* at *8.

Patent-Eligible Subject Matter: Application of *Myriad*

- *In re BRCA1- & BRAC2-Based Hereditary Cancer Test Patent Litigation*
 - Two Types of Claims Asserted:
 - Primer Claims: pairs of single stranded primers for use in determining the nucleotide sequence of BRCA1 or BRCA2 genes
 - Method Claims: processes of comparing and analyzing BRCA1 and BRCA2 DNA

Patent-Eligible Subject Matter: Application of *Myriad*

- The District Court found a substantial question as to whether the Primer Claims are patent eligible:
 - “The Primer Claims’ nucleotide sequences complement BRCA1 and BRCA2 sequences found in nature. Notwithstanding this, Plaintiffs argue that because their Primer Claims are drawn to synthetic DNA, their BRCA1 and BRCA2 primers are therefore patent eligible.”

Patent-Eligible Subject Matter: Application of *Myriad*

The District Court rejected Plaintiffs’ argument:

- “First, the only synthetic DNA the [*Myriad*] Court expressly found patent eligible was cDNA. Even then, the Court held [] that **cDNA may be patent ineligible in some circumstances.**”
- “Second, if the dispositive issue for patent eligibility was simply whether a DNA composition is synthetic, the Court’s analysis of cDNA might have begun and ended with the fact that **cDNA is created in a laboratory. But the Court went well beyond this in its analysis**, discussing its view of cDNA’s important uniqueness.”

Patent-Eligible Subject Matter: Application of *Myriad*

- The District Court also found a substantial question as to whether the Method Claims are patent eligible:
 - “Plaintiffs argue that the Method Claims here are patent eligible because they employ specific laboratory testing processes that apply Myriad’s discovery the the BRCA1 and BRCA2 genes to develop physical steps that were not well-understood, routine, or conventional at the time the patents were filed.”

Patent-Eligible Subject Matter: Application of *Myriad*

The District Court rejected Plaintiffs’ argument:

- “A close reading of Plaintiffs’ briefing reveals that the only ‘inventive concepts’ in their Method Claims are the patent ineligible naturally occurring BRCA1 and BRCA2 sequences themselves. **The claims contain no otherwise new process** for designing or using probes, primers, or arrays beyond the use of BRCA1 and BRCA2 sequences in those processes.”
- Followed *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*

Patent-Eligible Subject Matter: *Alice Corp.*

- *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 189 L. Ed. 2d 296 (2014)
 - Decided: June 19, 2014
 - Holding: Generic computer implementation of an abstract idea fails to transform the abstract idea into a patent-eligible invention.

Patent-Eligible Subject Matter: *Alice Corp.*

- Supreme Court applied the “**framework for distinguishing patents that claim laws of nature, natural phenomenon, and abstract ideas from those that claim patent-eligible applications of those concepts**” set forth in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012).

Patent-Eligible Subject Matter: *Alice Corp.*

Two step analysis:

- “First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, ‘what else is there in the claims before us?’ To answer that question, we consider the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application. We have described step two of this analysis as a search for an ‘inventive concept’—i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent on the ineligible concept itself.’” *Id.* at 2355.

Claim Definiteness

35 U.S.C. § 112, ¶ 2: “The specification shall conclude with one or more claims **particularly pointing out and distinctly claiming** the subject matter which the applicant regards as his invention.”

Claim Definiteness: *Nautilus*

- *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 189 L. Ed. 2d 37 (2014)
 - Decided: June 2, 2014
 - Holding: A patent is invalid for indefiniteness if its claims, read in light of the patent's specification and prosecution history, fail to inform, with **reasonable certainty**, those skilled in the art about the scope of the invention.

Claim Definiteness: *Nautilus*

- Factual Background:
 - Patent related to heart rate monitor for use during exercise
 - Claim comprised, among other things, a live electrode and common electrode mounted in "spaced relationship" with each other
 - District court: "spaced relationship" was indefinite

Claim Definiteness: *Nautilus*

Federal Circuit's Decision:

- Indefiniteness standard:
 - Terms not “amenable to construction”; or
 - Terms are “insolubly ambiguous”
- Federal Circuit concluded the patent-in-suit survived indefiniteness review under this standard.

Claim Definiteness: *Nautilus*

- Supreme Court reverses and establishes new test for indefiniteness
 - Section 112, ¶ 2 requires that a patent's claims, “viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.”
 - Court reasoned that definiteness requirement served public notice function and Federal Circuit's imprecise test fostered innovation-discouraging “zone of uncertainty”

Claim Definiteness: Application of *Nautilus*

- *MyCone Dental Supply Co., Inc. v. Creative Nail Design, Inc.*, No. 11-4380, 2014 US. Dist. LEXIS 93051 (D.N.J. July 9, 2014)
 - Defendants moved to supplement claim construction with expert declaration
 - Defendants argued that *Nautilus* requires consideration of claim terms from position of a person of ordinary skill in the art and that expert testimony now relevant in *Markman* hearing

Claim Definiteness: Application of *Nautilus*

- *MyCone Dental Supply*
 - Patent had several terms where Defendants alleged invalidity based on indefiniteness
 - Patent related to nail coating product

Claim Definiteness: Application of *Nautilus*

- *MyCone Dental Supply*
 - Terms included:
 - “substantially acid-free”
 - “liquid substantially acid-free hydrophilic acrylate monomer composition”
 - “liquid substantially acid-free hydrophilic monomer composition”
 - “substantially enhances adhesion”

Claim Definiteness: Application of *Nautilus*

- *MyCone Dental Supply*
 - District Court:
 - *Nautilus* indicates that experts may have more importance at claim construction in order to illuminate the Supreme Court’s new “reasonable certainty” standard
 - Not holding that expert testimony is “required or necessary” but that Defendants’ request is reasonable

Attorneys' Fees Awards: *Highmark & Octane Fitness*

35 U.S.C. § 285: "The court in **exceptional cases** may award reasonable attorney fees to the prevailing party."

Attorneys' Fees Awards: *Highmark & Octane Fitness*

- *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 188 L. Ed. 2d 829 (2014).
 - Decided: April 29, 2014
 - Holding:
 - Determination of exceptional case under 35 USC 285 should be reviewed under the abuse of discretion standard.
 - Federal Circuit's *de novo* review incorrect

Attorneys' Fees Awards: *Highmark & Octane Fitness*

- *Highmark*
 - Plaintiff was pursuing a strategy of litigation to identify companies potentially infringing its patent
 - Patent related to “utilization review” in “managed health care systems”
 - Federal Circuit reviewed *de novo* after District Court granted over \$5 million in fees and costs
 - Federal Circuit reversed
 - Supreme Court reverses and remands

Attorneys' Fees Awards: *Highmark & Octane Fitness*

- *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S. Ct. 1749, 188 L. Ed. 2d 816 (2014)
 - Decided: April 29, 2014
 - Holding:
 - Exceptional case standard has discretion to determine whether case is exceptional which is merely a case that stands out from others with respect to the substantive strength of a party's litigating position or the unreasonable manner in which the case is litigated.

Attorneys' Fees Awards: *Highmark & Octane Fitness*

- *Octane Fitness*
 - Plaintiff Icon Health & Fitness
 - Sued alleging patent infringement
 - Non-infringement found on summary judgment
 - Icon company e-mail highlighted by Supreme Court which referenced an “old patent ... that was sitting on the shelf.”

Attorneys' Fees Awards: *Highmark & Octane Fitness*

- *Octane Fitness*
 - Supreme Court:
 - Section 285 demands a simple discretionary inquiry
 - Based on all the circumstances
 - No specific evidentiary burden
 - Case by case exercise of district court's discretion
 - No precise rule or formula for making the determination

Other Legal Developments: *Medtronic*

- *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S.Ct. 843, 187 L. Ed. 2d 703 (2014)
 - Decided: January 22, 2014
 - Holding: When a licensee seeks a declaratory judgment against a patentee that its products do not infringe the licensed patent, the patentee bears the burden of persuasion on the issue of infringement.

Other Legal Developments: *Limelight*

- *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S.Ct. 2111, 189 L. Ed. 2d 52 (2014)
 - Decided: June 2, 2014
 - Holding: A defendant is not liable for inducing infringement under § 271(b) when no one has directly infringed under § 271(a) or any other statutory provision.

Questions?

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