

Recent Developments in Patent Law: Implications for Life Sciences

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BIO-IT World Conference
April 7, 2016

It Started with Business Methods

- Not too long ago, getting patents on software and business methods was all the rage
- Federal Circuit's (patent appeals court) 1998 *State Street* decision opened the door to getting patents on conventional processes (there, a method for managing a mutual fund portfolio) implemented on a computer
- You could claim it as the method implemented on a computer (process), the computer programmed to do the process (product), or even a storage medium with the program (product)

But Now a 180 Degree Turn

- Series of Supreme Court cases (*Bilski*, *Mayo*, *Alice*) has put the brakes on method patents generally
- In life sciences, *Myriad* (a product case) got the headlines, but the others have more long-term consequences for the field
- Good thing or bad?—depends on whether you're a producer or consumer

Why Should Bioinformatics People Care?

- You use complex statistical techniques to try to draw clinically useful inferences from genetic and other raw data
- Advances in sequencing technology have increased the data flow from a trickle to a flood
- As analysis tries to catch up, software plays an indispensable role
- Whether that software can be patented is a question of enormous economic significance to the bioinformatics industry—good for some, bad for others

Patent Basics

- Invention must be patentable subject matter (section 101), novel (102), nonobvious (103), and useful (101 again)
- “Anything under the sun made by man”
- Case law excludes ***products of nature, laws of nature, and abstract ideas***
- Until last five + years, courts and USPTO held almost everything to be patentable subject matter, relied on 102/103 to weed out really bad patents

What Can Be Patented?

- **Generally:** new, useful (101) and nonobvious (103) inventions
- **Patentable subject matter** (101): machines, manufactures, compositions of matter, processes; improvements thereon
- **What you can't patent:**
 - abstract ideas, laws of nature (including pure mathematical algorithms), products of nature
 - None of these are “inventions”

Software-Based Methods Pre-2010

- Under *State Street*, virtually no patentable subject matter limits
- Federal Circuit developed ***machine or transformation test***: a conventional process could become eligible for patenting if claim tied the process to a particular machine (a computer) or transformed something in the real world
- Usually, the only point of novelty was computerizing the calculation
- Aggressive claiming extended from finance to diagnostics and medical analysis

Then the Supreme Court Got Interested in Subject Matter

- ***Bilski*** (2010): Court rejected claim to method of hedging risk in commodities transactions
- This well-known strategy was merely an ***abstract idea*** so fails 101 test
- Multiple opinions yielded no clear rationale
- Rejected ***machine or transformation*** as **exclusive** test but provided no substitute

Medical Methods and Laws of Nature: *Mayo v. Prometheus* (2012)

- Rejected (9-0!) patent on a drug-dosage adjustment method for claiming a ***law of nature***—even though Federal Circuit had twice upheld it
- Claim: administer the drug, determine metabolite levels, compare to thresholds and adjust dose as necessary

Mayo v. Prometheus

- Claim steps take **law of nature** (correlation between metabolite levels and efficacy/toxicity) and “simply tell doctors to gather data from which they may draw an inference in light of the correlation”
- Claimed method thus adds nothing beyond “well understood, routine, **conventional activity**”
- Not enough added—but what would be enough??

Products of Nature: *AMP v. Myriad Genetics* (2013)

- Highly controversial BRCA gene case
- Supreme Court rejected claims to merely *isolated* DNA—not sufficiently distinct from natural version, thus an invalid claim to a ***product of nature***
- But cDNA *is* patentable subject matter—a synthetic product not chemically identical to anything in the body (DNA with noncoding regions spliced out)
- A product (not method) case, but strengthens overall message about subject matter scrutiny

Myriad on Methods

- Fed. Cir. rulings stand, as S. Ct. didn't address—but vastly underrated part of case
- Myriad's claims to methods of screening potential cancer treatments by analyzing growth rates of cells with mutated BRCA genes in the presence or absence of the treatments **are** patentable subject matter
- But claims to methods of analyzing BRCA gene sequences and comparing those with cancer-predisposing mutations to normal sequences **aren't** patentable subject matter

Methods and Abstract Ideas: *Alice Corp. v. CLS Bank Int'l* (2014)

- Rejected claims to methods and systems for using a computer as a third-party intermediary to ensure that both parties to a financial transaction meet their obligations
- Two-part test for method claims that involve ***abstract ideas*** (neutral intermediary)--

Alice

- (1) Ask whether claim is “directed to” an ***abstract idea***
- (2) If so, do “the ***additional elements***” supply an “***inventive concept***” in the physical realm of things, and ensure that the patent is on something “***significantly more than***” the ***abstract idea itself***?
- Here, yes on (1) and no on (2): not much guidance on (2), but simply implementing the idea on a computer is not enough

Post-Alice Subject Matter Crackdown in Lower Courts and USPTO

- *buySAFE, Inc. v. Google, Inc.* (2014): Federal Circuit rejected *Alice*-style claims to “methods and machine-readable media encoded to perform steps for guaranteeing a party’s performance of its online transaction”
- *Ultramercial v. Hulu* (2014): Fed. Cir. rejected claims to method for distributing copyrighted media products over the Internet where consumer receives product at no cost in exchange for viewing ads
- Claims directed to ***abstract ideas***; added technical elements were merely ***conventional*** and thus did not contribute a sufficiently ***inventive concept***

One Exception: *DDR Holdings v. Hotels.com* (Fed. Cir. 2014)

- Patent addressed problem of “host” website losing Internet shoppers diverted by clicking on another merchant’s ad
- Claimed method involved software that generates composite web page that displays product information from third-party merchant while giving the shopper the impression of staying on host website
- Claim involved ***no abstract idea*** from pre-Internet world: so an inventive concept
- ***New solution to new problem*** that had arisen from ***new technology*** was ***sufficient inventive concept***

But Then a Life Sciences Shocker: *Ariosa Diagnostics v. Sequenom* (Fed. Cir. 2015)

- Claims to methods of detecting paternity-- identifying DNA in a maternal serum or plasma sample—an innovative and highly sophisticated paternity test
- Unanimous court acknowledged value of invention but said, in effect, “we’re sorry, but *Mayo* made us do it”

Ariosa Diagnostics v. Sequenom

- The problem: method “begins and ends with a ***natural phenomenon***”—cell-free fetal DNA (cffDNA), which method is designed to detect in the maternal sample
- Method doesn’t add sufficient ***inventive concept***, since it “amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA”—exactly how the Supreme Court characterized the method in *Mayo*

Ariosa Diagnostics v. Sequenom

- One judge noted that before this invention, “*no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers,” whereas *Mayo* method claimed “the very steps doctors were already doing”
- But even he conceded that “the sweeping language” of *Mayo* required rejection of the Sequenom method

Ariosa v. Sequenom Fallout

- Patent lawyers apoplectic
- Federal Circuit has surrendered in the subject matter war
- Previously, some judges tried to resist the Supreme Court—argued for letting almost everything in under section 101 and leaving the real scrutiny to 102 (novelty) and 103 (obviousness)
- But Supreme Court has now said unanimously in three different contexts that section 101 has to be taken seriously as an initial and significant criterion

Practical Implications for Life Sciences

- USPTO and lower courts are giving close subject matter scrutiny to all biomedical method patents—whether for diagnosis, treatment, or analysis
- Seems to be a presumption that most or all start with a ***law or product of nature***; analysis often starts with ***abstract idea***
- *Ariosa v. Sequenom* indicates that it's ***very*** hard to add a sufficient ***inventive concept***, even with a complex and innovative analytical technique

Practical Implications for Life Sciences

- *Alice*: computerized versions of established processes not patentable
- Simply making a calculation or other process faster and more efficient is not enough
- Instead, computerized process must be solving a **new** technological or other tangible problem

Practical Implications for Life Sciences

- Particular barrier to patenting analytical methods in bioinformatics
- From the law's perspective, a statistical analysis—however complex or innovative—is an abstract idea or law, and probably also involves laws of nature
- Thus, to be patentable subject matter the new method must do more than simply automate or accelerate the analysis

Practical Implications for Life Sciences

- **Algorithms** by themselves—again, however complex or innovative—are always treated as laws of nature
- So the creation of a new bioinformatics algorithm cannot, in and of itself, lead to a patentable invention
- Very difficult to envision a new method of data analysis that will clear the new and significantly higher subject matter bar
- *Ariosa v. Sequenom* makes the broader point that the bar is also higher for other methods of diagnosis or analysis of medical data
- Concurring judge's effort to distinguish that case from *Mayo* seemed persuasive, but in the end he couldn't even persuade himself

Good News or Bad?

- ***Bad*** financial news if your business model depends on having exclusive rights to an analytical or medical method
- Relevant patents will be extremely hard to get, and existing patents may be invalidated if you sue someone for infringement (defendants can win by showing invalidity)

Good News or Bad?

- News is all **good** if your business or research may be threatened by these kinds of patents held by others
- Patentees will be less likely to sue for infringement, and those who do get sued will have a clear avenue of defense
- Note Myriad's Plan B: the much-maligned proprietary data option
- Will that be an option for others?

Good News or Bad?

- Note Myriad's post-patent Plan B: the much-maligned proprietary data option
- Keeping data s trade secret is legally doable, certainly in U.S. and probably abroad
- No current legal or regulatory barriers to doing so
- Will that be an option for others?