



Post-Mayo/Alice Update

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Beyond Borders

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Mayo v. Prometheus Labs # 6,355,623 (1)

Claim 1:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

Administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder, and;

Determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

Wherein the level of 6-thioguanine less than about 230pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject, and

Wherein the level of 6-thioguanine greater than about 400pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to the subject

Mayo v. Prometheus Labs (2)

U.S. Supreme Court:

- Do claims add limitations to the discovered natural correlations sufficient to allow the claimed processes to qualify as patent-eligible (albeit including natural phenomena exception)? **Holding: NO**
 - **Must transform or reduce article ‘to a different state or thing’ (Needed for a process claim that does not include a particular machine).**
 - “We have neither said nor implied that machine or transformation test trumps the “law of nature” exclusion.”
 - A person may have “invented” a machine or manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.
- Need to include an **inventive concept**.

Alice v CLS Bank

U.S. Supreme Court:

- Do the patent claims add enough to functional limitations of an abstract idea of human behavior, performed on a generic computer qualify as patent eligible? **Holding: NO**
- Courts and USPTO since then require application of Mayo “2-part” test to abstract non-life science inventions, too.
 - 1: Process, Machine, Manufacture, Composition of Matter? If no, then not eligible.
 - 2a: Even if so, an abstract idea, natural phenomena, or law of nature? If no, then eligible.
 - 2b: If including an abstract idea, natural phenomena, or law of nature, then is there more sufficient to provide the inventive concept required by Mayo?

Ariosa Diagnostics v. Sequenom– #6,258,540 (1)

Claim 1:

A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises:

Amplifying a paternally inherited nucleic acid from the serum or plasma sample, and

Detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Ariosa Diagnostics v. Sequenom– #6,258,540 (2)

Claim 24:

A method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises:

Removing all or substantially all nucleated and anucleated cell populations from the blood sample,

Amplifying a paternally inherited nucleic acid from the remaining fluid and subjecting the amplified nucleic acid to a test for the paternally inherited fetal nucleic acid.

Ariosa Diagnostics v. Sequenom– #6,258,540 (3)

Claim 25:

A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises:

Obtaining a non-cellular fraction of the blood sample,

Amplifying a paternally inherited nucleic acid from the non-cellular fraction, and

Performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

Ariosa Diagnostics v. Sequenom (4)

U.S. Federal Circuit:

A claim must “contain an inventive concept sufficient to transform the claimed naturally occurring phenomenon into a patent-eligible application.”

Ariosa Diagnostics v. Sequenom (5)

U.S. Federal Circuit, Citing Mayo:

Sequenom's methods were "well-understood, conventional, and routine."

Ariosa Diagnostics v. Sequenom (6)

U.S. Federal Circuit:

“Thus, in this case, appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept.”

Ariosa Diagnostics v. Sequenom - USPTO (7)

- Nature-based

Explicitly identify in the specification any markedly different resulting structure, function or other feature, as compared to its natural state.

- If even one example falls within the BRI and lacks the difference, it is deemed ineligible.
- Meant to prevent tying up naturally occurring product
- Mere isolation or purification by itself will not suffice. The change must result in a markedly different function.
 - Biological or pharma functions or activities
 - Chemical and physical properties
 - Phenotype, shape size color behavior of organism
 - Structure and form, chemical genetic or physical

Ariosa Diagnostics v. Sequenom - Tips (8)

- Recite interaction between natural phenomenon and routine steps
 - Instead of simply reciting limitations, see what new characteristics/structure/results necessarily occur because of combination and claim them
- Look for non-routine steps/limitations
 - Non-widely used procedures
 - Be careful about merely “detecting” subject of natural phenomena so as to avoid claiming correlation (despite USPTO Life Science Example 29, Claim 1)
- For natural products, does the different structural element (or the result of its combination) provide a “markedly different characteristic” in terms of function or structure? (Part of 2A at USPTO).

Enfish, LLC v. Microsoft Corp #6,151,604 (1)

Alice does not invalidate all software claims

- Software and hardware are not automatically abstract
 - Some improvements in computer-related technology when appropriately claimed are undoubtedly not abstract
 - Inextricably tied to computer technology
 - Changed Alice test for computer-related technology
 - When asking “2A” (“Is it abstract”), held that for computer-related tech, question is “Are claims directed to an improvement to computer functionality?”
 - **Bascom Global v AT&T Mobility**
 - Patent on filtering internet content improved computer functioning, not an abstract idea

Enfish, LLC v. Microsoft Corp #6,151,604 (2)

Claim 17:

A data storage and retrieval system for a computer memory, comprising:

means for configuring said memory according to a logical table, said logical table including:

a plurality of logical rows, each said logical row including an object identification number (OID) to identify each said logical row, each said logical row corresponding to a record of information;

a plurality of logical columns intersecting said plurality of logical rows to define a plurality of logical cells, each said logical column including an OID to identify each said logical column; and

means for indexing data stored in said table.

VALID under 35 U.S.C. § 101

Enfish, LLC v. Microsoft Corp – Tips (3)

- Obfuscate any abstract ideas, by writing specification to highlight several conceptually separate other advantages of invention to remove the "abstract idea" per 2a.
- If not very technical, make sure your claims, as read in light of the specification at their core claim more than any abstract idea.
 - Find and tell a story about efficiencies in the data flow created on a larger scale network
 - Find and tell a story about computer security advantages

Enfish, LLC v. Microsoft Corp – Tips (4)

- Think deeply. "Jukujou shitte!" Go deeper into the functioning of the "stack" to mine these features.
- Mitigate preemption by optionally and separately representing the technical feature as broken into several pieces spread across multiple specifications.
- Recite new relationships "between" the routine ones (helps with § 103 too, via-a-vis KSR).
 - Insert other specific limitations that are not "plainly identifiable and divisible from the generic computer limitations" – See *e.g.*, DDR opinion claims

Enfish, LLC v. Microsoft Corp – Tips (5)

- Learn the case law facts and draft claims and specifications accordingly to distinguish bad cases and align your presented story to good ones
- Derive a check list of desirable “patent eligible” traits and emulate/incorporate them as you claim and describe your embodiments
 - Weave specific hardware and specific technical terms into the steps.

Enfish, LLC v. Microsoft Corp – Tips (6)

- Try to claim:
 - a challenge/solution particular to the internet “[computers and computer network]“ (for EPO, too).
 - specifically HOW the abstract idea is implemented, not simply that it is on a computer
- Look for an underlying technical features that:
 - correspond to and are necessary to achieve essential functions
 - are stated to avoid negative limitations
 - are sufficiently particular

Enfish, LLC v. Microsoft Corp – Tips (7)

- If still abstract, add “significantly more”:
 - improvements to another technical field (*e.g.*, imagine how software algorithm might enhance network security, speed, efficiently, etc.)
 - steps that leverage invention to make improvements to functioning of a computer itself
 - applied to, or by use of, a particular machine or article to transform or reduce to a different state or thing
 - adding a specific limitation other than what are well-understood or routine and conventional in the field , or unconventional steps that confine to a particular useful application (more specific hardware, *e.g.*, woven into steps).
 - Identify case example(s) and USPTO example(s) most similar to your preliminarily described and claimed invention, and use the above to draft, so as to avoid the same mistakes/or include the same types of eligible features.

USPTO Rejections (1)

- 1: Is it statutory?
- 2a: Is it one of the Supreme Court exceptions? (Includes “markedly different characteristic” analysis)
 - Fundamental economic practices (Bilski hedging; Alice settlement risk)
 - Certain methods of human activity (advertising, insurance, arbitration, buying and selling, games, mental processes)
 - Idea of itself (plan, scheme, mental process)
 - Mathematical relationships (See e.g., Floor, Benson, Mackey)
- 2b: are added elements or their COMBINATION to each other or the exception, substantially more?
 - Judicial notice allowed by examiner because a matter of law
 - Call out examiner immediately as with all judicial notice.

USPTO Rejections (2)

- Prima facie case for steps 2a and 2b requires 4 elements
 - ID judicial exception in claim
 - why it is considered exception
 - ID additional claim elements
 - why they do not amount to significantly more

CALL EXAMINER OUT IF AN ELEMENT IS MISSING

Thanks for your attention. Questions?



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