New York State Science and Technology Law Center

LAB to MARKET series

Prometheus v. Mayo

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BOND SCHOENECK & KING

Prometheus v. Mayo

- Background
- The Decision
- Implications
- The Aftermath
- Questions

Background

Prometheus & Mayo

The Patents-At-Issue

The District Court & Federal Circuit Decisions

Prometheus v. Mayo

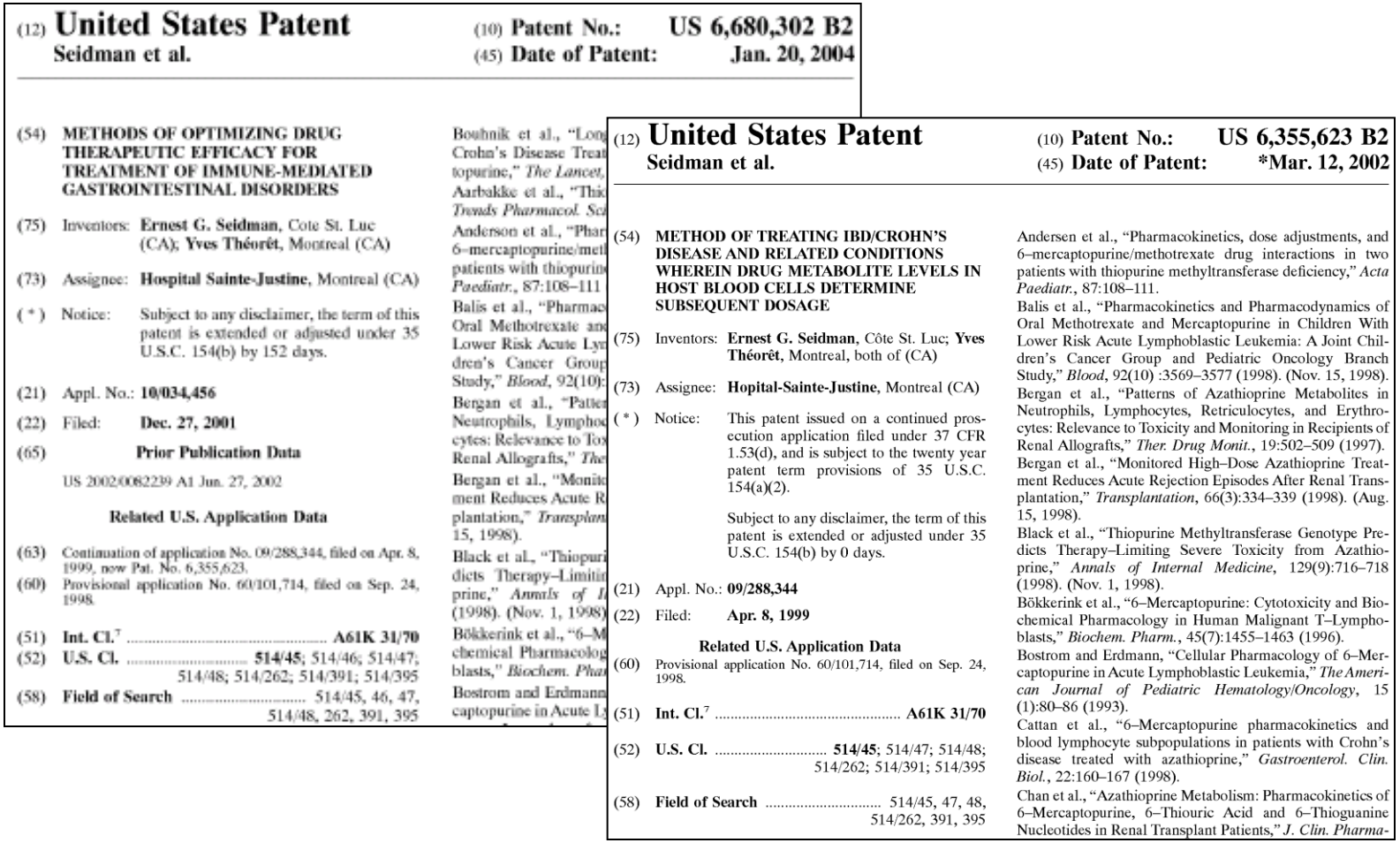
- **Prometheus Laboratories, Inc.**
  - Based in San Diego, CA
  - Sole and exclusive licensee of the two patents at issue

Prometheus v. Mayo

- **Mayo Clinic Rochester and Mayo Collaborative Services**
  - Originally purchased diagnostic tests that embody the processes the patents describe; stopped in 2004 & used and sold own tests

Prometheus v. Mayo

- The Patents (6,680,302 and 6,355,623)



(12) **United States Patent**
Seidman et al.

(10) **Patent No.: US 6,680,302 B2**
(45) **Date of Patent: Jan. 20, 2004**

(54) **METHODS OF OPTIMIZING DRUG THERAPEUTIC EFFICACY FOR TREATMENT OF IMMUNE-MEDIATED GASTROINTESTINAL DISORDERS**

(75) Inventors: **Ernest G. Seidman**, Cote St. Luc (CA); **Yves Théorêt**, Montreal (CA)

(73) Assignee: **Hospital Sainte-Justine**, Montreal (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 152 days.

(21) Appl. No.: **10/034,456**

(22) Filed: **Dec. 27, 2001**

(65) **Prior Publication Data**

US 2002/0082239 A1 Jun. 27, 2002

Related U.S. Application Data

(63) Continuation of application No. 09/288,344, filed on Apr. 8, 1999, now Pat. No. 6,355,623.
(60) Provisional application No. 60/101,714, filed on Sep. 24, 1998.

(51) **Int. Cl.**[7] **A61K 31/70**
(52) **U.S. Cl.** **514/45**; 514/46; 514/47; 514/48; 514/262; 514/391; 514/395
(58) **Field of Search** 514/45, 46, 47, 514/48, 262, 391, 395

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(12) **United States Patent**
Seidman et al.

(10) **Patent No.: US 6,355,623 B2**
(45) **Date of Patent: *Mar. 12, 2002**

(54) **METHOD OF TREATING IBD/CROHN'S DISEASE AND RELATED CONDITIONS WHEREIN DRUG METABOLITE LEVELS IN HOST BLOOD CELLS DETERMINE SUBSEQUENT DOSAGE**

(75) Inventors: **Ernest G. Seidman**, Côte St. Luc; **Yves Théorêt**, Montreal, both of (CA)

(73) Assignee: **Hopital-Sainte-Justine**, Montreal (CA)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/288,344**

(22) Filed: **Apr. 8, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/101,714, filed on Sep. 24, 1998.

(51) **Int. Cl.**[7] **A61K 31/70**

(52) **U.S. Cl.** **514/45**; 514/47; 514/48; 514/262; 514/391; 514/395

(58) **Field of Search** 514/45, 47, 48, 514/262, 391, 395

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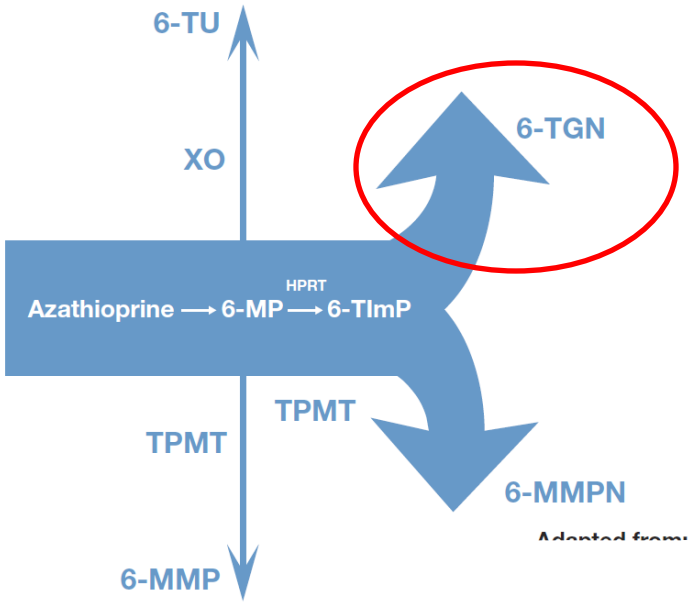
Prometheus v. Mayo

- <u>The Patents (6,680,302 and 6,355,623):</u>
  - Involve the use of thiopurine drugs in the treatment of autoimmune diseases (Crohn's disease, ulcerative colitis, etc)
  - There is a correlation between the concentration of metabolites (byproducts created when the body breaks down a drug) and the toxicity and efficacy of that drug:
    - If the concentration of byproducts in the bloodstream of a patient is too low, the current dosage of the drug may not be effective; if the concentration is too high, the dosage might be toxic.

Prometheus v. Mayo

Thiopurine drug metabolism[1]



- Metabolites 6-TGN and 6-MMPN are created in the body; both present potential risks to the patient at high levels

Thiopurines are metabolized to 2 key metabolites:

- 6-TGN is associated with efficacy and potential risk of myelotoxicity[1]
- 6-MMPN is associated with the potential risk of hepatotoxicity[1]

Because each patient metabolizes thiopurines differently, the **efficacy and toxicity of thiopurines can vary widely from patient to patient.**

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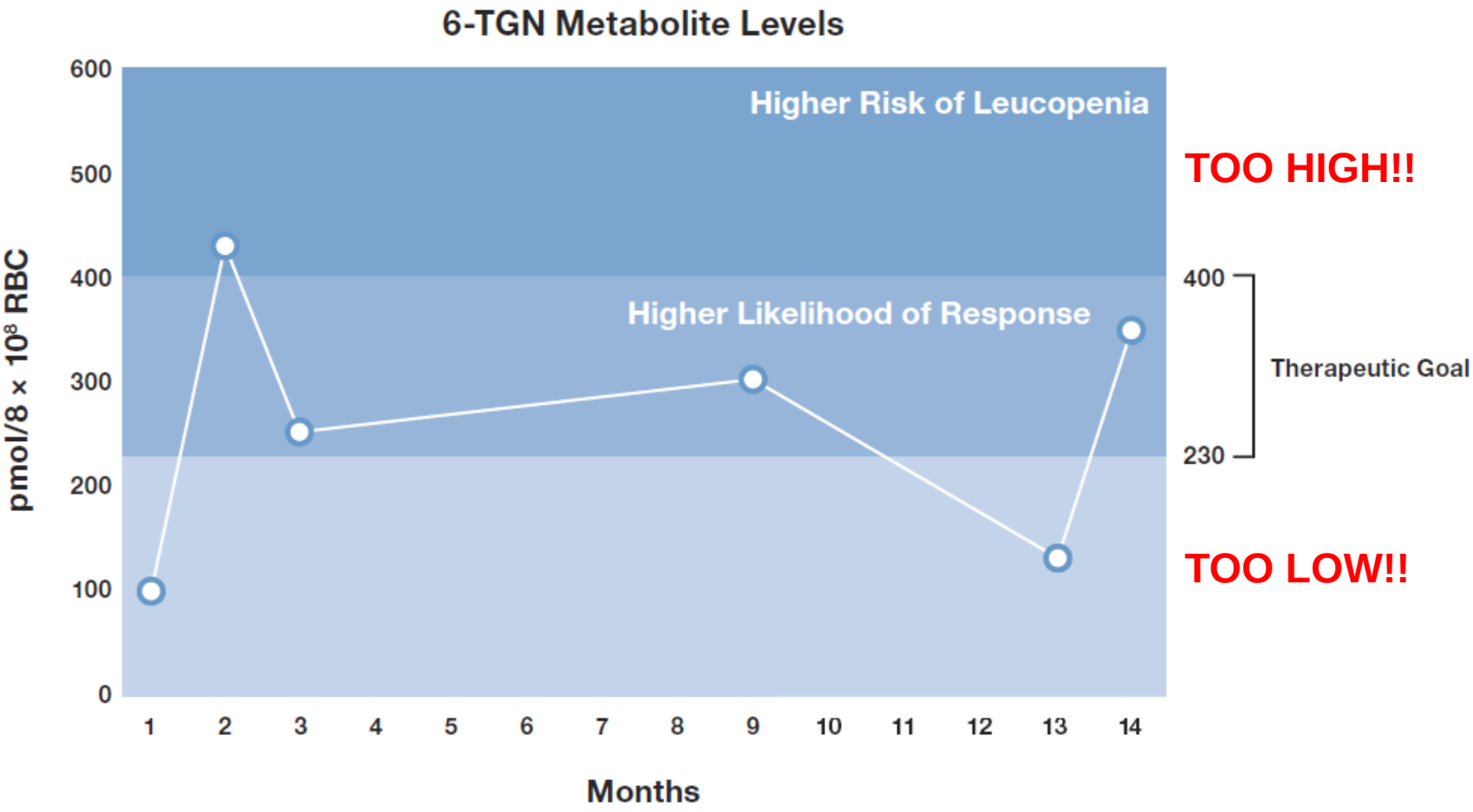

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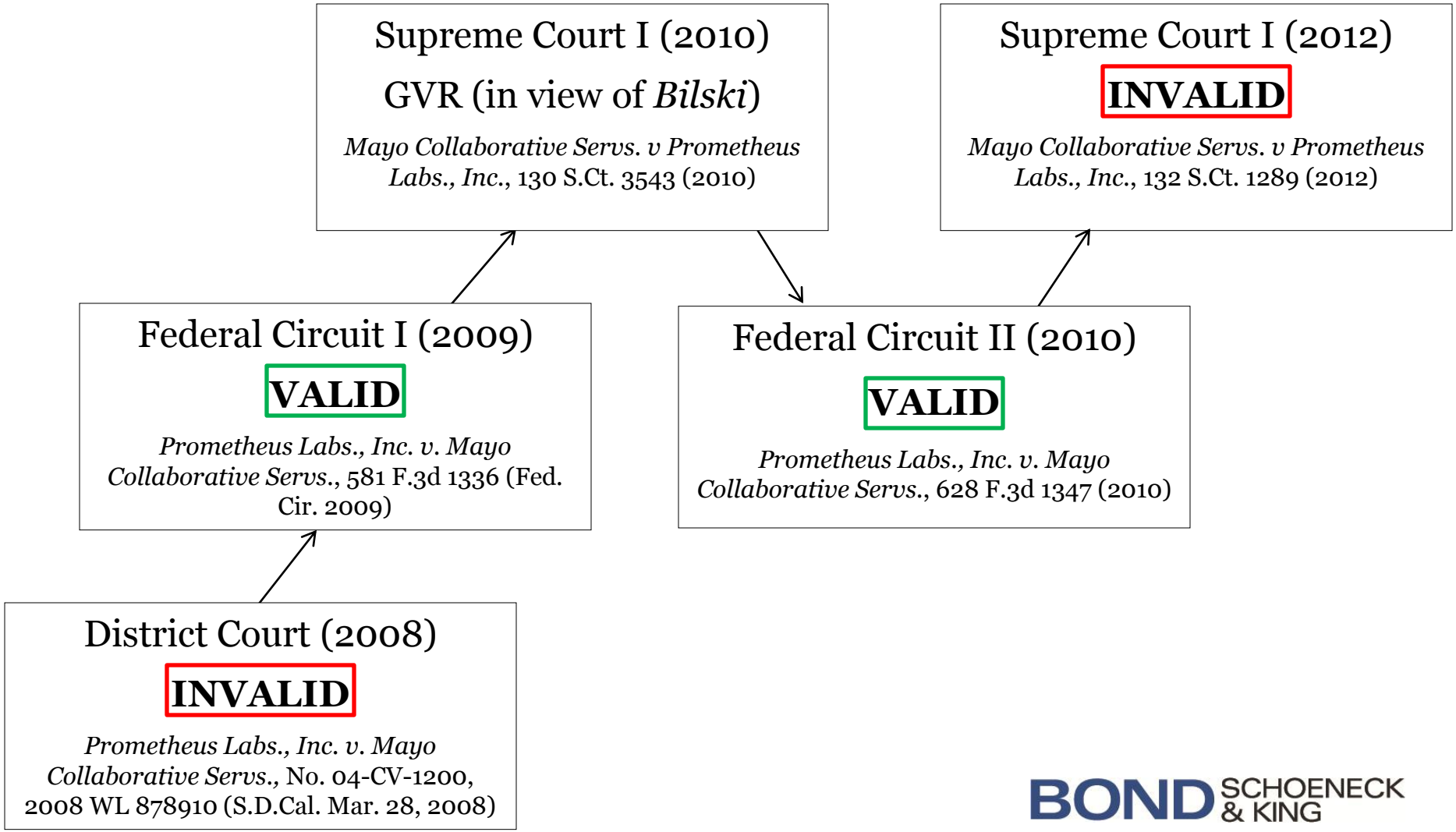
Prometheus v. Mayo

- The Patents (6,680,302 and 6,355,623):
  - The claims involve two steps:
    1. an “administering” step in which the drug is given to patients suffering from an autoimmune disease; and
    2. a “determining” step in which the concentration of the metabolites in the patient are determined.
  - The patient’s metabolite concentration is then compared to claimed ranges, and the physician can increase or decrease the amount of drug given to the patient depending on the comparison.

Prometheus v. Mayo

- Claim 1 of the ‘623 patent:
  - A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
    - (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
    - (b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
    - wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ 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 400 pmol per $8x10^8$ red blood cells **indicates a need to decrease** the amount of said drug subsequently administered to said subject.

Prometheus Timeline



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Prometheus v. Mayo

- The District Court (S.D.Ca.) Decision (2008):
  - Held that Mayo's test infringed the '623 patent
  - But:
    - Held that the patents claimed natural laws or natural phenomena – (i.e., the correlation between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages) – and so were not patentable
  - Summary judgment granted to Mayo and Prometheus appealed

Prometheus v. Mayo

- The Federal Circuit (Sept. 16, 2009):
  - Reversed
    - Held that the steps of "administering a drug" to a patient and "determining the level" involve the transformation of the human body or of blood taken from the body
    - Thus the patents satisfied the "machine or transformation test" under §101
  - Mayo filed petition for writ of certiorari

Prometheus v. Mayo

- The Supreme Court (June 29, 2010)
  - GVR Order:
    - Petition for writ of certiorari granted
    - Judgment vacated
    - Remanded to Federal Circuit for further consideration in light of *Bilski*
      - In *Bilski,* Supreme Court rejected the machine-or-transformation test as the sole, definitive test for determining the patent eligibility of a process under § 101

Prometheus v. Mayo

- The Federal Circuit (Dec. 17, 2010):
  - Again reversed District Court decision:
    - Again held that the treatment methods in Prometheus' patents transform the human body and the metabolites (enabling them to be measured)
    - *"The asserted claims are in effect claims to methods of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."*
  - Mayo filed petition for writ of certiorari

The Decision

Prometheus v. Mayo

- Law of Nature:
  - Relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.
    - “The relation is a consequence of the ways in which thiopurine compoundsare metabolized by the body—entirely natural processes. ”

Prometheus v. Mayo

Claim 1 of the ‘623 patent:

- A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
  - (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

- The “administering” step “simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs”
- The “prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.’” (quoting *Bilski*)

Prometheus v. Mayo

Claim 1 of the ‘623 patent:

- …wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ 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 400 pmol per $8x10^8$ red blood cells **indicates a need to decrease** the amount of said drug subsequently administered to said subject.

- The “wherein” clauses “simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient.”

Prometheus v. Mayo

Claim 1 of the ‘623 patent:

- …(b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

- The “determining” step simply tells the doctor to engage in “well-understood, routine, and conventional activity that doctors had been doing long before the patent.”
- “Purely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law”

Prometheus v. Mayo

- The Court then considered controlling precedent *Diehr* and *Flook* in more detail
  - *Diamond v. Diehr*, 450 U.S. 175 (1981) – held patent eligible
  - *Parker v. Flook*, 437 U.S. 584 (1978) – held patent ineligible

Prometheus v. Mayo

- *Diehr*
  - Method for molding raw rubber into molded product
    - Used a known mathematical equation to determine when to open the press
  - Court:
    - While the basic mathematical equation was not patentable, the overall process patentable because the additional steps integrated the equation
    - **No suggestion that the steps were "in context obvious, already in use, or purely conventional."**

Prometheus v. Mayo

- *Diehr cont'd*
  - In other words, the patentees did not "seek to pre-empt the use of the equation" but "transformed the process into an inventive application of the formula."

Prometheus v. Mayo

- *Flook*
  - Process provided a method for adjusting alarm limits in the catalytic conversion of hydrocarbons.
  - Court:
    - The basic mathematical equation was not patentable
    - Overall process NOT patentable because it did nothing other than provide “a[n unpatentable] formula for computing an updated alarm limit”
    - The other steps were already “well known”

Prometheus v. Mayo

- *Flook cont'd*
  - ""[P]ost-solution activity" that is purely "conventional or obvious can[not] transform an unpatentable principle into a patentable process."

Prometheus v. Mayo

- Applying *Diehr* and *Flook*:
  - The claims are similar to *Flook*:
    - "the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular laws of nature to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law."
    - "These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."

Prometheus v. Mayo

- Other considerations:
  - Court considered several other cases which offer "further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature…cannot make those laws…patentable."
    - *Nielson, Bilski, Benson*

Prometheus v. Mayo

- Other considerations cont'd:
  - Patent law should "not inhibit further discovery by improperly tying up the future use of laws of nature."
    - Here, the claims tell the doctor to measure metabolite levels & consider the resulting measurements in light of the correlation (i.e, the law of nature)
    - This threaten[s] to inhibit the development of more refined treatment recommendations" such as the one that Mayo later used

Prometheus v. Mayo

- The Federal Circuit's "transformation"
  - Fed. Cir. held that steps of "administering a drug" to a patient and "determining the level" involve transformation of the human body or of blood taken from the body
  - Supreme Court = no transformation:
    - **administering** – "simply helps to pick out the group of individuals who are likely interested in applying the law of nature"
    - **determining** – "could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation"

Prometheus v. Mayo

- Lastly:
  - In Brief for United States as *Amicus Curiae,* government argued that any step beyond a bare statement of a law of nature should make the claim eligible
    - Filtering will be done by §§ 102, 103, and 112 (obviousness, enablement, etc)
  - Court:
    - This approach would eviscerate the “law of nature” exception to § 101; and
    - Case law has relied on § 101, not on later sections

Prometheus v. Mayo

- Holding:
  - The claims are invalid under § 101
  - Federal Circuit's judgment reversed

The Aftermath of *Prometheus*

The Aftermath of Prometheus v. Mayo

- "If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."
  - Can't draft a law of nature together with well-known elements or as part of a prior art process and expect it to be patent eligible;
  - Claim must include more than a general instruction to apply a law of nature; it must transform a process "into an inventive application of the formula."
  - BUT *Promethus* does not provide clear guidance as to what types of activities will transform a process into an inventive concept that goes beyond a law of nature.
    - More like *Diehr*, less like *Flook*

The Aftermath of Prometheus v. Mayo

- The Supreme Court post-*Prometheus:*

  WildTangent, Inc., Petitioner v. Ultramercial, LLC

  - 2011: Federal Circuit held that claims for a method of monetizing copyrighted products involved steps that would require complex computer programming and thus did not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept.
  - Supreme Court ordered GVR in light of *Prometheus*
  - Currently before Federal Circuit

The Aftermath of Prometheus v. Mayo

- The Supreme Court post-*Prometheus:*

  Assn. for Molecular Pathology v. Myriad Genetics

  - 2011: Federal Circuit held that the claims covering isolated gene sequences are valid, and that the claims for diagnostic methods that compare or analyze sequences are invalid (i.e., not transformative)
  - Supreme Court ordered GVR in light of *Prometheus*
  - Currently before Federal Circuit:

The Aftermath of Prometheus v. Mayo

- District Courts post-*Prometheus*:
  - Nazomi Communs., Inc. v. Samsung Telecomms., Inc., 2012 U.S. Dist. LEXIS 39468 (N.D. Cal. Mar. 21, 2012)
  - SmartGene, Inc. v. Advanced Biological Labs., SA, 2012 U.S. Dist. LEXIS 44138 (D.D.C. Mar. 30, 2012)
  - Since the Court did not provide clear guidance as to what or how many extra elements or combination of elements are needed to transform a law of nature into a patent-eligible claim, much of this will play out in the lower courts

The Aftermath of Prometheus v. Mayo

- **Nazomi Communs., Inc. v. Samsung Telecomms., Inc.**
  - *Prometheus* mentioned in final paragraph:
    - "In distinguishing between processes that are patent eligible and those that are impermissibly broad, the [*Prometheus*] Court focused on whether the process contains additional steps that 'transform[] the process' from one that pre-empts all use of a natural law 'into an inventive application of the formula.'"

The Aftermath of Prometheus v. Mayo

- **Nazomi Communs., Inc. v. Samsung Telecomms., Inc.**
    - "The [*Prometheus*] Court rejected the claims at issue because the claims did little more than recite a law of nature and add the instruction 'apply the law.'"

The Aftermath of Prometheus v. Mayo

- Claim of the patent-at-issue:

  A method of executing an instruction comprising:

  obtaining from an instruction storage location, an instruction that references a data structure, the data structure storing an indication of a reference that may need resolution;

  obtaining data from the data structure including data from a resolution data field;

  using data from resolution data field as an index to a jump table to determine whether to do a resolving step; and

  thereafter, if the data in the data resolution field indicates that the reference was not resolved, resolving the reference and, thereafter, modifying the data in the data structure including modifying the data in the resolution data field to indicate that the reference is resolved, wherein the data in the instruction storage location is not modified.

The Aftermath of Prometheus v. Mayo

- **Nazomi Communs., Inc. v. Samsung Telecomms., Inc.**
    - "Here, the claims of the [patent-at-issue] do more than recite an abstract idea and say 'apply it.' Rather, they recite specific steps that confine the claims to a specific, useful application."

The Aftermath of Prometheus v. Mayo

- **SmartGene v. Advanced Biological Labs.**
  - *Prometheus* discussed in detail: "the *Prometheus* Court distilled the guideposts from its earlier section 101 cases into the following "warnings":
    - The Supreme Court warned "against interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws],'" and warned against "upholding patents that claim processes that too broadly preempt the use of a natural law."
    - A "process that focuses upon the use of a natural law" must "contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."

The Aftermath of Prometheus v. Mayo

- **SmartGene v. Advanced Biological Labs.**

1. A method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, said method comprising:

(a) providing patient information to a computing device comprising:

a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;

a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;

a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens; and

(b) generating in said computing device a ranked listing of available therapeutic treatment regimens for said patient; and

(c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

The Aftermath of Prometheus v. Mayo

- **SmartGene v. Advanced Biological Labs**
  - Applying *Prometheus:*
    - Similar to Prometheus, the steps "describe abstract ideas that are commonly performed by medical professionals in evaluating, considering and constructing treatment options for a patient presenting a specific medical condition"
    - Accordingly, the "steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." (quoting *Prometheus*).

The Aftermath of Prometheus v. Mayo

- The PTO post-*Prometheus*:
  - 3-Page Memorandum dated March 21, 2012:
    - Summarizing the holding of *Promethues,* the memo stated that claimed processes containing laws of nature are NOT patent-eligible unless "they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the [law of nature]."

The Aftermath of Prometheus v. Mayo

- The PTO post-*Prometheus* cont'd:
  - Preliminary guidance:
    - "examiners should continue to examine patent applications for compliance with section 101 using the existing *Interim Bilski Guidance* issued July 27, 2010, factoring in the additional considerations below"

The Aftermath of Prometheus v. Mayo

- The PTO post-*Prometheus* cont'd:
  - "Examiners must continue to ensure that claims…are not directed to an exception to eligibility such that the claim amounts to a monopoly on the law of nature, natural phenomenon, or abstract idea **itself**."
  - To be patent-eligible, "a claim that includes an exception should include other elements or combination of elements such that, in practice, the claimed product or process amounts to significantly **more than** a law of nature…with conventional steps specified at a high level of generality appended thereto."

The Aftermath of Prometheus v. Mayo

- The PTO post-*Prometheus* cont'd:
  - More to come:
    - "The USPTO is continuing to study the decision in *Mayo* and the body of case law that has evolved since *Bilski* and is developing further detailed guidance on patent subject matter eligibility under 35 U.S.C. § 101."

The Aftermath of Prometheus v. Mayo

- The PTO post-*Prometheus* cont'd:
  - The PTO's Take-Home:
    - A claim that includes a law of nature, a natural phenomenon, or an abstract idea "should include other elements or combination of elements such that, in practice, the claimed product or process amounts to significantly more than a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto."

The Future

- Claim Strategies:
  - Claims that simply compare or analyze information or data, or otherwise have no transformative step, will be subject to attack under §101 at the PTO or during litigation.
    - Example - Diagnostic Claim: detecting a genetic mutation and correlating it with a probability of disease
      - The correlation is a law of nature, and sequencing DNA is a “routine and conventional” activity

The Future

- Claim Strategies:
  - VARIETY - draft claims to include varying scope
  - Draft claims to include a sufficiently novel transformative element that applies the law of nature
    - Something MORE than “routine and conventional” laboratory or diagnostic activity
  - Emphasize that the claimed diagnostic applications of a correlation were previously poorly understood and were NOT “routine and conventional activity” that doctors/researchers had been doing prior to the inventive method

The Future

- Claim Strategies:
  - For personalized medicine or diagnostic inventions, consider drafting treatment claims rather than, or in addition to, diagnostic claims:
    - In *Prometheus*, for example, the claims could be treatment claims by adding a step of adjusting the drug or otherwise treating the patient using the metabolite information
  - Example on next slide…

The Future

- Claim Strategies:

  Example from another Prometheus patent (6,987,097):

  – 1. A method for optimizing therapeutic efficacy in a subject in need thereof, said subject receiving a drug providing 6-thioguanine, said method comprising:

    (a) determining a level of 6-thioguanine in said subject; and

    (b) **increasing the subsequent dose of said drug when** said level of 6-thioguanine is less than a member selected from the group consisting of about 230, 240, 250, 260, 280, and 300 pmol per 8×10^8 red blood cells.

  – Still unclear whether this is enough…could be considered "routine and conventional"

The Future

- Claim Strategies:
  - Be mindful of the Medical Practitioner Exception:
    - "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity."
    - 35 USC 287(c)

The Future

- Claim Strategies:
  - While the Medical Practitioner Exception may not include assays such as the one at issue in *Prometheus* (see below), it can include many other diagnostic methods:
    - "'medical activity' means the performance of a medical or surgical procedure **on a body**, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent."
    - "on a body" typically not interpreted to include assays performed on samples taken **from** the body

Questions?

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