PATENT LAW

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CLASS 4

Novelty Under the AIA pt. 2; Novelty Pre-AIA; Eligibility pt. 1; ST: Patent Searching

Novelty Under the AIA pt. 2

Grace Periods

- AIA
 - §102(b) provides exceptions to §102(a) when the subject matter was previously disclosed directly from the inventor or indirectly (e.g., through someone else) who received the information from the inventor)
- Pre-AIA
 - Broader grace period

2

Experimental Use

City of Elizabeth v. American Nicholson Pavement Co.

- · Issue:
 - Was the invention in public use or on sale for more than the allowable period of time prior to patenting?

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City of Elizabeth v. American Nicholson Pavement Co.

- Invention
 - Wooden pavement
- Timing
 - The wooden pavement was in use for 6 years before the inventor filed for patent

City of Elizabeth v. American Nicholson Pavement Co.

 What did Nicholson do to keep track of the pavement?

City of Elizabeth v. American Nicholson Pavement Co.

- "[T]he nature of a street pavement is such that it cannot be experimented upon satisfactorily except on a highway, which is always public.
- "When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, with the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation.

City of Elizabeth v. American Nicholson Pavement Co.

- "So long as he does not voluntarily **allow others** to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to the patent.
- "But if the inventor allows his machine to be used by other persons generally, either with or without compensation, or if it is, with his consent, put on sale for such use, then it will be in public use and on public sale, within the meaning of the law.

Lough v. Brunswick Corp.

- "An evaluation of a question of public use depends on how the **totality of the circumstances** of the case comports with the **policies underlying the public use** bar.' ... These policies include:
- (1) discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available; (2) favoring the prompt and widespread disclosure of inventions; (3) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and (4) prohibiting the inventor from commercially exploiting the inventor for a period greater than the statutorily prescribed time."

Lough v. Brunswick Corp.

- What factors are used in the totality of circumstances test?
- What factors are used in the totality of circumstances test? To determine whether a use is "experimental," a question of law, the totality of the circumstances must be considered, including various objective indicia of experimentation surrounding the use, such as the number of prototypes and duration of testing, whether records or progress reports were made concerning the testing, the existence of a secrecy agreement between the patentee and the party performing the testing, whether the patentee received compensation for the use of the invention, and the extent of control the inventor maintained over the testing, ... The last factor of control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about the testing or receive reports concerning the results, similarly, he is not experimenting.

11

Experimental Use

- · As a general rule, an experimental use only negates a statutory bar when the inventor was testing claimed features of the invention.
- · Courts view the totality of the circumstances when determining whether an invention was on sale or in public use
- · The experimental use exception does not include market testing.

12

Experimental Use/On Sale

· Can a use still be found to be experimental if a sale was made?

AIA Grace Period Examples

Example 1

- A invents a new widget with features
 A, B, C, and D on 2/1/13
- B independently invents the same new widget with features A, B, C, and D on 4/1/13
- B files a patent application on 5/1/13
- A files a patent application on 6/1/13

15

Example 2

- A invents a new widget with features A, B, C, and D on 2/1/13
- A publicly discloses the new widget on 2/15/13
- B independently invents the same new widget with features A, B, C, and D on 4/1/13
- B files a patent application on 5/1/13
- A files a patent application on 6/1/13

16

Example 3

- A invents a new widget with features A, B, C, and D on 2/1/13
- B independently invents the same new widget with features A, B, C, and D on 4/1/13
- A & B are both obligated to assign rights to C
- B files a patent application on 5/1/13
- A files a patent application on 6/1/13

17

Example 4

- A invents a new widget with features A, B, C, and D on 2/1/13
- B independently invents the same new widget with features A, B, C, and D on 4/1/13
- · A & B are both obligated to assign rights to C
- A publicly discloses on 4/15/13
- B files a patent application on 5/1/13
- A files a patent application on 6/1/13

18

Example 5

- A publicly discloses a new widget with features A, B, C, and D on 2/1/13
- B publicly discloses a new widget with features A, B, C, and D' on 4/1/13, where D' is an obvious variation of D
- B files a patent application on 5/1/13
- A files a patent application on 6/1/13

How Does the Grace Period Work?

- Inventor must disclose the invention publicly first
 - Less than one year before filing
 - Before a third-party discloses
- · How will proof of disclosure be measured?
 - Don't know
- · Is experimental use still a viable exception?
 - Don't know

20

Obvious Subject Matter

- The AIA grace period only protects the novelty of publicly disclosed subject matter.
- If a third party subsequently publicly discloses an obvious variation of the subject matter, that variation becomes prior art against the inventor who was otherwise first in time to publicly disclose.

21

Novelty Pre-AIA

22

§102(b)(pre-AIA)

A person shall be entitled to a patent unless – ...

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States ...

23

3rd Party Statutory Bar (pre-AIA)

- What are the implications of someone other than the inventor putting the invention into the public use or on sale before the critical date?
- · 3 categories:
 - Uses which themselves inform others about the invention
 - Uses which by their nature do not inform others about the invention
 - Secret uses

24

Electric Storage Battery Co. v. Shimadzu

- "[A public use is] where the use was without consent or knowledge of the applicant for patent."
- "[T]he evidence is that the petitioner ... has continuously employed the alleged infringing machine and process for the production of lead oxide powder used in the manufacture of plates for storage batteries which have been sold in quantity."

W.L. Gore & Associates v. Garlock

 The secret commercialization of a product or method by a third party does not provide a statutory basis to bar an applicant from obtaining a patent on the product or method.

26

W.L. Gore & Associates v. Garlock

 "As between a prior inventor who benefits from a process by selling its product but suppresses, conceals, or otherwise keeps the process from the public, a later inventor who promptly files a patent application from which the public will gain a disclosure of the process, the law favors the latter."

27

AIA Changes

- · Public Use and On Sale bar
 - §102(b)(pre-AIA) US only
 - §102(a)(1) anywhere
- · Otherwise available to the public
 - §102(b) no such language
 - §102(a)(1) language included; exact meaning and potential limiting effect on other language unknown
- · Grace period applicability
 - §102(b) grace period prevents bar when activity by inventor or other took place was less than a year
 - §102(a)(1) §102(b)(1) only prevents bars when activity by inventor took place less than a year; all third party activity creates a bar

28

§102(c)(pre-AIA)

A person shall be entitled to a patent unless - ...

(c) he has abandoned the invention

29

§102(d)(pre-AIA)

A person shall be entitled to a patent unless - ... (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

30

Novelty: Prior Invention

- 102(a) prior public knowledge of the inventor's invention
- 102(e) secret knowledge of a first inventor's work
- 102(g) basis for an interference proceeding

and

102(f) – derivation from another

§102(a)(pre-AIA)

A person shall be entitled to a patent unless - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, **before the invention** thereof by the applicant for patent ...

32

"Know or Used"

- What type of activity constitutes known or used under 102(a)?
 - Informing use?
 - Non-informing use?
 - Secret use?

33

Woodcock v. Parker

"The first inventor is entitled to the benefit of his invention, if he reduce it to practice and obtain a patent therefor, and a subsequent inventor cannot, by obtaining a patent therefor, oust the first inventor of his right . . ."

34

Application of §102(a)(pre-AIA)

- US under the '52 ACT was a first to invent system
- If more than 1 application is filed on the same invention, the patent is awarded to the applicant who--
 - establishes earliest acts of invention in US and
 has not after that suppressed, abandoned or concealed invention
 - (Ex. Keeps as trade secret; or abandons efforts)
- Potential novelty-destroying technology is measured from the date of invention, not the filing date.

35

Gillman v. Stern

- Issue:
 - Will a secret process by a third party be an activity known or used under 102(a)?
- Invention
 - Pneumatic puffing machine

Gillman v Stern

 "... it is clear that [Hass's puffing machine] was never in prior "public use" and that Haas was not a "first inventor". ... Haas kept his machine absolutely secret from the outside world except to secure selling agents for its product, and then it was only its performance, not its construction that even they learned."

Gillman v Stern

 [A secret use] is clearly not a 'public' one, and such an inventor is not a 'first inventor'."

30

Use = Public Use

- "Under section 102(a), even though the text only requires that the prior invention be 'known or used,' the challenger must show public knowledge or use, where the 'public' means those skilled in the art. This does not require actual knowledge or use by the public, just that the prior invention was publicly accessible."
- · Levi Strauss & Col v. Golden State, S.r.L.

39

How Much Knowledge?

- "The knowledge required by §102(a) involves some type of public disclosure and is not satisfied by knowledge of a single person, or a few persons working together."
- National Tractor Pullers Ass'n v. Watkins

40

Corroboration Rule

- "Because uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide clear and convincing evidence required to invalidate a patent on this ground, the judgment is reversed."
- Woodland Trust v. Flowertree Nursery, Inc., 143 U.S. 275 (1891)

41

Public Use

"Public use is use by the inventor, or by a person who is not under any limitation, restriction, or obligation of secrecy to the inventor."

Patents and the Federal Circuit, 7th Edition

42

Establishing a Date of Invention: Rule 131

Filing Date v. Invention Date

- When filed, an invention is deemed "invented" as of the filing date, even though the invention may have (and likely has) been "invented" prior to file.
- During prosecution of the patent application, the Examiner may cite a reference against the applicant that is before the filing date but after the date the invention was invented.
- How can an applicant move the invention date back in time from the filing date to the invention date?

44

"Swearing Behind" a Reference

- Under rule 131 (pre-AIA)
 - Applicants can declare an invention date prior to the date of a prior art reference.
 - Termed "swearing behind" or "antedating" a prior art reference
 - Can overcome a 102(a) or 102(e) rejection
 - Cannot overcome a 102(b) rejection—why?
- Invention date is revealed on an ad hoc basis

45

RULE 131

- Applicant can show by verified proof that the invention was completed (reduction to practice) before the filing date of the patent or publication
- Unless patent or publication date is more than one year before Applicant's filing date.
- Rule 131 is not applicable where the subject matter sought to be antedated is claimed in the reference patent

46

RULE 131(b)

"The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained."

47

§102(g)(pre-AIA)

A person shall be entitled to a patent unless -

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

48

§ 102(g)

- 102(g)(1) provides a "mechanism for resolving disputes relating to so called 'priority of inventions."
- 102(g)(2) provides the general priority rule and also provides a source of prior art

102(g) Background

- 102(g)(1) mechanism for resolving which party is entitled to a patent on same invention
- · "Winner take all"
- Only the person or party that first developed the technology will be awarded the patent

50

102(g) Background

- "A person shall be entitled to a patent unless... before the applicant's invention thereof the invention was made in this country by another."
- Exception
 - If the first inventor has "abandoned, suppressed or concealed" the invention, then the first inventor has forfeited special status under 102(g)(2).

51

Patent Interferences

Terminology

- Interference an inter partes priority proceeding held at the PTO between two or more inventors
- Senior party the first filer (i.e., the party with the earliest effective filing date)
- Junior parties subsequent filers

52

Interfering Patents

- What happens if two patents issue on same inventive concept?
 - Section 291 of the Patent Act
 - Owners of interfering patents may have their respective rights determined by a federal district court following the filing of a civil suit.

53

Determination of First Inventor

- The US patent system statutorily provides effect that only one patent may be granted for each invention.
- To be granted to the first inventor, provided that the first inventor can establish compliance with certain requirements.
- The determination of the first inventor is determined by a patent interference

54

Patent Interference Applicability

- If two or more applications are filed in the PTO for the same invention, a complicated set of proceedings called an INTERFERENCE PROCEEDING. Interference between:
 - two or more **PENDING APPLICATIONS** or
 - between PENDING APPLICATION AND ISSUED PATENT if during the first year after patent issued when declared by patent examiner or provoked by patent applicant

Prevailing in an Interference Proceeding

 Among the requirements for a patent applicant to prevail in an interference proceeding, certain <u>key events</u> and occurrences must be CORROBORATED.

These key events include

- · CONCEPTION of the invention and
- · its REDUCTION TO PRACTICE

56

Determining Priority

- GENERAL RULE for determining priority comes from 2d sent. of Sec. 102(g)(2):
- "In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

57

Diligence Requirement

 GENERAL RULE: The first inventor is the person (or persons, if there are multiple inventors of the same invention) who first conceives of the invention, provided that this person is DILIGENT from a time prior to the conception of the invention by a second inventor to the time that the first inventor reduces the invention to practice.

58

Timing of Diligence

 DILIGENCE: Such an inventor must have been diligent in actively seeking to reduce the invention to practice.
 R/P may be actual (e.g., actual construction or successful testing) or constructive (by filing of a patent application in the PTO). Diligence must be proven by convincing evidence.

59

The Rule of Priority

- In short,
 - The first inventor to reduce the invention to practice wins, unless
 - If the inventor who was first to conceive, but second to reduce to practice can show diligence from the time of conception to reduction to practice, then this inventor will displace the first inventor who reduced to practice.

60

Priority Example 1

- B conceives of an improved bottle opener on 1/1/2000, reduces the invention to practice on 6/1/2000, and files the patent application on 2/1/2001.
- M conceives of the same bottle opener on 3/1/2000, reduces it to practice on 8/1/2000, and files a patent application on 12/1/2000.
- Which party is entitled to priority of invention?

Priority Example 2

- On July 4, 2003, H conceives of a novel clock recovery circuit. He sets the project aside until 11/25/2003, and after several weeks of experimenting ultimately reduces the invention to practice on 12/25/2003. H files the patent application on 1/1/2004.
- N conceives of the same circuit on 8/1/2003, reduces it to practice on 9/1/2003, and files a patent application on 10/1/2003.
- Which party is entitled to priority of invention?

62

Priority Example 3

- H conceives a new optical recording media on 3/21/2003. H never builds a prototype but diligently files a patent application claiming the recording media on 12/1/2003.
- M conceives of the identical recording media on 4/1/2003, diligently works on the invention until reducing it to practice on 5/1/2003, and files a patent application claiming the recording media on 8/15/2003.
- Which party is entitled to priority of invention?

63

Oka v. Youssefyah

- 1998 Federal Circuit Panel Decision
- Invention
 - A compound possessing angiotensin converting enzyme inhibition activity

64

Oka v. Youssefyah

"Conception requires (1) the idea of the structure of the chemical compound, and (2) possession of an operative method of making it. ... Conception may conveniently be considered as consisting of two parts. The first part is 'the directing conception' and may be defined as the idea or conception that a certain desired result may be obtained by following a particular general plan. The directing conception is often referred to as the inventive concept, thought or idea. The second part of conception is 'the selection of the means for effectively carrying out the directing conception."

65

Oka v. Youssefyah

- Junior Party Youssefyeh
- Senior Party Oka
- Oka's date Oct 31, 1980 (filing date)
- Youssefyeh's dates
 - Feb 27, 1980 idea of making the select compounds
 - Oct 10, 1980 method of making a compound outside of count
 - Last week of Oct 1980 species of the selected compounds
- Oka as senior party was presumed to get award of priority ("In event of a tie . . . Priority must be awarded to the senior party")

66

Showing Conception

 "To show conception, an inventor must present proof showing possession or knowledge of each feature of the count and communicated to a corroborating witness in sufficient detail to enable one of skill in the art to replicate the invention."

Reduction to Practice

- · Reduction to practice by:
 - 1) Constructively by filing a patent application
 - **2) Actually** by building and testing a physical embodiment of the invention

68

Scott v. Finney

- Senior Party Finney
- Junior Party Scott
- Reduction to Practice question of law

69

Scott v. Finney

 "To show reduction to practice, the junior party must demonstrate that the invention is 'suitable for its intended purpose."

70

Scott v. Finney

- "When testing is necessary to show proof of actual reduction to practice, the embodiment relied upon as evidence of priority must actually work for its intended purpose..."
- "... [T]he testing requirement depends on the particular facts of each case..."

71

Diligence

- "The party chargeable with diligence must account for the entire period during which diligence is required."
- · Gould v. Schawlow

72

Must Everyone Show Diligence?

 "The inventor who is both first to conceive and first to reduce an invention to practice wins the priority contest without having to show diligence.... Only one party's diligence is relevant in a priority contest."

Corroboration

 The showing of conception, reduction to practice and diligence requires corroboration.

74

Woodland Trust v. Flowertree Nursery, Inc.

- 1998 Federal Circuit Panel Decision
- Invention
 - Method and apparatus for protecting a plot of foliage plants from freezing by establishing an insulating covering of ice over ground level watering.
- Issue
 - Is uncorroborated oral testimony sufficient to invalidate a patent?

75

Woodland Trust v. Flowertree Nursery, Inc.

- "[I]n order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public."
- Excludes private knowledge not known to the public

76

Woodland Trust v. Flowertree Nursery, Inc.

- Corroboration of oral evidence of prior invention is the general rule in patent disputes.
- What criteria did the court use in assessing corroboration?

7

Woodland Trust v. Flowertree Nursery, Inc.

- Holding
 - "Because uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide clear and convincing evidence required to invalidate a patent on this ground, the judgment is reversed."

78

Winning a Patent Interference

- Party that proves FIRST R/P of invention will win UNLESS:
 - Party's invention was derived from other party
 - Party with first R/P abandoned invention
 - Party with first R/P suppressed or concealed invention
 - Other party conceived invention first and was diligent from just prior to first party's conception to the opponent's own later R/P
- BUT success or failure of motions at outset of interference may affect outcome.

Recommendations (under old 102)

- Use company or personal invention notebooks and create detailed records of inventive activities.
- Retain all papers and documents which may show diligence.
- Get corroboration by witnessing by competent others
- Keep daily records, correspondence, memos, phone, fax and e-mail records, travel records, and evidence of steps taken daily and weekly on reduction to practice of the invention.

80

Corroborating Witnesses

- Witnesses
 - should do more than merely sign notebook pages with a "READ AND UNDERSTOOD" notation.
 - should be familiar with every effort and every success and step of the development.
 - may need to submit affidavits or live testimony concerning these activities but preference is a written record or tangible facts.

81

Deliberate?

 "In general, suppression or concealment must be deliberate or intentional ... but a lengthy delay between the making of the invention and filing for a patent can give rise to an inference of concealment. ... However, the inference created by delay can be overcome ..."

82

§102(e)(pre-AIA)

A person shall be entitled to a patent unless - ...

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language ...

83

§102(e)(pre-AIA)

- The prior art patents and publications count as prior art based on their filing date, not the publication date or issue date
- Differences with §102(a)(2)(a)
 - Rule 131 possible pre-AIA; not possible under AIA
 - First actual filing date in the US v. priority date anywhere in the world

84

§102(f)(pre-AIA)

- A person shall be entitled to a patent unless –
- (f) he did not himself invent the subject matter sought to be patented.

Eligibility pt. 1

Patent Eligibility

- Is a particular invention of a kind that the patent laws intended to protect?
- Subject matter open to patenting
 - Are there subject matters that are not open to patenting?
 - · Natural Laws
 - Phenomena of Nature
 - Abstract Principles
- Technology = useful arts

87

Diamond v. Chakrabarty

- · Issue:
 - Can micro-organisms qualify as patentable subject matter (without Congress's express authorization)?

88

Diamond v. Chakrabarty

7. A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

89

Diamond v. Chakrabarty

- · What are canons of construction?
- What is the legislative history?
- Why does the court focus on whether the microorganism is an unknown natural phenomenon?

90

Diamond v. Chakrabarty

- What if the technology involved a shift from one known form to another form—could the shift form then be patentable?
- Must Congress expressly authorize protection?
- What policy issue does the court discuss?

Diamond v. Chakrabarty

- Holding
 - Congress hasn't excluded organisms produced by genetic engineering from \$101.

92

Products of Nature

- Patents are not available for products of nature per se.
- However, patents on "isolated" or "purified" products that are not naturally found in nature were generally patentable prior to Mayo

93

Mayo Collaborative Services v. Prometheus Labs., Inc.

- · 2012 Supreme Court Decision
- · Laws of nature v. patentable subject matter
- · Prometheus
 - sole and exclusive licensee of the '623 and '302 patents
 - sells diagnostic tests that embody the processes the patents describe
- Mayo
 - Originally bought Prometheus tests
 - Later decided to use its own tests

94

Mayo Collaborative Services v. Prometheus Labs., Inc.

- Laws of nature, natural phenomena, and abstract ideas are not patentable
- They are the basic tools of scientific and technological work
- Monopolization of these tools would impede, instead of encourages, innovation
- Applications of laws of nature are not per se unpatentable

95

Mayo Collaborative Services v. Prometheus Labs., Inc.

• "The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful sideeffects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable."

96

Mayo Collaborative Services v. Prometheus Labs., Inc.

"[Precedent] insist[s] that a process
that focuses upon the use of a natural
law also 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."

Mayo Collaborative Services v. Prometheus Labs., Inc.

- · What is the technology?
- What was the state of the research in this area?

98

Mayo Collaborative Services v. Prometheus Labs., Inc.

Claim

- "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 6thioguanine less than about 230 pmol per 8x10⁸ 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 8x10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."

99

Mayo Collaborative Services v. Prometheus Labs., Inc.

- · What happened at D.C.?
 - Finding that Mayo infringed claim 7
 - But ruled summary judgment in favor of Mayo on grounds that the patent claimed natural laws
- · What happened at Fed. Cir.?
 - Reversed
 - Additional steps involve the transformation of the human body or of blood taken from the body and thus satisfied the machine or transformation test

100

Mayo Collaborative Services v. Prometheus Labs., Inc.

 "[D]o the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no."

101

Mayo Collaborative Services v. Prometheus Labs., Inc.

 "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."

102

Mayo Collaborative Services v. Prometheus Labs., Inc.

 "[T]he claims inform a relevant audience about certain laws of nature; any additional 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."

Mayo Collaborative Services v. Prometheus Labs., Inc.

 "[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."

104

Mayo Collaborative Services v. Prometheus Labs., Inc.

"And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify."

105

Post Mayo Claim Drafting

- In the claims, have something beyond steps or combination of steps that are in context obvious, already in use, or purely conventional
- If your claims include a natural law, make sure to structure the claim (or step(s) of the claim) as an inventive application of the natural law

106

Association for Molecular Pathology v. Myriad

- 2013 Supreme Court Case
- isolated DNA
 - not patentable subject matter
- cDNA (synthetic versions of DNA that omit non-coding portions)
 - patentable

107

Association for Molecular Pathology v. Myriad

 "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. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."

108

Association for Molecular Pathology v. Myriad

"[T]he 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 was 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."

Association for Molecular Pathology v. Myriad

 "We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."

110

Patent Office Post-Myriad

"As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. §101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility."

111

Ariosa Diagnostics v. Sequenom

- 2015 Fed. Cir. Panel of <u>Reyna</u>, Linn, and Wallach
- Invention
 - methods of using cffDNA

112

Ariosa Diagnostics v. Sequenom

"Like the patentee in Mayo, Sequenom contends that the claimed methods are patent eligible applications of a natural phenomenon, specifically a method for detecting paternally inherited cffDNA. Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum."

113

Ariosa Diagnostics v. Sequenom

"It is important to note [by the District Court]
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."

114

Ariosa Diagnostics v. Sequenom

"[P]atent claims should not prevent the use of the basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws. While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. In this case, Sequenom's attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter."

Patent Searching

Patent Searches

- When should a patent search be performed?
 - Prior to drafting an application
 - Before filing an application
 - During the drafting of an application
 - After issuance; possible reexamination

110

Patent Searches

- Why should a search be performed?
 - Worthwhile investment
 - Identify possible scope
 - Draft around the art

118

Patent Searches

- Where/how should the search be performed?
 - Performed online
 - Search patents and published patent applications
 - Search for other possible art

119

117

Patent Searches

- · Type of Searching
 - Key word search
 - Inventor search
 - Assignee search
 - Limitation of what's listed without separate assignment search
 - Classification Search

120

Patent Searches

- How is prior art disclosed to the patent office?
 - IDS