BIO subject matter eligibility
US/European differences and TRIPS

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Treaties and legislation

UK Statute of Monopolies 1624

- Section 6:
  - Provided alsoe That any Declaracion before mencioned shall not extend to any tres Patents and Graunt of Privilege for the tearme of fowerteene yeares or under, hereafter to be made of the sole working or makinge of any **manner of new Manufactures within this Realme**, to the **true and first Inventor and Inventors of such Manufactures**, which others at the tyme of makinge such tres Patents and Graunts shall not use, soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raisinge prices of Commodities at home, or hurt of Trade, or generallie inconvenient…

- Introduced by Sir Edward Coke.
- Remains part of the law in Canada, Australia and New Zealand.
- Influential on US law since "manufacture" is a category within 35 USC §101

US Constitution

Article I, Section 8, Clause 8

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and **Inventors** the exclusive Right to their respective Writings and **Discoveries**.

US Patent Statute

35 USC 100

When used in this title unless the context otherwise indicates—

(a) The term “invention” means invention or discovery.

(b) The term “process” means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

35 USC 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 therefor, subject to the conditions and requirements of this title.

Judicial exceptions

Laws of nature

Abstract ideas

Natural phenomena (allegedly includes products of nature)

Diamond v Chakrabarty
Justice Burger – general approach:

- **Begin with the language of the statute**. *Southeastern Community College v. Davis*,442 U. S. 397, 442 U. S. 405 (1979).

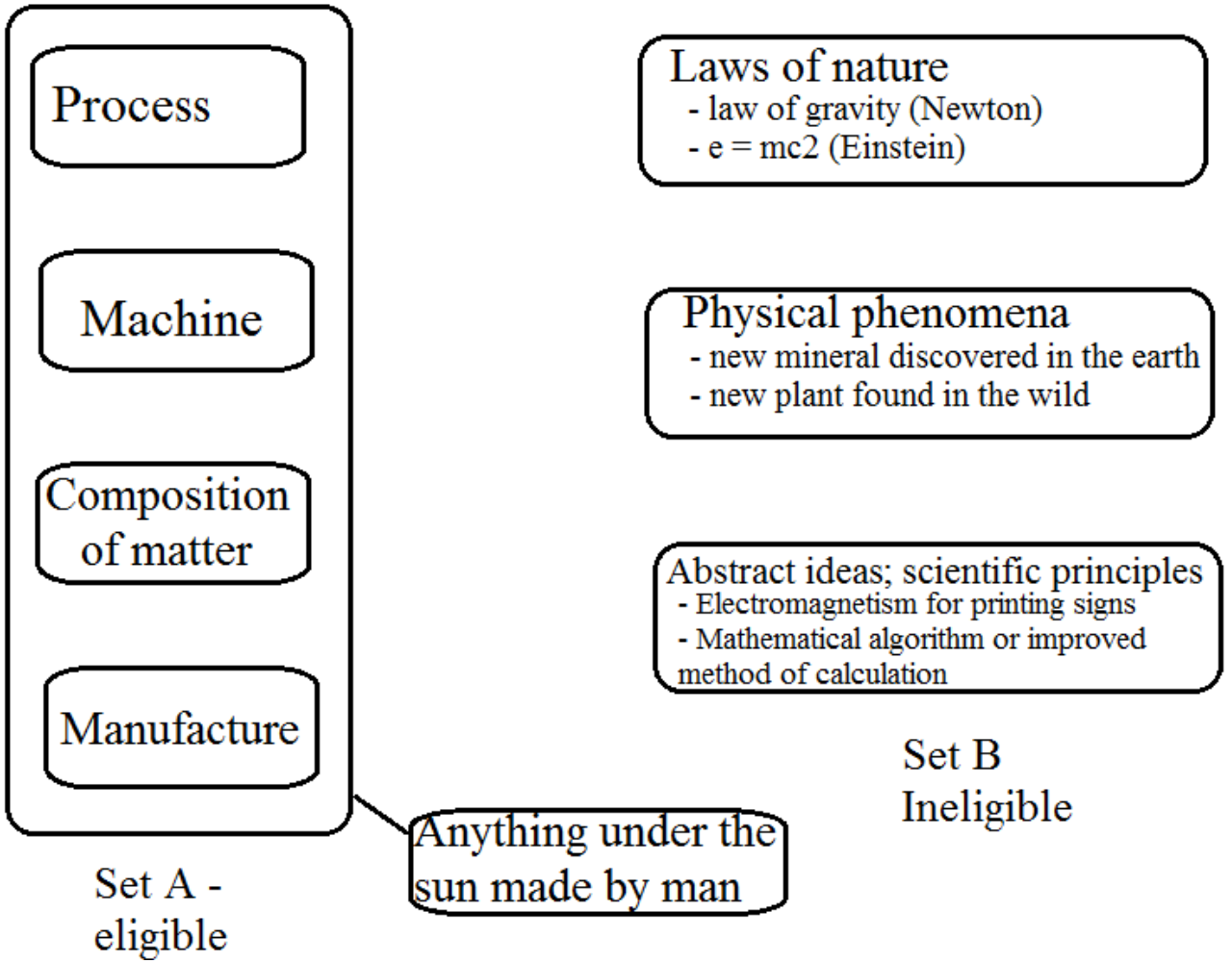
- **Words take their ordinary, contemporary, common meaning**." *Perrin v. United States*,444 U. S. 37, 444 U. S. 42 (1979).

- **Courts "should not read into the patent laws limitations and conditions which the legislature has not expressed**." *United States v. Dubilier* Condenser Corp.,289 U. S. 178, 289 U. S. 199 (1933) .

Substantive conditions for §101 entitlement

- Invention or discovery of an inventor
- Novelty
- Utility or improvement
- Categorical compliance (note Constitutional ref. to “useful arts”)
  - Process
  - Machine
  - Manufacture
  - Composition of matter
- An invention complying as a matter of substance as opposed to mere outward presentation with each of these requirements cannot be ruled ineligible by judicial exception without breach of the separation of powers doctrine (Scalia and Garner, *Reading Law*, West, 2012; see also the *Chakrabarty* prohibition)
- Should meet the obligations of any international agreement binding the US: Marshall J., *Murray v. Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804)

35 USC 101 and exceptions – Venn diagram

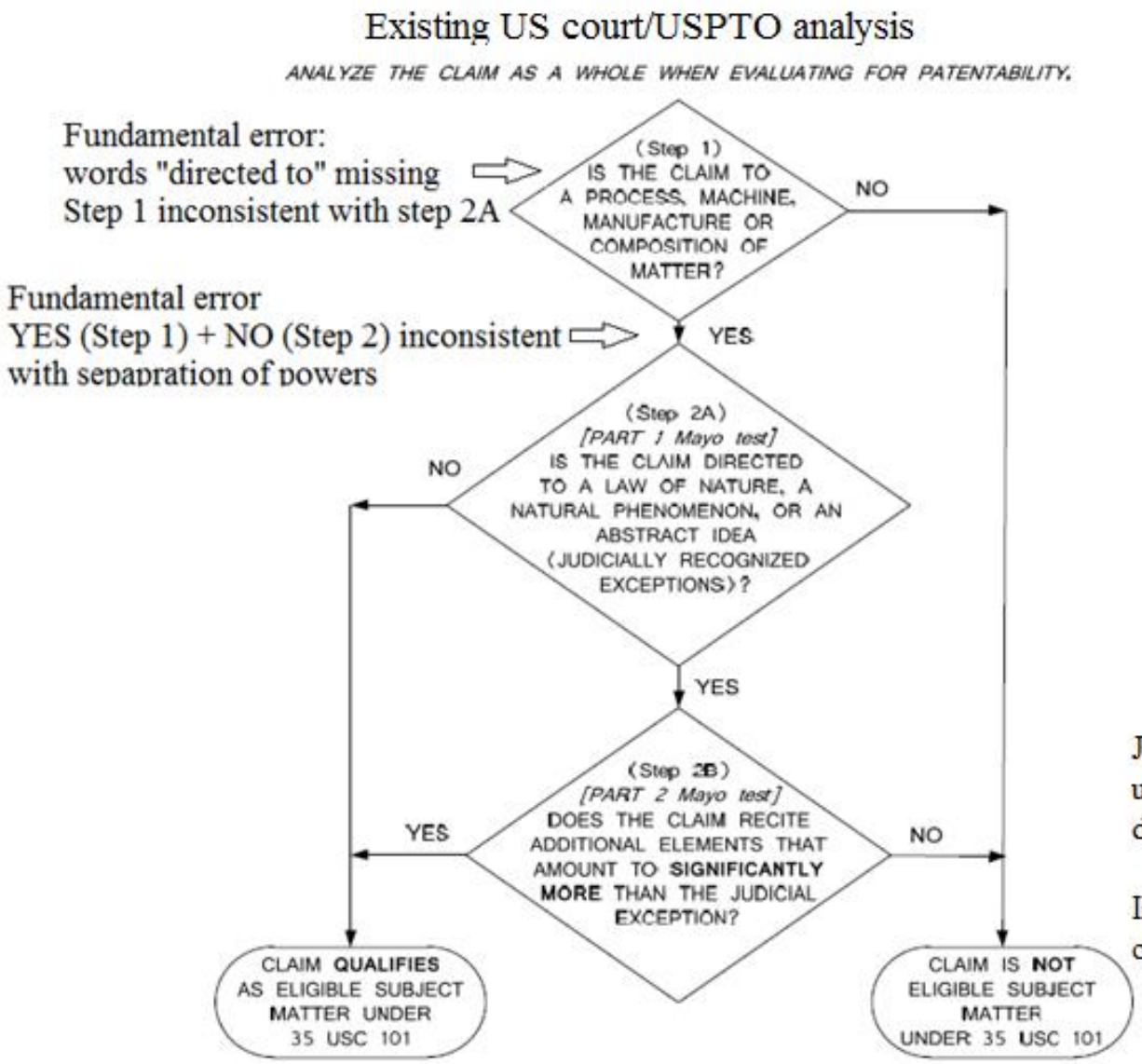


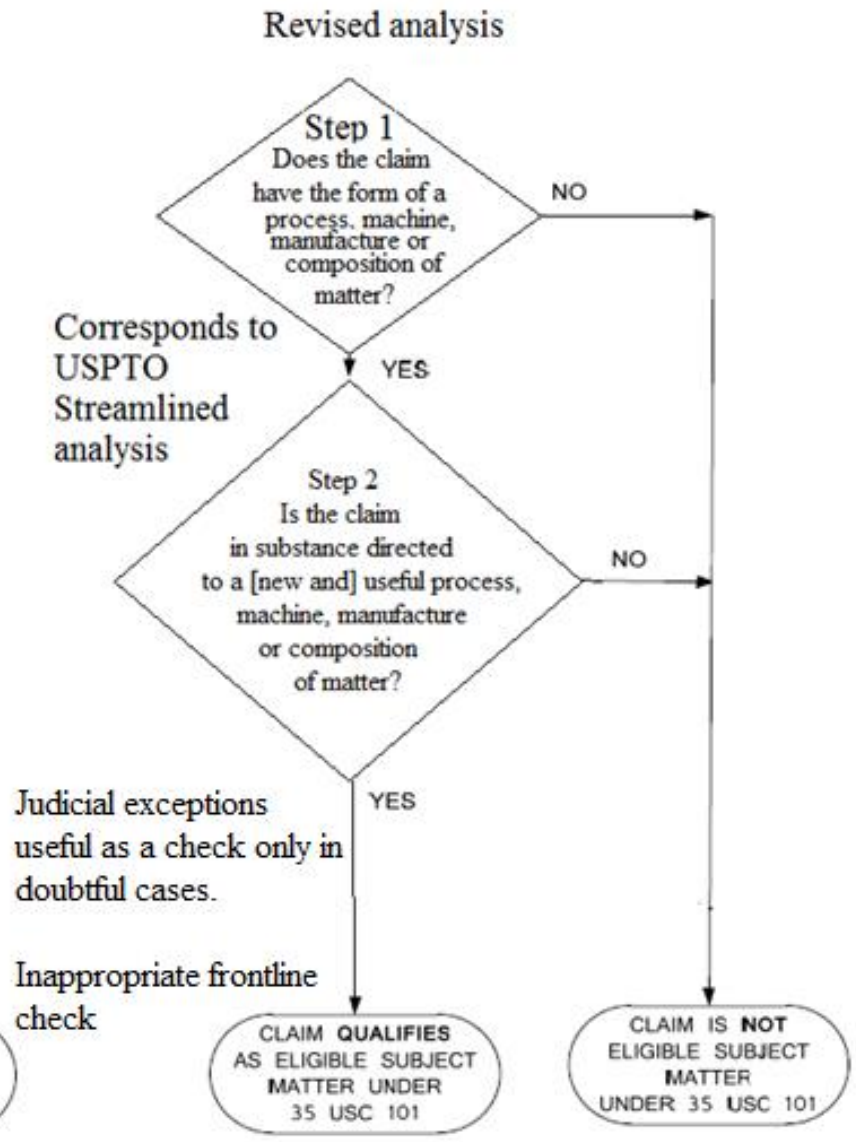
As originally stated set B does not intersect with set A.

Under current practice set B should not intersect with set A.

Intersection of set B with set A and exclusion of overlapping regions raises Constitutional objections based on separation of powers.

35 USC 101 analysis algorithms





Key test for revised step 2

- Does the claim have a feature which
  - (a) clearly contributes to novelty and utility and
  - (b) is defined in terms clearly falling within one of the eligible categories of §101?
- See practical approach of Judge Breyer in *Mayo* v *Prometheus* discussed below
- Owing to the "avalanche effect" it is inadvisable to present in examination or rely in litigation on main independent claims that do not satisfy this test.

Manufacture: *Hartranft v. Wiegmann* 121 U. S. 609, 121 U. S. 615 (1887).

- Blocks of marble – not manufactures
- Washed and scoured wool; cleaned and ginned cotton - not manufactures.
- Hay packed in bales – not manufactures.
- Copper plates with upturned edges – not manufactures.
- Shoes from the sap of a rubber tree hardened in a mould – manufactures

- An article does not become a manufacture simply on change of form or on isolation from impurities
- **But** such a change suffices if accompanied by the additional reason of new utility. **KEY: DIFFERENCE + NEW UTILITY**

Manufacture - Justice Burger in *Chakrabarty* 447 U.S. 303 (1980):

Guided by these canons of construction, this Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean

> "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand labor or by machinery."

American Fruit Growers, Inc. v. Brogdex Co.,283 U. S. 1, 283 U. S. 11 (1931) ….

His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter **-- a product of human ingenuity "having a distinctive name, character [and] use."** *Hartranft v. Wiegmann*, 121 U. S. 609, 121 U. S. 615 (1887) ...

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility.

Both ***Hartranft*** and ***Chakrabarty*** quoted with approval by Justice Thomas in ***Myriad***.

Composition of matter

- Chief Justice Berger in *Chakrabarty*:

  "[C]omposition of matter" has been construed consistent with its common usage to include "**all compositions of two or more substances** and . . . **all composite articles**, whether they be the results of **chemical union**, or of **mechanical mixture**, or whether they be gases, fluids, powders or solids." *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (DC 1957) (citing A. Deller, *Walker on Patents*, **14**, p. 55 (1st ed. 1937))

- Isolated naturally-occurring DNA segment e.g. gBRCA1
  - arguably **not** within the above definition.
    - Single substance; **not** the result of chemical union (i.e., synthesis by the hand of man) - but instead merely an otherwise unchanged fragment of a larger naturally-occurring molecule.
    - Qualifies (if at all) as a manufacture.
- Pair of single-stranded DNA primers –
  - qualifies as a composite article.
    - New utility (enabling amplification of a specific DNA sequence)
    - *University of Utah v Ambry Genetics* (CAFC, 2014) arguably in error.

35 USC 101 “Process”

- *Gottschalk v. Benson*, *409 U.S. 63, 70, 175 USPQ 673, 676 (1972) quotes* *Cochrane v. Deener*, 94 U.S. 780 (1876) (flour milling; affirmed) where Justice Bradley stated:
  - A process is a mode of treatment of certain materials to produce a given **result**. **It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing.** If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art. The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new **result**. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.

TRIPs Agreement, a.27
Patentable subject-matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for **any inventions**, whether products or processes, in **all fields of technology**, provided that they are new, involve an inventive step and are capable of industrial application… patents shall be available and patent rights enjoyable without discrimination as to the place of invention, **the field of technology** and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect **ordre public or morality**, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

   (a) **diagnostic, therapeutic and surgical methods** for the treatment of humans or animals;

   (b) **plants and animals other than micro-organisms**, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof…

Note 5: For the purposes of this Article, the terms **"inventive step"** and **"capable of industrial application"** may be deemed by a Member to be synonymous with the terms **"non-obvious"** and **"useful"** respectively.

35 USC 101/TRIPS compliance

- Subject matter compliance –
  - Manufacture or process
  - Useful arts/all fields of technology; no discrimination as to technical field
- Utility/capacity for industrial application
- Latitude for national interpretation – implied by “May be deemed” in Note 5

Directive 98/44/EC
Mentions TRIPS at Recitals, 1.2, 3.6 and Article 2.

2.1. For the purposes of this Directive,

(a) “biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) “microbiological process” means any process involving or performed upon or resulting in microbiological material.

3.1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable **even if they concern a product consisting of or containing biological materia**l or a process by means of which biological material is produced, processed or used.

3.2. Biological material which is **isolated** from its natural environment or **produced by means of a technical process** may be the subject of an invention **even if it previously occurred in nature.**

5.2. **An element isolated from the human body** or **otherwise produced by means of a technical process**, **including the sequence or partial sequence of a gene**, may constitute a patentable invention, **even if the structure of that element is identical to that of a natural element.**

5.3. The **industrial application** of a sequence or a partial sequence of a gene must be disclosed in the patent application. **NB** under TRIPS this equates to utility.

EPC provisions

a.52 EPC

(1) European patents shall be granted for any inventions, in **all fields of technology**, provided that they are **new**, **involve an inventive step** and are **susceptible of industrial application**.

(2) The following in particular shall **not** be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

a.53EPC

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "**ordre public" or morality …** such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) **plant or animal varieties** or **essentially biological processes for the production of plants or animals**; this provision shall **not apply to microbiological processes or the products thereof;**

(c) **methods for treatment of the human or animal body by surgery or therapy** and **diagnostic methods practised on the human or animal body**; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

EPC Implementing regulations

- **Rule 26:** (1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. **Directive 98/44/EC of 6 July 1998** on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation
- **Rule 27:** Biotechnological inventions shall also be patentable if they concern:
  - (a) **biological material** which is **isolated** from its natural environment or produced by means of a technical process even if it previously occurred in nature;
  - (b) **plants or animals** if the technical feasibility of the invention is not confined to a particular plant or animal variety;
  - (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

EPC r. 29 The human body and its elements

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

gDNA and natural product claims in the US, Europe and Australia

European authorities confirming isolated sequence/natural product claims are eligible

- *EPO Guidelines for Examination* at Part G, Chapter II, 3.1 (www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm).
- T 272/95 *Relaxin/HOWARD FLOREY INSTITUTE*.
- 1213/05 *Breast and ovarian cancer/UNIVERSITY OF UTAH*
- T 0018/09 *Neutrokine/HUMAN GENOME SCIENCES*
- *Human Genome Sciences* [2011] UKSC 51.

Myriad claim and decision 133 S.Ct. 2107

- **An isolated DNA** coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2. (BRCA1)
- Held ineligible by Justice Thomas:
  - Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes.
  - Finding and separating an important and useful gene from its surrounding genetic material does not create anything and is not an act of invention.
  - Claim not expressed in terms of composition and not depending on the creation of a unique molecule, so creation of a non-naturally occurring molecule during isolation by severing chemical bonds irrelevant.
  - Claim is primarily concerned with the information content of the genetic sequence
  - [**Key holding]** A naturally occurring DNA segment is a product of nature and not patent eligible **merely because** it has been isolated … 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.
- **Note** reasoning in US Government *amicus* brief.

Reaction and follow-up to Myriad

- **Nancy Linck** to [then] Deputy Commissioner Drew Hirschfeld 06-27-2014:

  "Addressing the Myriad case, the actual holding is that isolated DNA, if it is the same as naturally occurring DNA, is not patent eligible. Period. Thus, the PTO cannot issue patents to such DNA molecules just because the DNA is isolated. Please seriously consider limiting the guidelines to that holding. That would be a service to biotechnology and to the PTO."

- **Compare** *Yvonne D'Arcy v Myriad Genetics*, [2015] HCA 35
  - decision to accord or refuse patentability to a particular class of claims could have implications for Australia's obligations under international law.
  - The law of other countries should be taken into account, e.g. China, Japan, Korea, Singapore and India.
  - But the Court was not concerned with "gene patenting" generally, but with a limited eligibility issue.
- *IN RE BRCA1- AND BRCA2-BASED HEREDITARY CANCER TEST PATENT LITIGATION* – ***University of Utah v Ambry Genetics*** (Fed Cir, 2014)
  - pair of primers similar to that in nature ineligible
  - **contrast** claims approved in T1213/05 and T 666/05.

University of Utah v Ambry Genetics - inconvenient technical and legal facts

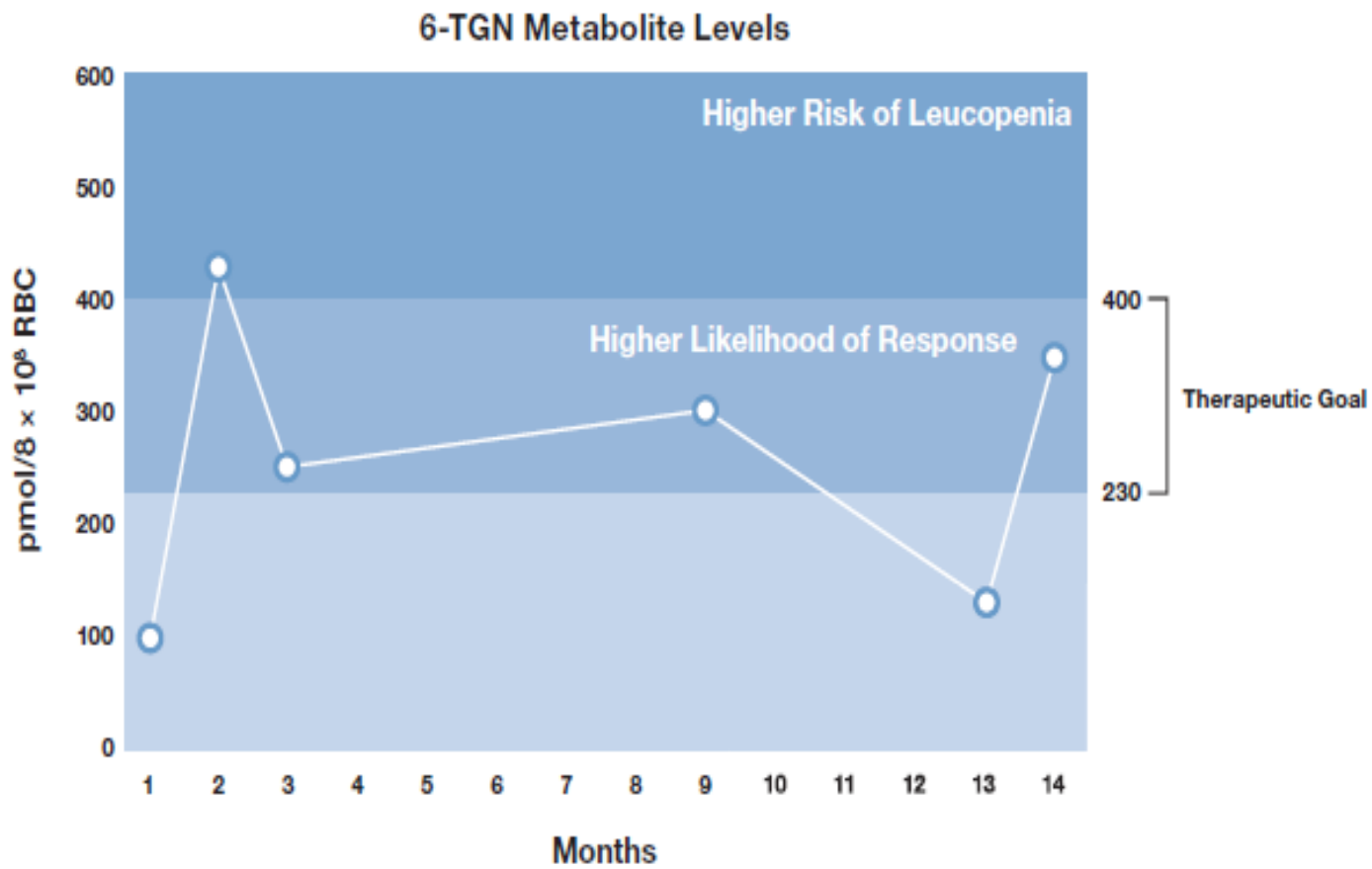
- Pair of primers, not just a single primer claimed; claim arguably as a matter of substance within the composition of matter category.
- Each primer is synthetically created and does not occur as a distinct entity within the human body.
- For PCR functionality each primer DNA sequence is in vastly greater abundance than in nature, hence arguably also a qualifying manufacture.
  - Nothing in *Myriad* to indicate intention to overrule by a side-wind *Parke-Davis & Co. v. H.K. Mulford Co*., 189 F. 95 (C.C.S.D.N.Y. 1911) (adrenalin), *Kuehmsted v. Farbenfabriken of Elberfeld Co*., 179 F. 701 (7th Cir. 1910) (aspirin), *Merck & Co. v. Olin Mathieson Chem. Corp*., 253 F.2d 156 (4th Cir. 1958) (vitamin B12).
- Their ordered combination gives rise to the new function that "the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene."

T 1213/05 *Breast and ovarian cancer/UNIVERSITY OF UTAH*

- Claims allowed in European opposition appeal as industrially applicable diagnostic tools:
  - 1. A nucleic acid probe wherein the nucleotide sequence of said probe comprises the following DNA sequence: [listing] or a DNA probe comprising a nucleotide sequence selected from the group consisting of SEQ ID NOs: 35, 38, 41, 42, 47, 57, 62, 66, 67, 72 and 81.
  - 2. A replicative cloning vector which comprises (a) an isolated DNA according to claim 1 and (b) a replicon operative in a host cell for said vector.
  - 3. Host cells in vitro transformed with a vector as claimed in claim 2.
- Federal Circuit holding in *University of Utah:*
  - arguably grounded in mistakes both as to technical facts and as to established US domestic law
  - in direct conflict with EU Directive 98/44/EC and consequential EPO rules
  - in direct conflict with EPO Appeal Board decisions
  - principle of law arguably in breach of US obligations under TRIPS

Process claims in the US and Europe

Mayo v Prometheus 132 S.Ct. 1289



Prometheus claim (ineligible under § 101)

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 **[known]**; and

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

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 **[abstract information]** 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 **[also abstract information].**

Opinion of Judge Breyer

- [Known] administration and analysis steps not evaluated as eligible “processes.”
- Focus was on the **novel** features which were a consequence of how the body metabolised thiopurine compounds [**but individually were ineligible**].
- Question was whether the patent claims added **enough** to allow the processes they described to qualify as patent-eligible processes that ***applied*** natural laws?
- **Administering step** simply referred to doctors as the relevant audience.
- **Determining step** was well-understood routine activity.
- Additional steps in **ordered combination** consisted of **well understood, routine, conventional activity** already engaged in by the scientific community and when viewed as a whole **added nothing significant beyond the sum of their parts taken separately**.

EPO style approach to the claim (EP-B-1115403)

- "Any hardware" approach first set out in T 931/95 *PBS PARTNERSHIP/Controlling pension benefits system* and approved by the Enlarged Appeal Board in in G 3/08 *PRESIDENT'S REFERENCE*.
- Administering a drug providing 6-thioguanine to a subject and determining the level of 6-thioguanine in said subject self-evidently a patent-eligible process - determination is a blood test carried out using HPLC.
- Process steps should not become ineligible merely by inclusion of particular criteria for interpretation of the results (c.f. second Federal Circuit opinion).
- If final features not treated as a technical contribution to therapeutic efficiency (see the file of similar EP-B-1695092) but disregarded as mere presentation of information, then it might be objected that the claim lacked novelty (also a requirement of §101). [see Cole, *Prometheus v. Mayo – The Wrong Rat?* IPWatchdog, 2012]

Viable European claim (not in the granted patent)

An azopurine drug for administration to a subject having an immune-mediated gastrointestinal disorder

at a dosage providing a level of 6-thioguanine is in the range of about 230 pmol per $8x10^8$ red blood cells to about 400 pmol per $8x10^8$ red blood cells,

said level being maintained by periodically determining in vitro a level of 6-thioguanine in a sample from said subject and adjusting the dosage to maintain said level.

- Many subsequent US method of treatment claims have issued in this general format.

Post-*Mayo* Federal Circuit opinions

- *University of Utah v Ambry Genetics* (Fed. Cir. 2014); compare T 0666/05 *Mutation/UNIVERSITY OF UTAH* and T 80/05 *Method of Diagnosis/UNIVERSITY OF UTAH*

- *Ariosa Diagnostics, Inc. v. Sequenom, Inc.], 788 F.3d 1371 (Fed. Cir. 2015)*, en banc rehearing and certiorari denied, compare T 0146/07 *Prenatal diagnosis/ISIS*

- *Genetic Technologies v Merial* (Fed Cir., Apr 8 2016) – EP-B-0414469, no opposition filed

Conflicting EP/US holdings

- ***Genetic Technologies v Merial***
  - "…under the Mayo/Alice framework, a claim directed to a newly discovered law of nature (or natural phenomenon or abstract idea) cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility".
- ***Case Law of the Boards of Appeal of the European Patent Office***, 7th Ed 2013 p. 15
  - If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1) EPC. If, however, that property is put to practical use, then this constitutes an invention which may be patentable. To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable…."
- See also G 2/88 *Friction-reducing additive III/MOBIL OIL*

Sequenom/Isis 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 [**starting material newly selected and obtained by the hand of man**], which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample [**transformative operation new for this starting material and providing new utility]** and

detecting the presence of a paternally inherited nucleic acid of foetal origin in the sample. [**operation performed (implicitly on the transformed starting material) and providing new utility**]

Substantive eligibility in *Sequenom* – I see CIPA brief

- Deriving a paternally inherited nucleic acid from the maternal serum or plasma of a pregnant female was a transformation or reduction of that nucleic acid to a different state or thing and was neither a well-understood, routine, conventional activity previously engaged in by researchers in the relevant field nor a mere recitation of a law of nature.

Substantive eligibility in *Sequenom* – II

- Amplifying nucleic acid of the specified provenance was also not a well-understood, routine, conventional activity previously engaged in by researchers in the field of non-invasive prenatal detection. The panel opinion confused what was conventional in that field with what was conventional in different scientific fields, for example the cancer detection. Its finding that the product of amplification was a mere natural phenomenon was both a legal and a factual misclassification.
- concentration 1000-1,000,000 times that of the original cffDNA

Substantive eligibility in *Sequenom* – III

- The detection step which is the third element of the claimed method also makes a hitherto unacknowledged contribution to process-eligibility.
- The panel opinion erred in discounting the new utility of the ordered combination of claimed elements considered as affirmative evidence of eligibility and, instead, erroneously concluded that the claimed method of detecting paternally inherited cffDNA is not new and useful. *Evans v Eaton*, 20 US 356, 399 (1822), *Webster Loom Co. v. Higgins*, 105 U.S. at 591, *KSR v Teleflex* 550 U.S. at 416.

Summary and conclusions

Summary and conclusions

- US position on TRIPS should be leadership, not reaction.
- Although Supreme Court opinions present difficulties, the main problems have been over-reaction in the CAFC and the USPTO.
- USPTO should treat *University of Utah v Ambry Genetics*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc*. and *Genetic Technologies v Merial* as non-precedental
  - "The Office can always distinguish bad law, if it so chooses. That was the approach the Office took when Bruce Lehman was Commissioner and I was the Office's Solicitor. Our position was that bad law should not prevent patentable inventions from receiving protection or cause valid patents to be struck down. Since Bruce left, I fear the Office has not been willing to take that leadership role**. Former Solicitor of Patents and Trademarks [Nancy] Linck** (Patent Docs, May 25, 2016).
- The Federal Circuit should also consider treating these decisions as of low precedential value and the point should be made in future attorney briefs.
- Claims should not be of undue breadth and novel features should be drafted so as to comply positively with the appropriate eligibility category.
- Our clients/profession can do much to minimise damage absent/before Congressional legislation.