

Issues in Global Patent Protection for Life Sciences and Health Care

Presented by
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Patentable Subject Matter and Evisceration of Congressionally-Mandated Tests under Sections 102 and 103

Two Steps:

- **Step 1**
Heightening of Utility Standard in Section 101; and
- **Step 2**
Reversing Course in Redefining “Manufacture” and “Composition of Matter” vs “Law of Nature” in Section 101

Step 1: The Heightening of the Utility Standard

- 1952 Patent Act, Section 101:

*“Whoever invents or discovers any new and **useful** process, machine, **manufacture, or composition of matter**, or any new and useful improvements thereof, may obtain a patent”*



The Supreme Court Changes the Standard for Utility (1966)

- *Brenner v. Manson*, 383 U.S. 519 (1966)
No. 58

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The 2001 USPTO Utility Guidelines

- *Implementing the heightened Utility Standard of Brenner*
- *Specific and Substantial Utility Required*
- *Compare to plain language of Section 101.*



In re Fisher, 421 F.3d 1365 (2005)

- The CAFC endorsing the 2001 PTO Utility Examination Guidelines, holding that *Brenner v. Manson* applies broadly to the fields of chemistry and biology and that ***the PTO had not applied a heightened standard for utility of ESTs.***
- **Substantial Utility:** "an asserted use must show that the claimed invention has a significant and presently available benefit to the public."
- **Specific Utility:** "an application must disclose a use which is not so vague to be meaningless" and "an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public."
- *Compare again with plain language of Section 101.*

Section 101 Elevated at the Expense of Sections 102 and 103

- The decision to deny protection to inventions that contribute to the "useful arts" but not to an extent justifying the exclusive right afforded by a patent is more properly founded in the nonobviousness requirement of 35 U.S.C. § 103 than in the utility requirement of 35 U.S.C. § 101.
- There is only a statutory requirement that the invention be "useful"...there is no requirement that the invention be rejected on subject matter grounds if judged not sufficiently useful.

Result of the Heightening of Section 101 Standard

- Easier for USPTO to reject patent applications
- Easier for Courts to invalidate issued patents
- Impacting Corporate Decisions for pursuing potentially significant discoveries that are perceived to be within the margins of “Useful” and “Substantially Useful”
- Fewer patents filed
- This, in turn, impacts us in innumerable ways, including but not limited to basic scientific research leading to improvements in Public Health and Healthcare.

Step 2: Reversing Position Composition of Matter vs Law of Nature

- Ironically, this reversal came only 3 months after the US implements “first-to-invent” in the US on global harmonization grounds. The reversal dramatically disharmonizes US patent law from many non-US jurisdictions.
- The US Constitution and the Congressional implementation in Section 101 clearly provide a wide gateway to the USPTO and analysis under Sections 102 (novelty) and 103 (obviousness).
- See, e.g., US Supreme Court *Diamond v. Chakrabarty* (1980) analyzing the statute and many earlier US precedential cases.

Diamond v Chakrabarty (US Supreme Court, 1980)

- “**Anything under the sun that is made by man...**”
- 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.”
- Similarly, “**composition 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.”

2001 USPTO Guidelines Follow Chakrabarty

- “Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended ‘*anything under the sun that is made by man*’ to be eligible for patenting.’ S. Rep. No. 1979, 82d Congress, 2d Sess., 5 (1952). . . .

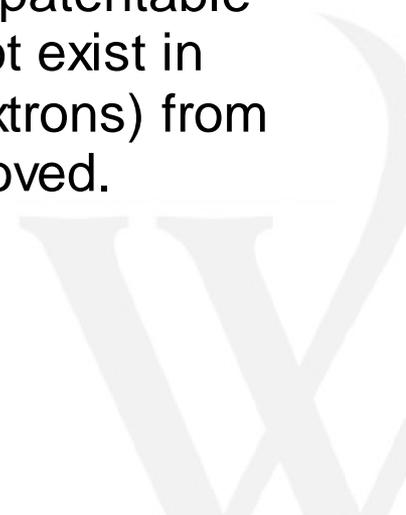
The Supreme Court interprets the statute to cover a ‘nonnaturally occurring manufacture or composition of matter—a product of human ingenuity.’ *Diamond v. Chakrabarty* (1980)”

2001 USPTO Utility Guidelines Comments

- “Thus, **an inventor’s discovery of a gene can be the basis for a patent of the genetic composition isolated from its natural state** and processed through purifying steps that separate the gene from other molecules naturally associated with it.”
- **“Patenting compositions or compounds isolated from nature follows well-established principles,** and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873 claiming “[y]east, free from organic germs of disease.” Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: “even if it were merely an extracted product without change, there is no rule that such produces are not patentable. . . .” *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.Y.Y. 1911) (J. Learned Hand).”
- See also *In re Bergstrom*, 427 F.2d 1394, 1401 (CCPA 1970) (“**what appellants claim is not ‘naturally occurring’.** **Those compounds...do not exist in nature in pure form** and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature’s storehouse. . . .”

Abrupt Reversal on June 14, 2013 (Myriad Genetics Case)

- *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2013 BL 155804, 106 U.S. P.Q.2d 1972 (2013) (86 PTCJ 332, 6/14/13)
- Holding that **isolated genomic DNA is not patentable subject matter** because it is simply a product of nature.
- In so holding, the Court distinguished complementary DNA (cDNA) from the claimed genomic DNA, reasoning that cDNA is patentable subject matter because it is created by man and does not exist in nature. cDNA consists only of protein encoding DNA (exons) from which all of the non-coding DNA (introns) has been removed.



The Conflict Created by Myriad

- *Myriad* is in Direct Conflict with Court Precedent and 2001 USPTO Guidelines
- USPTO issued new Patentable Subject Matter Guidelines in March 2014, implementing *Myriad*...but now is apparently contemplating updating them as they've admitted perhaps "going too far". We shall see...
- Incidentally, the USPTO Guidelines now go well beyond biotechnology or chemical inventions, providing an argument that gunpowder is an unpatentable composition of matter as each of the elements making up the composition are found in nature.

The Disharmonization Created by Myriad

- *Myriad* also places the US in direct conflict with the laws of at least:
 - Australia** (affirming in Sept 2014 that the purified/isolated genomic DNA of Myriad Genetics is patentable);
 - Europe** (with the exception of purified human embryonic stem cells, purified stem cells and other isolated proteins are patent eligible);
 - Japan** (purified genomic DNA patent eligible);
 - Canada** (purified genomic DNA patent eligible);



The Impact of The Heightened Utility Standard and the Myriad Reversal of “Manufacture” and “Composition of Matter”

- 1. Corporate Decision Making** – require well-settled law and expectations to make long-term financial investments. The reversal of course combined with the disharmonization of US patent law in the areas of “manufacture” and “composition of matter” creates unnerving uncertainty as well as potentially vulnerable patent portfolios obtained under the Chakrabarty regime.

Patent Strategies must adapt to maximize global protection.

- *Pursue purified/isolated protein claims in Europe, Australia, Canada and Japan*
- *Pursue method of use (therapeutic use) claims in the US (but understand that the USPTO will require data, which can be filed by Declaration post-filing of the patent application)...as a result, these can be done concurrently with the non-US filings.*

The Impact (Cont)

- 2. Disincentive to Certain Useful Discoveries** -- Discoveries within the margins of “useful” and “substantially useful with an immediate and specific benefit” must be considered not patentable in the US when allocating resources and in corporate decision making. Fewer resources in this space, fewer publically and economically beneficial discoveries as a result.

- 3. Impact on Public Health**– Great Disincentive to pursue/discover/develop Naturally Occurring Therapeutics (Penicillin, Tetracycline, Taxol, Insulin, Streptomycin, etc.)

- 4. Patent Litigation** – Courts are now ruling specifically on the Section 101 issues raised by Myriad. See, e.g., *Genetic Technologies, Ltd v. Laboratory Corp. of America Holdings* (D.Del. 2014) and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (N.D. Cal. 2013). *Entire portfolios (and companies built on those portfolios are now at risk).*

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