Can We Find a Rational, Principled, Expansive, and Politically Palatable Approach to Statutorily Defining Patent Eligibility?

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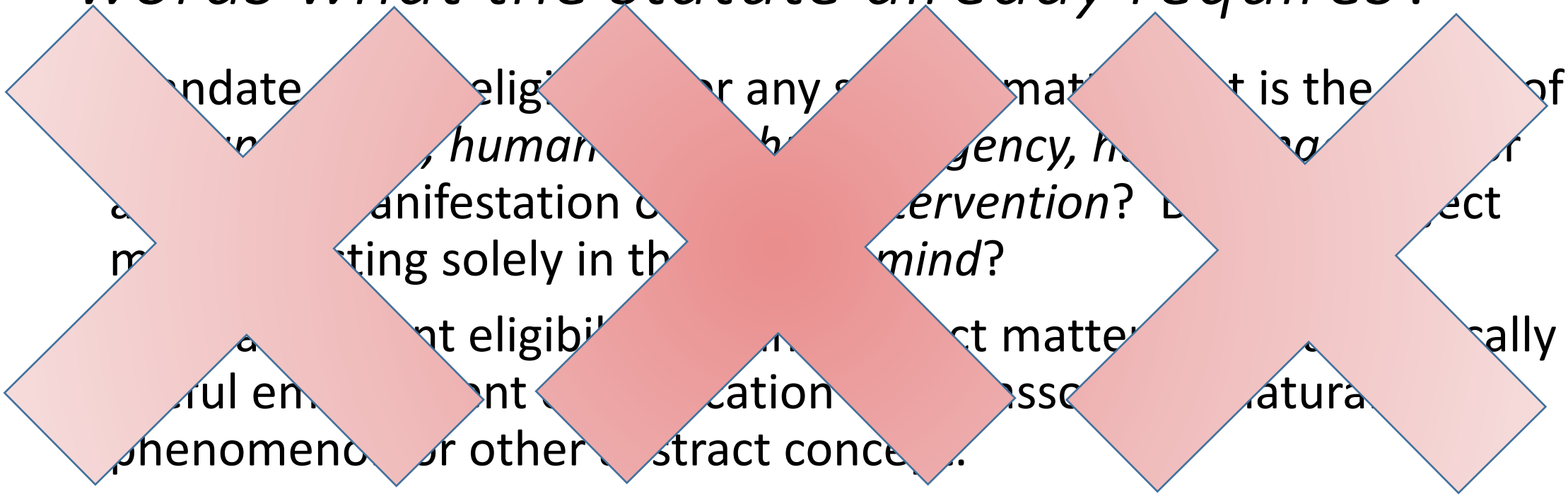
USPTO Roundtable 2 – Patent Eligibility Contours

"Reprising" approaches? *Restate in different words what the statute already requires*?

- Mandate patent eligibility for any subject matter that is the result of ***human activity, human effort, human agency, human ingenuity***, or any other manifestation of ***human intervention***? Bar only subject matter existing solely in the ***human mind***?
- Mandate patent eligibility for any subject matter that is a ***practically useful embodiment or application*** of any associated natural law or phenomenon or other abstract concept.

"Reprising" approaches? *Restate in different words what the statute already requires*?



The patent statute already limits patents to the novel work of human inventors—and already limits patents to new and useful processes, machines, manufactures, and compositions of matter.

A Proposed Path Forward for Legislatively Addressing Patent Eligibility Law

From the conference:

PATENTING GENES, NATURAL PRODUCTS AND DIAGNOSTICS: CURRENT STATUS AND FUTURE PROSPECTS

Held at The Banbury Center, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY

On November 9-11, 2016, a group of 22 IP professionals met at the Banbury Center to discuss the impact of United States Supreme Court decisions limiting available patent protection for natural products and diagnostics. Under these decisions, biopharma inventions that are readily patentable in other industrialized countries have been found to be ineligible for patenting in the United States, thereby erasing incentives to invest in developing such inventions.

Beginning with its 2010 decision in *Kappos v. Bilski*, the Supreme Court has progressively limited patent eligibility in the United States. Currently, it does so through a two-part test that has proven to be highly subjective and arbitrary in its application. The Court has justified its actions on the ground that the statutory limitations on patenting offer insufficient assurance that valid patents will not preempt access to the basic tools of science and technology, *e.g.*, natural laws, products, and phenomena, as well as other types of abstract concepts.

The participants in the Banbury Conference discussed in detail three measures that Congress could take to remedy the problems created by Supreme Court jurisprudence and restore the historic availability of patent protection for medicines and diagnostics based on the discovery of natural principles or products. These are:

1. Clarify that patent protection shall be available for inventions in all fields of *technology* and better conform U.S. patent law with internationally accepted norms of patentability. To this end, a number of participants recommended that Congress enact a substitute requirement limiting patent eligibility to technological inventions, *i.e.*, inventions contributing to the *technological arts*. Such a measure would codify the standard set out in the concurring opinion in *Kappos v. Bilski* and foster greater harmony between U.S. patent law and the patent law in Europe."
2. Enact a substitute, statutory eligibility standard that overrules the "implicit exception" and the two-part test used to implement it. The Court's rationale for imposing a judicial exception fails to take full account of the collective effect of the set of statutory requirements that limit the availability of conceptual patents—and that preclude the possibility that patents can either cover or preclude access to natural materials, laws, or phenomena. Maintaining a judicial exception is, therefore, unnecessary for any articulated constitutional or policy reason.
3. Exempt from patent infringement research uses of patented inventions where the exempted experimentation is limited to activities to better understand or improve the patented subject matter. Such an exemption should be limited and targeted in a manner that is consistent with the 2006 recommendation of the National Academies for doing so. This clarification that research performed on patented inventions is non-infringing would assure that no vestige remains of the Supreme Court's justification for imposing a judicial eligibility exception.

The Banbury Statement—Three Pronged Legislative Approach:

1. ***Technological arts*** **limitation per *Bilski* concurring opinion.**
2. **Abrogate "implicit" exception and its two-part test.**
3. **"Research Use" exemption: 2006 NAS recommendation.**

https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf

SUPREME COURT OF THE UNITED STATES

No. 08–964

BERNARD L. BILSKI AND RAND A. WARSAW, PETITIONERS *v.* DAVID J. KAPPOS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 28, 2010]

JUSTICE STEVENS, with whom JUSTICE GINSBURG, JUSTICE BREYER, and JUSTICE SOTOMAYOR join, concurring in the judgment.

The word "art" and the phrase "useful arts" are subject to many meanings. There is room on the margins to debate exactly what qualifies as either. There is room, moreover, to debate at what level of generality we should understand these broad and historical terms, given that "[a] rule that unanticipated inventions are without protection would conflict with the core concept of the patent law," *Chakrabarty*, 447 U. S., at 316. It appears, however, that regardless of how one construes the term "useful arts," business methods are not included.

Noah Webster's first American dictionary[26] defined the term "art" as the "disposition or modification of *things* by human skill, to answer the purpose intended," and differentiated between "useful or mechanic" arts, on the one hand, and "liberal or polite" arts, on the other. 1 An American Dictionary of the English Language (1828) (facsimile edition) (emphasis added). Although other dictionaries defined the word "art" more broadly,[27] Webster's definition likely conveyed a message similar to the meaning of the word "manufactures" in the earlier English statute. And we know that the term "useful arts" was used in the founding era to refer to manufacturing and similar applied trades.[28] See Coulter, The Field of the Statutory Useful Arts, 34 J. Pat. Off. Soc. 487, 493–500 (1952); see also Thomas, The Patenting of the Liberal Professions, 40 Boston College L. Rev. 1139, 1164 (1999) ("[The Framers of the Constitution] undoubtedly contemplated the industrial, mechanical and manual arts of the late eighteenth Century, in contrast to the seven 'liberal arts' and the four 'fine arts' of classical learning"). Indeed, just days before the Constitutional Convention, one delegate listed examples of American progress in "manufactures and the useful arts," all of which involved the creation or transformation of physical substances. See T. Coxe, An Address to an Assembly of the Friends of American Manufactures 17–18 (1787) (listing, *inter alia*, meal, ships, liquors, potash, gunpowder, paper, starch, articles of iron, stone work, carriages, and harnesses). Numerous scholars have suggested that the term "useful arts" was widely understood to encompass the fields that we would now describe as relating to technology or "technological arts."[29]

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Guidelines for Examination

"'An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture'. 'Industry' should be understood in its broad sense as including any physical activity of '*technical character*' …, *i.e.* ***an activity which belongs to the useful or practical arts as distinct from the aesthetic arts*** … ." (https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iii_1.htm).

"[T]he invention **must be of 'technical character' to the extent that it must relate to a *technical field*** …, must be concerned with a *technical problem* …, and must have *technical features* in terms of which the matter for which protection is sought can be defined in the claim … ." (https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_i_2.htm)

The European standard for "industrial applicability" could be adapted into a constitutionally consonant eligibility standard based on defining inventions that contribute to the "useful arts."

§ 101. Right to patent inventions; eligible subject matter required.

"(a) RIGHT TO A PATENT; USEFUL ARTS DEFINED.—An inventor shall be entitled to a patent for an invention that *contributes to the*

Add a "right to patent" provision missing from AIA; reaffirm that patents cannot be denied or invalidated absent a "finding."

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An amended § 101 could abrogate the Supreme Court's "implicit exception" and the two-part *Mayo-Alice* test, make explicit the bar to eligibility of any natural law or phenomenon or other abstract concept, and offer a substitute eligibility standard that might garner a political consensus…

…by distinguishing between technological and non-technological claimed inventions.

of a natural law or phenomenon

deemed not to contribute to the

preceding sentence, *eligibility for patenting under this section shall not be negated because a claimed invention is based upon or otherwise relates to an abstract concept.*

Add a new "safe harbor" patterned on the overruling of *Cuno Engineering*—2nd sentence of § 103 "negating" the flash-of-genius test.

"(d) ADDITIONAL LIMITATIONS AND EXCEPTIONS BARRED.—No additional limitations on or exceptions to eligibility for patenting ***shall exist or may be implied for a claimed invention that meets the requirements for eligibility under this section***.

Overrule the two-part test and the "implicit exception" through an unambiguous statutory provision.

§ 101. Right to patent inventions; eligible subject matter required.

"(a) RIGHT TO A PATENT; USEFUL ARTS DEFINED.—An inventor shall be entitled to a patent for an invention that ***contributes to the useful arts***, absent a finding that one or more conditions or requirements under this title have not been met. For the purposes of this section, ***the useful arts refer to all fields of technology, without restriction or limitation***.

"(b) ELIGIBLE CATEGORIES; PRACTICAL UTILITY REQUIRED.—Subject matter may not be patented unless ***claimed in terms of a practically useful process, machine, manufacture, or composition of matter, or a practically useful improvement thereto***.

"(c) ELIGIBLE SUBJECT MATTER LIMITATION; RELATIONSHIP TO ABSTRACT CONCEPTS.—For the purposes of this section, the discovery of a natural law or phenomenon or other abstract concept shall be deemed not to contribute to the useful arts. Notwithstanding the preceding sentence, ***eligibility for patenting under this section shall not be negated because a claimed invention is based upon or otherwise relates to an abstract concept***.

"(d) ADDITIONAL LIMITATIONS AND EXCEPTIONS BARRED.—No additional limitations on or exceptions to eligibility for patenting ***shall exist or may be implied for a claimed invention that meets the requirements for eligibility under this section***.

Add a "right to patent" provision missing from AIA; reaffirm that patents cannot be denied or invalidated absent a "finding."

Make *explicit* the constitutionally *implicit* need to contribute to the "useful Arts" and expressly *bar patenting for non-technological inventions.*

Recodify unchanged the existing § 101 requirement on statutory categories and codify *Brenner v. Manson* on "utility."

Add a specific sentence that is a *per se* bar on the patenting of a natural law or phenomenon or other abstract concept.

Add a new "safe harbor" patterned on the overruling of *Cuno Engineering*—2nd sentence of § 103 "negating" the flash-of-genius test.

Overrule the two-part test and the "implicit exception" through an unambiguous statutory provision.

Leverage the bar on patenting non-technological inventions to eliminate piecemeal limitations

- Repeal the remedies limitation for non-technological medical and surgical procedure patents (35 U.S.C. § 287(c)).
- Repeal the patentability limitations on tax strategy patents (AIA § 14).
- Repeal the bar on "human organism" patents (AIA § 33).
- Limit the availability of the transitional procedure for covered business method patents to non-technological claimed inventions. (AIA § 18).

The field of technology limitation on eligibility responds to concerns with permitting patent protection in areas outside the traditional notion that patents serve to protect new technological innovations.

Enact the National Academies' twice-recommended "research use" exemption—

Congress should consider exempting research "on" inventions from patent infringement liability. The exemption should state that making or using a patented invention should not be considered infringement if done to discern or to discover:

a. the validity of the patent and scope of afforded protection;

b. the features, properties, or inherent characteristics or advantages of the invention;

c. novel methods of making or using the patented invention; or

d. novel alternatives, improvements, or substitutes.

"Recommendation 10" of the 2006 National Academies' publication "Reaping the Benefits of Genomic and Proteomic Research," at https://www.nap.edu/read/11487/chapter/2.

Conclusions

- The preemptive priority for any legislative effort should be the abrogation of the implicit exception and the two-part test used to implement it.
- Doing so may not be politically possible without adding some additional threshold test limiting patent eligibility.
- The “reprising approaches” fall short on both legal and political grounds.
- The “useful arts” approach, although by no means perfect, could be leveraged to remove recent patent-limiting encrustations on the law.