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Flashback 2009: Patent-Eligibility in the Life Sciences

Below is the text of a brief paper of mine regarding patent eligibility that was published by IP 360 on October 19, 2009. I proposed a simple restatement of the law of patent eligibility: "A process or thing that exists in nature independent of human action, and which is merely discovered by a human being rather than created by one, is not patent-eligible." This was at a time when the Supreme Court was actively shaping the law in this area and there was room to maneuver.

The approach that I outlined was not the direction the Supreme Court chose in subsequent cases. Nevertheless, I believe that my proposal is still a good one. Patent eligibility has become such an unpredictable and expensive mess, and needlessly so since the Constitutional underpinnings can be readily satisfied and vindicated by a simpler, lower-threshold standard than is currently in use.

Eight years after my publication, in 2017, the Intellectual Property Owner's Association published a proposed amendment to 35 USC §101 that urged a similar "restatement" of the law of patent eligibility: "A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind." A legislative fix is likely the only path forward today, and I hope that such a fix happens in the near future.

The U.S. Supreme Court determined long ago that not everything that literally falls within the subject matter set forth in 35 U.S.C. §101 is necessarily patent-eligible. Over the years, and in the context of evolving technology, the analytic framework for determining patent-eligibility became (or was revealed as) imprecise, lacking clear focus on a specific policy justification, and unpredictable. More recently, the application of patent-eligibility to life sciences technologies has caused uncertainty in the life sciences community regarding the value of certain kinds of patents.

This brief note examines the purpose and justification for imposition of extra-textual limitations on patent-eligibility, and proposes that a simpler and more general approach clearly linked to that justification would provide better results and enhance predictability.

A. Extra-Textual Limits on Patent-Eligibility.

Section 101 provides that "any new or useful process, machine, manufacture, or composition of matter" is patent-eligible. The Supreme Court cases on patent-eligibility focus on whether a patent claim forecloses the use by others of a "fundamental principle" or "natural phenomenon" such as gravity, the heat of the sun, electricity, electromagnetic motive force, steam expansion, chemical hydrolysis, natural properties of bacteria, or mathematical formulas/algorithms.

As summarized in *Gottschalk v. Benson*, 409 U.S. 63 (1972), extra-textual limitation on patent-eligibility is based on the desire to ensure that despite the broad language of §101 "the basic tools of scientific and technological work" remain free for all to use:

Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.

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He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

409 U.S. at 67.

Protecting the basic tools of scientific and technological work was echoed by Justice Breyer in his dissent to the dismissal of certiorari in *Laboratory Corp. of America v. Metabolite Laboratories*, 548 U.S. 124 (2006), in which he also cited a Constitutional basis for imposing extra-textual limits on patent-eligibility:

[The Court] has treated fundamental scientific principles as part of the storehouse of knowledge and manifestations of laws of nature as free to all men and reserved exclusively to none. And its doing so reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself.

* * *

[T]he reason for the exclusion is that sometimes too much patent protection can impede rather than promote the Progress of Science and useful Arts, the constitutional objective of patent and copyright protection.

548 U.S. at 127-28.

In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), however, the Court approached the issue from a different angle, explaining that “a product of human ingenuity having a distinctive name, character, and use” is patent-eligible, and that the genetically-engineered bacterium at issue “is not nature’s handiwork, it is [the inventor’s] own; accordingly it is patentable subject matter under §101.” *Diamond v. Chakrabarty*, 447 U.S. at 309-10. The Court also quoted (at n.6) the statement by the principal drafter of the 1952 Patent Act that patent-eligible subject matter includes “anything under the sun that is made by man.”

The expression of the scope of patent-eligibility in *Chakrabarty* facially appears more expansive than in other Supreme Court cases. But, when viewed in the context of the purpose and justification for imposing extra-textual limits, *Chakrabarty* can be readily and productively harmonized with the other cases, and the appropriate standard for extra-textual limits on patent-eligibility can be usefully restated.

B. Harmonizing the Supreme Court Cases.

In my view, the common thread through the cases is the notion that things available in nature, whether or not already discovered by humans, should be maintained free for all to use in creating new and useful things. For example, sunlight, gravity, electromagnetism, mathematical relationships, and the chemical, physical, and biological properties of natural substances and organisms each exists in nature independent of human action. At most, humans merely “discover” these processes and things rather than “create” them.

In contrast, uses of natural processes and things should be patent-eligible to the extent those uses are not found in nature, and instead depend on human action for their existence. Similarly, substances and organisms that are created by humans and not found in nature should be patent-eligible, as should biological and chemical substances that are isolated or purified from their natural milieu.

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Before restating the standard, however, the strength and source of the justification for imposing extra-textual limits must be considered.

C. Justification for Imposing Extra-Textual Limits on Patent Eligibility.

Legitimate justification is required to impose additional limitation on the otherwise broad language chosen by Congress for patent-eligibility. See, e.g., *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 460-62 (2002) (“courts must presume that a legislature says in a statute what it means and means in a statute what it says there,” and “[w]hen the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete”). The justification presented in the cases has varied over time and from case to case, including naked declarations of policy, divining Congressional intent, and clarifying perceived ambiguity in the statutory language. But the strongest, and perhaps only legitimate, justification is the Constitutional basis presented by Justice Breyer in *Laboratory Corp.*

In my view, justification for imposing extra-textual limitation on a statute is strongest, and perhaps only defensible, when based on clear legislative history or the Constitution. The legislative history of the Patent Act is not particularly helpful because it suggests Congress intended a broad meaning (e.g., “anything under the sun that is made by man”). The Constitutional justification is then the only legitimate basis, which informs the level at which the bar for extra-textual should properly be set.

D. The Bar for Patent-Eligibility Should Be Set Low.

Because the limits are extra-textual, separation of powers and restraint should be the guiding principles regarding how much to raise the bar above the level expressly set by Congress. See, e.g., *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 460-62 (2002) (altering statutory text is a “battle that should be fought among the political branches and the industry” and the “parties should not seek to amend the statute by appeal to the Judicial Branch”). Thus, to preserve legitimacy, the patent-eligibility bar should be raised only to the extent necessary to avoid undermining the Constitutional objective of promoting the progress of science and useful arts.

The patent-eligibility bar should also be kept low to avoid convoluting it with and usurping the substantive requirements for patentability. In *Parker v. Flook*, 437 U.S. 584 (1978), for example, patent-eligibility of a method claim was approached by assuming that a natural phenomenon was in the prior art and asking whether there was anything patent-worthy in the remainder of the claim. Concepts of prior art and patent-worthiness are, and should be kept, distinct from the issue of patent-eligibility under §101.

In addition, to help ensure that the doctrine is applied narrowly and does not stray too far from the statute, it should be phrased in the negative, in terms of what is not patent-eligible despite the broad language of the statute.

E. Restatement.

Accordingly, I propose the following restatement of the appropriate scope of extra-textual imitation on patent-eligibility:

A process or thing that exists in nature independent of human action, and which is merely discovered by a human being rather than created by one, is not patent-eligible.

In my view, this restatement provides a relatively low bar to patent-eligibility, is consistent with the purpose expressed in the Supreme Court cases, and, perhaps most importantly, does not exceed the legitimate justification for imposing extra-textual limits on patent-eligibility.

F. Application to Method Claims.

Application of the Supreme Court's extra-textual limits on patent-eligibility has been problematic in the context of method claims, as exemplified by the *Bilski* case. The proposed restatement is easily applied to compounds, compositions of matter, and other "things," and I submit that it is also readily applicable to method claims, as illustrated by a few pharmaceutical/biotech examples.

Example No. 1:

Consider a method of administering a human-made or human-purified drug compound that yields a particular metabolite and determining the plasma level of that metabolite, wherein metabolite levels outside a given range indicate a need to modify drug dosage (see *Prometheus Laboratories*, 86 USPQ2D 1705, 2008 WL 878910 (SD Cal March 28, 2008)). This method involves several things that do not exist in nature independent of human action: (i) the human-made/purified drug, (ii) administration of the drug to a patient, (iii) determining metabolite levels, and (iv) correlating metabolite levels with drug dosage. The method also makes use of a phenomenon that exists in nature independent of human action: the activity of an endogenous enzyme that converts the drug compound to the metabolite.

In my view, this claim should be patent-eligible because the human actions remove the overall method from the universe of purely natural processes and there is no pre-emption of all practical uses of the activity of the endogenous enzyme (e.g., neither the natural activities of endogenous enzyme nor the activity of that enzyme on other drug compounds is embraced by the claim).

Example No. 2:

Now consider a method of measuring the plasma level of an amino acid, wherein a level that is elevated as compared to a normal level indicates a vitamin deficiency (see *Laboratory Corp. of America Holdings v. Metabolite Laboratories*, 548 U.S. 124 (2006)). Measuring plasma amino acid levels and correlating them to potential vitamin deficiency are human actions, while the biochemical pathways and metabolic relationship between the amino acid and vitamin levels exist in nature independent of human action. Although the human actions remove the overall method from the universe of purely natural processes, there is a significant question of whether the claim pre-empts a natural process and is therefore effectively a claim to the natural process itself.

In my view, the claim probably does pre-empt all practical uses of the metabolic relationship between the amino acid and vitamin levels because there appears no practical use of the relationship that would not be within the scope of the claims. Thus, the subject matter as claimed should not be patent-eligible.ⁱⁱ

Example No. 3:

Finally, consider a claim to a method for inhibiting expression of a set of genes by reducing activity of a transcription factor (see *Ariad Pharmaceuticals v. Eli Lilly*, 529 F.Supp.2d 106 (D Mass. 2007)).ⁱⁱⁱ The only human action involved in this claim is the possibility that a human would perform an unstated act by which the transcription factor's activity is reduced. The subject matter as claimed is really nothing more than the relationship between the transcription factor activity and the expression of certain genes. Although that relationship may have been discovered by the applicants, it exists in nature independent of human action and was not "created" in any way by the applicants. Thus, in my view, this claim should not be patent-eligible.

Had the applicants in *Ariad* discovered or created a compound that would, when administered to a patient, reduce the activity of the transcription factor, then a patent-eligible claim could have been drafted (e.g., a claim to the compound, a claim to a method of treatment involving administering the



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compound, and a claim to a method for reducing the activity of the transcription factor by administering the compound).

G. Closing Thoughts.

Patent-eligibility should be a low-threshold determination based on the broad statutory language limited only by due consideration of the Constitutional objective of promoting the progress of science and useful arts. Focusing clearly on the purpose and justification for extra-textual limitation on patent-eligibility should yield the best, and most defensible, results.

ⁱ For clarity, I am not suggesting that IPO copied my proposal !! It is a common-sense approach and not surprising that multiple people would independently converge on it. IPO included a useful clause relating to abstract ideas -- "exists solely in the human mind" -- which I had not considered since I was focused on laws of nature and natural phenomena, which I viewed at that time as more relevant to life sciences.

ⁱⁱ To clarify this point, one needs to look at the claim carefully, figure out what it really covers, and then ask whether that thing "exists in nature independent of human action" and "is merely discovered by a human being rather than created by one." By pre-empting all practical uses of the metabolic relationship, the claim effectively covers the metabolic relationship (which was pre-existent in nature).

ⁱⁱⁱ This was a well-known case at the time -- neither the claims nor the specification specified *how* to reduce the activity of the transcription factor.