Patent Eligibility of Diagnostic Tools: Utility as the Key to Unlocking Section 101

By N. Scott Pierce / October 27, 2019

"Long before eligibility, novelty, and obviousness were distinct provisions under any patent act, broad preemption on one hand and bare novelty on the other were dueling concerns in patent law, and the jurisprudence surrounding notions of utility resolved the conflict."

A petition for *certiorari* was filed on October 1 in the case of *Athena Diagnostics v. Mayo Collaborative Services* asking the question:

> *Whether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the condition using novel man-made molecules and a series of specific chemical steps never previously performed.*

The claims at issue are directed to a "method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK]," and includes several steps that involve labeling the MuSK, such as by iodinization, "immunoprecipitating a…complex," and ultimately "monitoring" for the label, the "presence" of which is "indicative … that said mammal is suffering from said neurotransmitter or developmental disorder related to [MuSK]" [*Athena Diagnostics, Inc. et al. v. Mayo Collaborative Services, LLC*, 915 F.3d 743 (Fed. Cir. 2019); *reh'g and reh'g en banc denied*, 927 F.3d 1333 (Fed. Cir. 2019), *petition for cert. filed* (U.S. October 1, 2019) (No. 19-430)]. The developmental disorder is *Myasthenia gravis* (MG), an autoimmune disease that causes muscular weakness.

Benefit as a Policy Argument

As suggested by the question posed to the Supreme Court, the petitioners rely on the fact that the labeled MuSK does not occur in nature, is novel, and is employed in specific steps. As a consequence, according to the petitioners, the claimed methods are "not 'directed to' a natural law." Rather, "they are directed to a particular chemical process for detecting a previously unused biomarker and diagnosing illness." For the petitioners, the novelty of the labeled components employed and the specificity of the steps in the method set the "patent claims here … a world apart from the claims invalidated in *Mayo*." Athena's position is supported by Judge Stoll's dissent to the denial for rehearing where she stated that "[c]ertain diagnostic claims, such as the ones at issue in this case, are so narrowly tailored that preemption is not a reasonable concern." Accordingly, if, in the two-step test for eligibility promulgated in *Alice Corp. v. CLS Bank International* [134 S. Ct. 2347, 573 U.S. 208 (2014)] the claims are sufficiently narrow to not be "directed to" one of the exceptions to patent eligibility, then the second and, in this case, potentially more problematic step of identifying the presence of "invention" is effectively mooted, at least with respect to patent eligibility.

The petitioners hinge their argument throughout the brief on the novel beneficial utility of their claimed method, relying heavily on recitals in the eight concurring and dissenting opinions that accompanied the denial of rehearing and rehearing en banc by the Court of Appeals for the Federal Circuit. Summarizing, the petitioners conclude that the "members of the en banc Federal Circuit agreed with Athena that sufficiently specific diagnostic methods with proven utility like the ones here should be patent eligible." As stated by the petitioners, "[n]umerous government officials, practitioners, and scholars have echoed and amplified the message that the law of patent-eligible subject matter is in a state of turmoil and there is no more important question."

However, benefit has not always carried the day in recent eligibility analyses. For example, the Supreme Court stated in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* [133 S. Ct. 2107, 2117 (2013)] with respect to isolated genes, that "Myriad did not create anything. To be sure, it found an important and useful gene, but separating the gene from its surrounding genetic material is not an act of invention."

Moreover, benefit as a policy argument can fall on deaf ears given the refrain in *Funk Bros. Seed Co. v. Kalo Inoculant Co.* [333 U.S. 127,132 (1948)] that "the application of this newly-discovered natural principle…may well have been an important commercial advance…. But once nature's secret…was discovered, the state of the art made…production…a simple step. Even though it may have been the product of skill, it certainly was not the product of invention." The Court in *Myriad*, relying on *Funk Bros.*, concluded that "[g]round breaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." In other words, "preemption" as mentioned by petitioners, is "'the concern that drives,' the judicially-created exceptions to Section 101," and often has overridden the significance of benefits provided by advancements in technology, such as in the field of diagnostics.

Unlocking Eligibility with Utility

Nevertheless, and ironically, *Athena v. Mayo* may provide the vehicle for revamping the "unending chaos" and "mess" that is the current state of patent eligibility. The benefits recited by the petitioners and unanimously echoed by the judges are not just policy arguments; they reflect a view of eligibility and non-obviousness that is rooted in precedent and which obviates the crippling effects of preemption doctrine. That precedent is the jurisprudence of "utility," and provides the long-overlooked key to unlocking eligibility by bridging patent eligibility and patentable distinction.

As a preliminary matter, one must remember that patent eligibility has been linked to what we now consider to be "preemption" since the 18th century cases of *Boulton and Watt v. Bull* [(1795) 126 Eng. Rep. 651 (C.P.); 2 H. Bl. 463] and *Hornblower and Mayberly v. Boulton and Watt* [(1799) 101 Eng. Rep. 1285 (K.B.); 8 T.R. 95]. Watt's improved steam engine arguably was simply a different manner of using the well-known Newcomen engine (by condensing steam in a separate cylinder from that used for the power stroke). Lord Chief Justice Eyre famously stated in *Boulton v. Bull* that "principle alone [cannot] be the foundation of a patent." It is also important to understand that utility has been directly linked to the classes of invention eligible for patent protection since the first patent act in this country, enacted in 1790. Aptly entitled, "An Act to promote the progress of *useful* Arts," the 1790 act provided

protection for "any *useful* art, manufacture, engine, machine, or device, or any improvement therein not before known or used" [Patent Act of 1790, ch. 7, 1 Stat. 109-12 (Apr. 10, 1790) (repealed 1793) (current version at 35 U.S.C. § 101 (2013) (emphasis added)]. The key is this: long before eligibility, novelty, and obviousness were distinct provisions under any patent act, broad preemption on one hand and bare novelty on the other were dueling concerns in patent law, and the jurisprudence surrounding notions of utility resolved the conflict. The historical role of utility in eligibility and patentable distinction obviates the problem of "preemption" and the current two-step prescription dictated by the Supreme Court in *Mayo*, *Alice*, and *Myriad*.

Positive and Comparative Utility Doctrines

Utility, as a concept, split during the nineteenth century into "positive utility," which is now embraced in 35 U.S.C. § 101, and "comparative utility," which was a test for a "substantial difference of structure or mode of operation" that would indicate patentable distinction [G. T. Curtis, *A Treatise on the Law of patents for Useful Inventions* (Little, Brown and Co., 4th ed., 1873) [hereinafter *Curtis I*] at 110)]. "Positive utility" required only a "description of a class of inventions which can be the subject of valid patents." Under 35 U.S.C. § 101, "utility" has, of course, been overlaid with additional considerations by imposing "specific," "substantial," and "currently available" (or credible) criteria. [*See*, *Brenner v. Manson*, 383 U.S. 519 (1966)].The term "useful," in the sense of "positive utility" under 35 U.S.C. § 101, however, has never included a test for "invention."

"Comparative utility," also referred to as "substantial novelty," on the other hand, was an early test for invention beyond bare novelty of the eligible subject matter of the invention. The test for "comparative utility" was based on the statutory language of the 1790 act of "sufficiently useful and important," and the 1793 act of "an improvement in the principle of a machine, or in the process of any composition of matter." "Comparative utility" required, at least implicitly, a "substantial difference of structure or mode of operation" that would be "useful and important" or "an improvement in the principle…or process" relative to what was known in the art. In short, to be an

"invention," comparative utility mandated a *benefit* over subject matter that is already in the public domain.

Echoes of that early test of invention still ring familiar to patent practitioners, such as the adage that, "provided the invention is substantially new, it is or no consequence whether a great or small amount of thought, ingenuity, skill, labor, or experiment has been expended, or whether it was discovered by accident" (G. T. Curtis, *Treatise of the Law of Patents for Useful Inventions in the United States of America*, Charles C. Little and James Brown, 1849 [Hereinafter *Curtis II*] at 5.) This language, of course, is reflected in the last paragraph of 35 U.S.C. 103, which reads: "Patentability shall not be negatived by the manner in which the invention was made."

G.T. Curtis, an early commentator, inverted this reasoning as a corollary:

> *Still it is sometimes necessary to ascertain what bearing the amount of thought, design, or ingenuity that may have been expended, has upon the question of novelty. It may not be necessary that there should be positive evidence of design, thought, or ingenuity; but if it is necessary that the possibility of these qualities having been exercised should not be excluded by the character of the supposed invention, then such possibility becomes one test of the sufficiency of invention. [Curtis II, supra note 27, at 6.]*

In essence, for the purpose of patentable distinction, the possibility of "design, thought, or ingenuity…becomes one test of the sufficiency of invention." The extension of this corollary being that, as stated by Curtis, because "a patent should be something that has not substantially existed before," the lack of possibility of design or study in the "production" of an "alleged invention" is "proof" of "frivolousness."

Utility v. Preemption

This basic distinction between "positive" and "comparative" utility is at the core of modern patent jurisprudence. While the fundamental exceptions to patent protection, namely laws of nature, naturally-occurring phenomena, and abstract ideas continued in American jurisprudence, they manifested themselves in the doctrines of new use and

aggregation, which became defunct in the face of separate statutory provisions for novelty and non-obviousness introduced in the Patent Act of 1952. With the new act, not only the notion of "invention," but also the significance of the exceptions to patentability were placed under considerations of statutory novelty and non-obviousness. As stated by Judge Learned Hand, for example, in *Lyon v. Bausch & Lomb Optical* shortly after passage of the 1952 Patent Act, the "definition of invention…[is]…now expressly embodied in § 103." [224 F.2d 530, 550 (2d Cir. 1955)]. It wasn't until the 1976 case of *Gottschalk v. Benson* (409 U.S. 63 [1972]) that confusion began to insert itself again by allowing overlap of criteria among the three statutory provisions of eligibility (101), novelty (102), and non-obviousness (103) in the form of "preemption." By this reasoning, if "preemption," as a doctrine, can be barred as a consideration in patent eligibility, thereby again limiting issues of laws of nature, naturally-occurring phenomena, and abstract ideas, as well as that of "invention" to statutory novelty and non-obviousness, then problems of patent eligibility, such as those presented in *Athena v. Mayo*, should fade.

In *Athena v. Mayo*, for example, by eliminating preemption as a consideration, Athena's method claim for diagnosing neurotransmission or developmental disorders related to MuSK in a mammal would clearly meet the test for "positive utility" in that it is a "process" and, therefore, among the classes of invention which can be the subject of a valid patent. We will presume that the overlay of "specific," "substantial," and "credible" under *Brenner v. Manson* is also met and that, therefore, the only remaining criteria are novelty and non-obviousness under 35 U.S.C. §§ 102 and 103, respectively. Is the process novel? Yes, not simply because of the novelty of the labeled compound and intermediate complexes that form as a result of the claimed method, but also in the manipulative steps taken to enable the observation that, as discovered by the inventors, is indicative of a condition that could not be positively determined prior to existence of the claimed method. In other words, the method is a novel combination of steps that was conceived by the inventors as a consequence of a discovery made by those inventors. The method, being novel, does not preempt anything.

That being said, the remaining test would be that of non-obviousness and, using the alternative view of utility, comparative utility, the question is no longer one of whether the labeled compound is itself novel (since the compound itself is not being claimed as such). Nor is the question whether, having made the discovery of the association between MuSK autoantibodies and MG, that discovery is inventive in and of itself, but instead whether the claimed method allows for the possibility of "design, thought, or ingenuity…." Again, Athena's claimed method clearly does. Proof of this can be seen by considering the extension to Curtis' corollary in that, if the claimed method did not permit the possibility of "design, thought, or ingenuity," it would, by definition, have to be a combination of elements that is random. Combinations of elements, such as method steps, that are random must be frivolous. If they are not, then they must, at least conceptually, admit the possibility of "design, thought, or ingenuity." Athena's diagnostic method is not only useful, but has a novel benefit linked to the novelty of the combined steps. A novel benefit is evidence that, not only is Athena's method not random, and therefore not "frivolous," but also that it represents an improvement in principle or process that clearly would have met the earlier standard of "substantial novelty." By this test, Athena's diagnostic method is not only eligible and novel, but also patentably distinct.

Application Beyond *Athena*

This test applies not only to diagnostics, which seem to have confounded the Federal Circuit under the current two-step analysis articulated in *Alice*, but also to other areas. While exemplification of all possibilities is not possible here, one example would be the patentability of isolated genes, which are now barred from patentability under *Myriad*. Specifically, genes are nucleic acids composed of sequences of nucleotides. Sequences of nucleotides that encode functional proteins are not random, regardless of whatever evolutionary process resulted in each particular sequence. Genes, of course, occur in nature, but not in isolation. Isolated genes can have benefits that genes in their native environment do not. Although the entire genome of an animal can be mapped, such as has been done for humans, the function of any given gene making up that genome may not have been determined. Identification of the function of a gene, and

determination of a beneficial use specific for that gene in isolation, means that the isolated sequence of nucleotides could be the product of "design, thought or ingenuity" and, therefore, would not be random. If the gene is novel in isolated form, it constitutes a "composition" that is new and useful within the meaning of 35 U.S.C. § 101. It is also novel within the meaning of 35 U.S.C. § 102 and meets the criteria of non-obviousness under 35 U.S.C. § 103, at least from the point of view of "comparative utility."

Application of concepts like "positive utility" and "comparative utility" may seem hopelessly anachronistic, but they have never been overturned or supplanted. Specifically, while "utility" as a doctrine has been overlaid with the criteria of "specific," "substantial," and "credible," as mentioned above, the basic notion persists that "positive utility" under 35 U.S.C. § 101 ascribes membership among the enumerated categories of eligible subject matter. Likewise, the idea that patentable distinction extends beyond bare novelty to "comparative utility" also continues, although it too has been overlaid. Specifically, modern notions of criteria for patentable distinction now include possession of "skill and ingenuity" beyond that of "an ordinary mechanic acquainted with the business," which was introduced by the Supreme Court *Hotchkiss v. Greenwood* [52 U.S. (11 How.) 248 (1850)], and "obviousness," a term that was considered by Judge Rich, one of the coauthors of the 1952 Patent Act, to be a "codification…and revision" of the judicial "invention" requirement.

Back to Basics

Patent eligibility, considered to be the most important question facing the patent system, poses insidious problems under current jurisprudence to some of the most beneficial cutting-edge technology available today. What is most curious, and the point here, is that this problem apparently can be solved simply by reaching back to the foundations of modern patent law and the underlying requirement that inventions be "useful," a term that has been baked into the statutory provisions since the first patent act.

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