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Boehringer Ruling Limits Treatment Method Patent Eligibility

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A recent decision from the District of New Jersey illustrates a potential challenge facing many life sciences patentees under the current patent-eligibility framework.


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In the decision, Judge Peter G. Sheridan of the U.S. District Court for the District of New Jersey dismissed Boehringer Ingelheim's claim alleging infringement of U.S. Patent No. 8,853,156 ("the '156 patent"), determining that the asserted patent claims were directed to patent-ineligible subject matter under 35 U.S.C. § 101.[1] The claims of the '156 patent involved a method of treatment for diabetes, specifically a method of administering a certain class of drugs where another was contraindicated. Although the decision has garnered relatively little attention, it shows that courts may be willing to invalidate method of treatment claims — on § 101 grounds — even where those claims involve administering non-naturally occurring medicines.

In August 2015, Boehringer Ingelheim asserted the '156 patent in an infringement lawsuit against a number of generic drugmakers. The complaint alleged that the defendants infringed the '156 patent, among other patents, in connection with their seeking approval to market generic versions of two of Boehringer's diabetes medications, Tradjenta and Jentadueto.

The '156 patent relates to the treatment of metabolic diseases, including diabetes. In particular, the patent describes the use of a known class of diabetes drugs, dipeptidyl peptidase IV ("DPP-IV") inhibitors, as a more appropriate treatment for patients ill-suited to another diabetes drug, metformin. Metformin, which is eliminated through the kidneys, is contraindicated in patients with renal disease or impairment. The '156 patent discloses that DPP-IV inhibitors, which are instead excreted through the liver rather than the kidneys, are suitable alternatives for patients for whom metformin would be inappropriate.

Accordingly, the claims of the '156 patent are directed to methods of administering DPP-IV inhibitors to patients for whom metformin is contraindicated. For example, Claim 1 of the '156 patent reads:

> 1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of:

renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance.

In July 2016, the defendants in the suit filed a Rule 12(c) motion for judgment on the pleadings challenging the asserted claims of the ’156 patent as invalid as directed to patent-ineligible subject matter. The motion argued that the asserted claims were patent-ineligible because they merely recited a natural law based on pharmacokinetic observations of diabetic patients. Boehringer countered that the claims required the administration of non-naturally occurring DPP-IV inhibitors that change the natural state of the body in a new and useful way and, consequently, do not constitute a natural law.

To evaluate subject matter eligibility, the district court employed the now-familiar two-part test set out by the U.S. Supreme Court in its Mayo and Alice decisions from 2012 and 2014, respectively. The first step asks whether the claims are directed to one of the recognized categories of excluded subject matter, i.e., laws of nature, natural phenomena, or abstract ideas. The second step asks, if the claim does involve excluded subject matter, whether the claim’s elements “add enough” to transform the claim into a patent-eligible application of the otherwise ineligible law of nature or abstract idea.[2] This step is often referred to as seeking an “inventive concept” that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible subject matter] itself.”[3]

In addressing the first step, although the defendants had argued that the asserted claims of the ’156 patent were directed to a patent-ineligible law of nature, the district court instead determined that the claims were directed to an abstract idea. The court explained that the claims of the ’156 patent were different from the claims at issue in the cases relied on by each of the parties, which addressed whether claims involved laws of nature.

For example, Boehringer had likened its claims to those at issue in CellzDirect. There, the Federal Circuit determined that claims directed to a method for preparing cryopreserved hepatocyte cells were patent-eligible, because the claims involved a series of steps that, altogether, provided a “new and improved way of preserving hepatocyte cells.”[4] But Judge Sheridan explained that Boehringer’s claims included only a single administration step that “provides no contribution over conventional knowledge of administering DPP-IV inhibitors.”[5]

On the other hand, the defendants had likened the claims to those at issue in Mayo. In Mayo, the Supreme Court determined that claims providing a method for optimizing the dosage of a drug were patent-ineligible, because the claims set forth a natural law, namely that certain metabolite levels indicated a need to increase the dosage and other metabolite levels indicated a need to decrease the dosage.[vi] While the district court stated that the claims in Mayo were more analogous than those in CellzDirect, it explained that Boehringer’s claims were, again, simpler, drawn to a single step, rather than requiring both administering a drug and determining metabolite levels.

After distinguishing both CellzDirect and Mayo, the court concluded that the “act of administering the DPP-IV inhibitor to the targeted patient population ... is an abstract idea.”[7] While not something that the defendants had argued, the court later elaborated that, in its view, the claims did not “amount to significantly more than an abstract idea of providing an instruction for a medical care professional who is treating the targeted patient population.”[8]

The court next turned to the second step of the Mayo/Alice framework. The district court noted that the other language in the asserted claims, relating to the contraindication of metformin in certain patients, recited only “well-understood, routine, and conventional activity” that could not confer patent-eligibility.[9]

After concluding that the asserted claims were directed to an abstract idea and lacked any inventive concept, the district court held that the claims were directed to patent-ineligible subject matter and granted the defendant's motion.

Boehringer's case will continue as several other asserted patents remain to be litigated. But, on March 3, 2017, Boehringer filed a motion to sever the invalidated claims of the '156 patent into a separate case where final judgment can be entered so that it can seek immediate appeal.

Other district courts considering § 101 motions on method of treatment claims in recent years have reached somewhat mixed results. In late 2015, in Endo Pharmaceuticals Inc. v. Actavis Inc., Judge Richard G. Andrews in the District of Delaware granted a motion to dismiss certain method of treatment claims as directed to a patent-ineligible law of nature.[10] Those claims called for treatment of a specific group (renally impaired patients) by administering a drug and then lowering the dosage of the drug based on its bioavailability.

And in a pair of decisions from early 2016, Judge Gregory M. Sleet in the District of Delaware denied two motions to dismiss, determining that although the asserted claims were directed to natural phenomena, additional factual determinations were required as to the second step of the Mayo analysis.[11] In those cases, which have since settled, the claims were directed to methods of treating cancer by administering an anti-PD-1 monoclonal antibody. The court determined that the patents were directed to a natural phenomenon because the effect of the administered drug was to enable the body's own, natural, immune response against cancer cells.

The Supreme Court has not indicated a willingness to offer any further guidance on the application of its Mayo test in life sciences cases anytime soon. In June 2016, the Supreme Court declined to take up a closely watched life sciences § 101 case, Sequenom Inc. v. Ariosa Diagnostics Inc. The case involved patent claims directed to methods for detecting fetal DNA in maternal plasma and using the detected fetal DNA for prenatal diagnosis.[12] On appeal, the Federal Circuit recognized that the inventors had made a "valuable contribution to science," but nonetheless determined the claims were patent-ineligible under Mayo, because the claims were directed to naturally occurring fetal DNA and did not otherwise include anything more than "well-understood, routine, conventional activities."[13]

Ariosa was notable because a number of judges, from both the original panel and the subsequent denial of rehearing en banc, expressed their concern that the Mayo test inappropriately excluded some life sciences-related inventions from patent-eligibility. For example, in a concurring opinion to the original panel decision, Judge Richard Linn noted that this "case represents the consequence — perhaps unintended — of [the broad Mayo test] in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."[14] The ensuing petition to the Supreme Court also garnered more than 20 amicus briefs in support. The Supreme Court nonetheless denied certiorari.

Without any additional guidance, life sciences patentees can continue to expect patent-eligibility challenges like those seen in Boehringer.

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[1] Boehringer Ingelheim Pharms., Inc. v. HEC Pharm Co., No. 15-cv-5982 (D.N.J. Dec. 7, 2016).

[2] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 132 S. Ct. 1289 (2012).

[3] Mayo, 132 S. Ct. at 1294.

[4] Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).

[5] Boehringer, at *16.

[6] Mayo, 132 S. Ct. 1289.

[7] Boehringer, at *17-18.

[8] Boehringer, at *21.

[9] Boehringer, at *20.

[10] Endo Pharm. Inc. v. Actavis Inc., No. CV 14-1381-RGA, 2015 WL 7253674 (D. Del. Nov. 17, 2015).

[11] Bristol Myers Squibb Co. v. Merck & Co., No. 14-1131 (D. Del. Mar. 17, 2016) (order denying motion to dismiss); Bristol Myers Squibb Co. v. Merck & Co., No. 15-572 (D. Del. March 29, 2016) (order denying motion to dismiss).

[12] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 19 F. Supp. 3d 938 (N.D. Cal. 2013).

[13] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1377 (Fed. Cir. 2015).

[14] Id. at 1380.
