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Fed. Circ. Ruling May Affect Eligibility Of Life Sciences Patents

By **David Ludwig and Ted Mathias**

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The U.S. Court of Appeals for the Federal Circuit's ruling in American Axle & Manufacturing Inc. v. Neapco Holdings LLC[1] last month might significantly impact patent eligibility for method-of-treatment and medical device claims.


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Although the claims at issue in American Axle related to a mechanical technology — namely propeller shafts, or propshafts, used in automobiles — that has not received regular scrutiny under Section 101, the court nevertheless found the claims invalid as claiming a patent-ineligible natural law.

The pharmaceutical, biotech and medical industries should pay close attention to the American Axle court's expansive application of patent ineligibility under Section 101.

Case Overview

The claims at issue in American Axle related to a method of manufacturing a propshaft comprising a hollow shaft member and a liner inserted into the shaft member. The liner is tuned by configuring its properties (e.g., mass, thickness, stiffness) and/or position to reduce both shell-mode vibrations and bending-mode vibrations in the shaft member. The claims provided no specifics for how to tune the liner to reduce these vibrations.

The U.S. District Court for the District of Delaware granted summary judgment to the defendants, finding that the claims recited patent-ineligible subject matter, and the Federal Circuit affirmed. U.S. Circuit Judge Timothy Dyk wrote for the majority, and U.S. Circuit Judge Kimberly Moore dissented.

Applying step 1 of the patent eligibility analysis, the majority found that the claims were directed to Hooke's law, "a natural law that mathematically relates the mass and/or stiffness of an object to the frequency with which that object oscillates (vibrates)."[2] The majority rejected the patentee's contention that the claims were per se eligible as being directed to a method of

manufacture.[3] Instead, the majority focused on the undisputed fact that "Hooke's law undergirds the design of a liner so that it exhibits a desired damping frequency pursuant to the claimed invention."[4]

Moving to step 2, the majority found there was no inventive concept that could render the claims patent-eligible. It was unmoved by the patentee's argument that using a liner "to damp two different vibration modes simultaneously" was novel and thus unconventional.[5]

Rather, the majority focused on the claims' failure to specify any concrete method of achieving the claimed result, stating that "the claims' instruction to tune a liner essentially amounts to the sort of directive prohibited by the U.S. Supreme Court in Mayo Collaborative Services v. Prometheus Laboratories Inc. — i.e. 'simply stat[ing] a law of nature while adding the words 'apply it.'"[6]

The majority did not consider any of the limitations of the dependent claims in this analysis, as it concluded that the patentee waived arguments directed to those claims by failing to raise them before the district court.

Judge Moore disagreed with the majority on both step 1 and step 2 and further accused the majority of confusing the patent eligibility requirements with that of enablement. Regarding step 1, Judge Moore argued that "[t]he focus of the claimed advance ... is to use liners (a physical liner) positioned inside a drive shaft to reduce shell mode vibration and bending mode vibration," as opposed to the claims being merely being directed to Hooke's law.[7]

Judge Moore thus applied a more lenient interpretation of step 1 than the majority did, focusing on the claimed application rather than the underlying physics. Regarding step 2, Judge Moore accused the majority of ignoring the undisputed fact that liners had not been used in the prior art for reducing the claimed vibrations — only plugs, weights and dampers had been used for this purpose.[8]

Judge Moore concluded that the majority's objection to the claims was essentially an enablement issue, namely whether the patent had provided adequate disclosure to enable one skilled in the art to accomplish the claimed tuning. Unlike enablement, however, which focuses on the specification's disclosure, an enabling disclosure in the claims themselves to satisfy the patent eligibility standard is what the majority appeared to require.

Post-American Axle, courts are more likely to find life sciences claims to be directed to a natural law/phenomenon under step 1.

The American Axle decision's finding that the claims were directed to a natural law appears to have broken with at least one interpretation of two leading Federal Circuit cases: Rapid Litigation Management Ltd. v. CellzDirect Inc.[9] and Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Internationall Ltd.[10]

Prior to American Axle, these cases could have been read to suggest that claims reciting a method of manufacture or method of treatment are not directed to natural laws/phenomena under

step 1 because they almost invariably recite a patent-eligible concept.

In CellzDirect, for example, the Federal Circuit found that a method of manufacturing liver cells was not directed to a natural law/phenomenon under step 1, even though the claims were premised on a discovery regarding liver cell biology. The CellzDirect court distinguished prior cases where the claims "amounted to nothing more than observing or identifying the ineligible concept itself."[11]

It reasoned that the asserted claims were not directed to the liver cell discovery because the claims recited "a new and useful laboratory technique" that applied that discovery, adding that "it is not enough [under step 1] to merely identify a patent-ineligible concept underlying the claim."[12]

The Vanda court similarly held that the asserted claims were not directed to a natural law/phenomenon under step 1 because they recited a specific treatment regimen, regardless of the fact that the regimen was premised on a discovery regarding the administered drug's effect on the body.

Under CellzDirect and Vanda, one could have reasonably expected the American Axle court to find that the claims were not directed to a natural law. After all, like the claims in CellzDirect, the American Axle claims recite a manufacturing method that applies a natural law/phenomenon to yield a new and useful product.

American Axle thus represents a potential shift in the way the Federal Circuit analyzes step 1, not merely by focusing on whether the claims recite a useful application, but rather by assessing whether the underlying concept of the claim, as a whole, is a natural law/phenomenon.

As American Axle appears to deviate from the more permissive interpretation of step 1 set forth in CellzDirect and Vanda, we will likely see more patent eligibility challenges to claims directed to the life sciences. Claims focused on pharmaceuticals, biologics and medical devices are often premised on natural laws/phenomena in a way similar to the claims in American Axle.

As several pre-Vanda courts have found in the pharmaceutical context, for example, method-of-treatment claims can be premised on the natural law/phenomenon of how an administered drug interacts with a patient's body.[13] The same reasoning could apply to other life sciences claims, such as claims to medical devices that interact with the body's natural processes. Although the pre-Vanda cases have been largely ignored following Vanda,[14] these cases could gain favor again in view of American Axle.

American Axle suggests that step 2 requires claims to explicitly recite the steps necessary to utilize the natural law/phenomenon to achieve claimed functions.

American Axle also puts patents claiming functional results squarely in Section 101's sights. Functional claiming is routine in life science patents. For example, a method-of-treatment claim might recite that a patient having received a dosage form will experience a particular pharmacokinetic profile, therapeutic result or reduced side effect.

A medical device claim might similarly recite that a patient having been implanted with the device will experience, for example, reduced pain. These claims often do not recite a formula for achieving the claimed function, instead relying on the specification to provide that information.

As Judge Moore pointed out in her dissent, such claims are typically scrutinized under Section 112 for potential over-breadth, i.e., where a patent provides insufficient disclosure to enable and provide written description support for the full scope of the claimed function. But cases before American Axle have not suggested functional claiming warrants greater scrutiny under Section 101.

The majority's opinion in American Axle suggests that where a claim is directed to a natural law/phenomenon under step 1, and the claim recites a result related to that natural law/phenomenon, then the claim must include a recipe for achieving the claimed result to be patent-eligible under step 2.

That could have a significant impact on life sciences patents, as life sciences claims frequently (1) are directed to a natural law/phenomenon under the American Axle interpretation of step 1 (discussed above), (2) define the invention in functional terms to distinguish prior art while retaining breadth, and (3) exclude physical characteristics of the dosage form/medical device and physician treatment details from the claims. Such claims might be patent-ineligible under American Axle.

Practice Tips

In view of American Axle, and more generally in view of the turbulent state of Section 101 case law, patent applicants should ensure they are claiming their inventions at various levels of detail to increase their odds of overcoming Section 101 challenges. While the common method of defining life sciences claims functionally may optimally distinguish prior art while capturing potential competitors, such claiming methods may draw more scrutiny under Section 101 moving forward.

Narrower nonfunctional claims might prove to be more resistant to Section 101 challenges. Conversely, patent challengers should consider such subject matter ineligibility defenses when faced with functional claims that have limited method or product details.

American Axle is also likely to cause litigants to focus on dependent claims. Although courts often ignore the dependent claims in Section 101 analyses, there is no rule requiring this. In American Axle, for example, the patentee did not do enough in the majority's view to press the eligibility of dependent claims at the district court level, thereby waiving its argument that the narrowing nonfunctional limitations in those claims provided the needed inventive concept under Step 2.

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[1] Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 939 F.3d 1355 (Fed. Cir. 2019).

[2] Id. at 1362.

[3] Id. at 1361 ("There is no legal principle that a claim to a method of manufacturing cannot be directed to a natural law, nor are there any cases saying so.").

[4] Id.

[5] Id. at 1367.

[6] Id. at 1362 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72 (2012)).

[7] Id. at 1369.

[8] Id. at 1370-71.

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

[10] Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).

[11] CellzDirect, 827 F.3d at 1048.

[12] Id. at 1048, 1050.

[13] See, e.g., Endo PharmacyInc. v. Actavis Inc., No. 14-1381, 2015 WL 5580488, at *6 (D. Del. Sept. 23, 2015), report and recommendation adopted, No. 14-1381, 2015 WL 7253674 (D. Del. Nov. 17, 2015) (finding "[a] method of treating pain" by administering oxymorphone at an adjusted dosage based on a patient's creatinine clearance rate to be directed to the natural law that "bioavailability of oxymorphone is increased in people with impaired kidney function"); Bristol-Myers Squibb Co. v. Merck & Co., No. 15-560, 2016 WL 1072841, at *1 n.1 (D. Del. Mar. 17, 2016) (finding methods of treating lung cancer by turning white blood cells against the cancer cells to be directed to a natural phenomenon).

[14] See, e.g., In re Biogen '755 Patent Litig., 335 F. Supp. 3d 688 (D.N.J. 2018); Genzyme Corp. v. Zydus Pharm. (USA) Inc., No. 16-540 (D.I. 105) (D. Del. Aug 8, 2018); Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd., No. 16-139, 2018 WL 2225113 (D. Del. May 15, 2018).