Method of treatment eligibility

Three cases in 2019 at the Federal Circuit have provided some clarity on the eligibility of method of treatment patents

Recent cases from the US Court of Appeals for the Federal Circuit (CAFC) have further clarified the patent eligibility of method of treatment patents under 35 USC § 101. In *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals International Ltd*,[1] the CAFC addressed patent eligibility of method of treatment patents. The method claims in *Vanda* were held patent-eligible because the subject matter of the method steps were not directed to a natural law or phenomenon.[2] The United States Patent and Trademark Office (USPTO) confirmed the importance of this ruling by issuing guidance following *Vanda* instructing that "'method of treatment' claims that practically apply natural relationships should be considered patent eligible ...."[3] *Vanda* and the USPTO's guidance have led many practitioners to believe that method of treatment claims are per se patent-eligible.

A survey of three recent eligibility decisions of method of treatment patents post-*Vanda* shows that while such patents are not per se eligible, they nonetheless have a good chance of being upheld, absent legislative efforts to change the analysis framework for patent eligibility or a clarifying decision by the Supreme Court of the US.

Post-Vanda: eligibility of methods of treatment

Under the two-step framework announced in *Mayo*[4] and applied in *Alice*,[5] even claims directed to patent-ineligible subject matter may become patent-eligible by applying the recited natural law. This application, however, must include something more than "conventional steps, specified at a high level of generality."[6] This year, the CAFC applied this framework to three patents claiming methods of treatment in the wake of Vanda, finding only two of those patents claimed patent-eligible subject matter under section 101. The disclosed methods in each of the three patents were similar, causing the CAFC to distinguish the claims narrowly based on their specificity and degree with which they required affirmative human action.

Natural Alternatives International, Inc v Creative Compounds

Natural Alternatives[7] involved claims reciting methods of treatment using beta-alanine to increase the anaerobic working capacity of muscle and other tissue.[8] The district court held that the claims were directed to "the natural law that ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentration in human tissue and, thereby, increase the anaerobic working capacity in a human" and "aid in regulating hydronium ion concentration in the tissue."[9]

The CAFC disagreed, citing *Vanda* for the proposition that "claims that are directed to particular methods of treatment are patent eligible."[10] The CAFC reasoned that the claims at issue recite a "'specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.'"[11] The court thus considered the claims a specific application of the natural law.[12]

Endo Pharmaceuticals, Inc v Teva Pharmaceuticals USA[13]

Just days after its decision in *Natural Alternatives,* the CAFC once again held claims to a method of treatment patent eligible under section 101. The claims in *Endo* recite a method of treating pain in a renally impaired patient with a controlled-release oxymorphone dosage form.[14] Specifically, the claims recite providing the patient with the dosage form, measuring the patient's creatinine clearance rate, and administering to the patient a lower dosage amount depending on the measured clearance rate.[15]

Drawing parallels to the claims in *Vanda*, the CAFC focused on the claims being directed to a method of treatment, with specific treatment steps and a specific dosing regimen, again emphasising that the claims are "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."[16]

The CAFC also relied on the claims' specificity to distinguish them from the patent-ineligible claims in *Mayo*, which describe a similar process of administering a drug to a patient with a certain disorder.[17] The court distinguished *Mayo* by finding that the claims in *Endo* went beyond claiming the relationship between oxymorphone and patients with renal impairment by claiming an application of that relationship to a specific method.[18] According to the CAFC, this made the claims "as specific as those in *Vanda* such that the patent claims do not 'tie up the doctor's subsequent treatment decision.'"[19]

INO Therapeutics v Praxair Distribution Inc[20]

In *INO*, however, the CAFC held method of treatment claims patent-ineligible for claiming a natural phenomenon. The claims in *INO* are directed to a treatment protocol wherein neonates with hypoxic respiratory failure who also present with left ventricular dysfunction (LVD) are identified and excluded from treatment using inhaled nitric oxide (iNO) due to possible fatality if administered.[21]

The CAFC affirmed the district court's patent-ineligibility determination, reasoning that the invention discloses a natural phenomenon paired with only well-understood, routine, and conventional steps.[22] Because the claims instruct medical professionals to withhold, rather than affirmatively administer treatment, the body's processes are left to transpire naturally.[23] What the patentee characterised as a "treatment protocol" for "selective administration",[24] the court saw as merely an instruction not to act and to allow the natural phenomena of the body to take place. The CAFC further

concluded that these natural phenomena are what the claims are "directed to", rather than the treatment protocol as a whole.[25]

The court focused heavily on the claims' failure to provide a new way of treating LVD patients.[26] "This is significant", the CAFC held, "because a claim not to treat – ie, not to disturb these naturally-occurring physiological processes within the LVD patient's body – risks monopolising the natural processes themselves".[27] It concluded that, "the claim language as a whole confirms that the focus of the invention is not on a new way of actually treating the underlying condition of hypoxic respiratory failure. Nor does it recite a way of reducing the risk of pulmonary edema while providing some level of treatment to those patients."[28] Rather, the court found that the claims focus on screening for a particular condition that, once identified, requires treatment be withheld.[29]

This decision suggests that an affirmative step must be taken to transform method of treatment claims to patent-eligible subject matter. Indeed, the court distinguished *Vanda* because the claims at issue in *Vanda* recited affirmative steps to provide a therapeutic benefit.[30] Likewise, *Natural Alternatives* and *Endo* were distinguished as inventions that "improve[d] treatment of the underlying conditions."[31] In applying step two of the *Mayo/Alice* framework, the court observed that the individual steps in the claimed method "(apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."[32] The CAFC once again rejected the "do not treat" step as being inventive.[33]

Judge Newman dissented, stating that "[t]he majority [did] not acknowledge that the claimed multi-step method of treatment of hypoxic respiratory failure does not occur in nature."[34] She further admonished the majority for ignoring the court's precedent holding method of treatment claims patent-eligible and for "improperly separate[ing] the claims into old and new steps, describ[ing] some claim steps as a 'natural phenomenon' and some steps as 'well-understood, routine, and conventional steps,' and avoid[ing] the requirement that a claimed invention is considered as a whole."[35]

Judge Newman's dissent highlights potential inconsistencies in the CAFC's application of the *Alice/Mayo* framework following *Vanda* – perhaps signaling a split in the court's view that method of treatment patents are per se eligible. Indeed, Chief Judge Prost (who authored the majority opinion in *INO*) dissented from the majority's holding in *Vanda*, finding that it did not faithfully apply *Mayo*, and would have held those claims patent-ineligible.[36]

To address the potential inconsistencies from these decisions, patentees and accused infringers will have to look to congressional legislation or a ruling from the Supreme Court for clarity.

First, the defendant in *Vanda* has appealed the CAFC's decision to the Supreme Court. The question presented to the court is whether method of treatment claims automatically satisfy section 101, "even if they apply a natural law using only routine and conventional steps."[37] And in March 2019, the court requested the views of the Solicitor General, which likely will result in a grant of review if the Solicitor General so recommends, as the court "has followed the recommendation of the Solicitor General in almost every patent case."[38]

Secondly, given the CAFC's decisions on section 101, Congress has been implored to amend the US patent laws to clarify what is and is not patent eligible. In May 2019, a bipartisan bill was proposed to remove the judicially created exceptions (abstract ideas, laws of nature, or natural phenomena) to patent eligibility.[39] The Senate recently held public hearings and closed-door meetings on the state of patent eligibility. While it remains to be seen what the final language of a bill amending section 101 may say, any such law that gets enacted may render the CAFC's and Supreme Court's precedents on this issue moot going forward.

Footnotes

1. *Vanda Pharm Inc v West-Ward Pharm Int'l Ltd*, 887 F.3d 1117 (Fed Cir 2018).
2. Id at 1134-35.
3. USPTO Memorandum re: Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals*, dated 7 June 2018 (emphasis in original).
4. *Mayo Collaborative Servs v Prometheus Labs*, 566 US 66 (2012).
5. *Alice Corp v CLS Bank Int'l,* 573 US 209 (2014).
6. *Mayo,* 566 US at 82.
7. *Nat Alts Int'l, Inc v Creative Compounds, LLC*, 918 F.3d 1338 (Fed Cir 2019).
8. Id at 1341.
9. Id. at 1344.
10. Id
11. Id at 1344 (quoting *Vanda*, 887 F.3d at 1136).
12. Id at 1345-46.
13. *Endo Pharm, Inc v Teva Pharm. USA, Inc*, 919 F.3d 1347 (Fed Cir 2019).
14. Id at 1350.
15. Id at 1350-51.
16. Id at 1353-54.
17. Id at 1354.
18. Id.
19. Id at 1355.
20. *INO Therapeutics LLC v Praxair Distribution Inc*, No 2018-1019, 2019 WL 4023576 (Fed Cir 27 Aug 2019).
21. Id at *2.
22. Id at *9-10.
23. Id at *9.
24. Id at *4.
25. Id at *9.
26. Id at *4-5.
27. Id at *4.
28. Id at *5.
29. Id at *6.
30. Id at *5.
31. Id at *6.
32. Id at *9.
33. Id
34. Id at *13 (Newman, J, dissenting).
35. Id
36. *Vanda*, 887 F.3d at 1140-43.
37. See Petition for a Writ of Certiorari at *i, Hikma Pharm USA Inc v Vanda Pharm USA, Inc*, No 18-817, (available at https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/18-817.html).
38. JF Murphy and MH McGinley, High Court Leaning on Views of Solicitor General More Often in Patent Cases, The Legal Intelligencer, 17 May 2019 (available at https://www.law.com/thelegalintelligencer/2019/05/17/high-court-leaning-on-views-of-solicitor-general-more-often-in-patent-cases/?slreturn=20190923110159).
39. Press Release, Thom Tillis, US Senator for N Carolina, (available at https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act).

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