Patent eligibility under US scrutiny

Claims drawn to methods of treating a disease by administering a pharmaceutical agent have long been thought to be patentable in the US, but is this still the case?

The US Supreme Court has been taking a closer look at the patent eligibility of life science inventions as demonstrated with its decisions in *Mayo Collaborative Servs v Prometheus Labs, Inc*, 566 US 66 (2012) and *Ass'n for Molecular Pathology v Myriad Genetics, Inc*, 569 US 576 (2013), and lower courts have followed.

One particular class of invention that courts have examined involves claims drawn to methods of treating a disease by administering a pharmaceutical product. Such claims have long been recognised as patent eligible under US patent law. However, in 2016 and 2017, there were several district court decisions and Patent Trial and Appeal Board (PTAB) *ex parte* appeals finding such claims ineligible for patent protection. Patent prosecutors should keep the differing approaches of district courts and the US Patent and Trademark Office (USPTO) in mind when drafting claims, to avoid rejections and invalidity challenges under 35 USC section 101.

Appellate and USPTO guidance

The patent eligibility analysis is a two-step inquiry. First, it must be determined whether a claim is directed to a patent-ineligible law of nature, natural phenomenon, or abstract idea. If it is not directed to one of these concepts, the claim is patent eligible. If it is, it must then be determined whether the additional elements of the claim transform it into "significantly more" than the ineligible concept.[1]

Any drug administered to a subject obeys natural laws that determine the effect of the drug on the subject. Despite this fact, the Federal Circuit recognised methods of treatment as patent eligible, noting that if method-of-treatment claims were simply directed to natural laws under the 101 inquiry, the court "would find patent-ineligible methods of… treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin)."[2]

The USPTO's *Subject matter eligibility examples: life sciences*[3] also state method-of-treatment claims are patent eligible, with an example of a claim that "does not recite or describe any recognised exception" to subject matter eligibility (Example 29, claim 7). Therefore, the first step of the 101 inquiry indicates the claim is not directed to an ineligible concept and is therefore patent eligible.

The Supreme Court has also recently acknowledged that such claims can be patent eligible. One of the patents in *Mayo* claimed a method of optimising therapeutic efficacy for treatment of a gastrointestinal disorder, wherein a level above or below a certain concentration of a drug indicates a need to change the amount of the drug administered. The court found this claim ineligible. Under step 1 of the 101 inquiry, the court found the claim was directed to a natural law because it simply describes a relationship between concentrations of the drug and the likelihood that a dosage will be ineffective or harmful. Under step 2, the administering step did not render the claims patent eligible because the drug was already known to treat the disease, so the administering step merely referred to a pre-existing audience interested in applying the recited natural law (doctors who treat patients with such diseases).

The court explained that such claims are ineligible because they tie up the use of natural laws, inhibiting future innovation more than the underlying discovery justifies. The court compared the ineligible claims to "a typical patent on a new drug or a new way of using an existing drug," which is confined to a particular application of natural laws and thus does not tie up their use.

Questioning eligibility

Despite the appellate court and USPTO guidance, district courts and the PTAB have questioned the patent eligibility of method-of-treatment claims over the past two years. One court held invalid a claim to a method of treating diabetes by administering a known compound to a patient who has one of several conditions rendering conventional therapy inappropriate, including renal disease.[4] Under step 1 of the 101 inquiry, the court found the step of "orally administering" a drug was an abstract idea that could be conducted via mental processes (although the parties had only argued whether or not the claim was directed to a natural law). It considered the asserted improvement over conventional therapy, but found the therapeutic benefits were due to natural biological processes. Under step 2, the additional claim limitations of selecting patients sensitive to the conventional therapy was a well-understood, routine, and conventional activity because it was known that this population experiences problems with the conventional therapy, even though it was not known that the claimed drug would solve those problems.

Other courts and the PTAB have found method-of-treatment claims invalid as directed to laws of nature because the activity of the recited drug was due to natural physiological responses.[5] The courts and PTAB

looked to the aspects of the claims that were known, and considered whether the drugs were known, which they were in all of these cases. They also considered whether the drugs were known to treat the recited disease, whether problems with conventional therapy were known, and when the claims recited a particular patient population or a biological indicator on which administration of the drug was determined, whether the methods of identifying that population or measuring that indicator were known.

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In some cases, courts have found method-of-treatment claims directed to ineligible subject matter under step 1 of the 101 analysis, but other limitations rendered the claims patent eligible. For example, in *Vanda Pharm Inc v Roxane Laboratories Inc* (D Del 25 August, 2016), the court found claims to performing a genotyping assay to determine the presence of a biomarker, and adjusting drug dosage accordingly to be patent eligible because the defendant failed to show the precise genotyping test was conventional, and found the process of using the results to inform dosage adjustment was not conventional.

Lessons for prosecutors

The USPTO guidelines and *Mayo* indicate that less is more. Claiming a method of treating a disease by administering a drug, without more, might stop the 101 analysis at step 1, as in Example 29, claim 7 of the USPTO guidelines.[6] Claims 5 and 6, however, include steps of obtaining a sample from a patient, detecting a biomarker, diagnosing based on the biomarker, and administering a drug. The guidelines instruct examiners to stop at step 1 for claim 7, but go on to step 2 for claims 5 and 6, because the diagnosing steps describe correlations based on natural laws that could be performed mentally. The *Mayo* claims also included diagnosing steps and were held invalid despite also reciting an administration step.

Of course, broad claims reciting only an administration step might raise prior art, written description, or enablement issues. This is particularly a concern for new uses of known compounds or natural products. For these types of inventions, prosecutors should identify what is new and decide whether it would be appropriate to describe them in the specification alone, or to also recite them in the claims. Thus, it is important to tell a good story in the specification as to why the invention is worthy of a patent. Although this type of information might seem more appropriate to an analysis of novelty or non-obviousness, the factors on which the courts are focusing in the 101 inquiry indicate this information must be considered as a threshold eligibility issue as well. For example, was the drug known to treat the recited disease? If not, it might be sufficient to describe in the specification the prior uses of the drug, and how the new indication was not known and could not have been derived from knowledge of the drug's utility or mechanism of action.

If, however, the drug is being used to treat the same disease for which it had previously been used, it might be necessary to recite novel aspects of the method in the claims, and clearly identify how those aspects are novel and non-obvious in the specification. This exercise will help to show patent eligibility under step 2 of the 101 inquiry, by identifying aspects of the invention that add significantly more than what is "well-understood, routine, conventional activity," as instructed in *Mayo*. It will also likely strengthen the claims against prior art concerns.

For example, were problems with conventional therapy previously unknown, such that the inventors discovered a drug should only be taken by a certain patient population? If so, include limitations directed to identifying that patient population, and explain in the specification that the problem was previously unknown. Of course, the more detail recited in the claim, the narrower the scope and the easier it is to design around. Thus, prosecutors must strike a balance to achieve a strong eligibility position while retaining commercial value.

For a method involving a diagnostic step, one should also consider whether the particular diagnostic test is routine or conventional, and whether the results of that test had previously been used to inform the activity recited in the claims. These novel aspects supported eligibility of the claims in *Vanda*.

Finally, prosecutors should identify whether there are any unconventional methods or technology used in the administration of the drug, and work those into the claims. One might consider adding other aspects of the invention such as dosing, dosing regimen, or combinations with other drugs.

Unfortunately, neither the courts nor the PTAB have provided clear guidance on when a method-of-treatment claim is patent eligible. However, by remaining mindful of the factors considered in the 101 analysis, prosecutors can tailor their applications to put their claims in the best position to overcome a 101 rejection or later invalidity challenge.

Footnotes

1. *Alice Corp Pty Ltd v CLS Bank Int'l* 134 S Ct 2347 (2014).
2. *Rapid Litig Mgmt v CellzDirect, Inc* 827 F3d 1042 (Fed Cir 2016).
3. https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility
4. *Boehringer Ingelheim Pharm Inc v HEC Pharm Co* (DNJ 7 Dec 2016).
5. *Mallinckrodt Hospital Prods IP Ltd v Praxair Distribution Inc.* (D Del 5 Sept 2017), *Natural Alternatives Int'l In. v Creative Compounds LLC* (S D Cal 5 Sept 2017), *Ex Parte Chamberlain* (PTAB 18 Jan 2017).
6. https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility

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