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With its Vanda Pharma and Berkheimer memos, USPTO provides increased clarity around personalized medicine patent eligibility

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In the time since the Federal Circuit issued its *Vanda Pharma* decision in April, *Vanda Pharm. Inc. v West-Ward Pharm. Intl. Ltd.* 887 F.3d 1117 (Fed. Cir. 2018) the US Patent and Trademark Office (USPTO) has issued two memos to the examining corps which provide increased clarity and predictability in the determination of patent eligibility which is more good news for the eligibility of claims relating to diagnostic or similar tests utilized in treating patients. If you're not familiar with the *Vanda Pharma* decision, and want more detail, see my previous post HERE.

With its latest memo, the USPTO has embraced the majority opinion in *Vanda Pharma* by expressly stating that "method of treatment claims that practically apply natural relationships should be considered patent eligible" under the first step of the Mayo inquiry (technically Step 2A). This is even better than the unofficial patent office policy which focused the analysis on the second part of the Mayo inquiry and asked whether the combination of steps not 'directed to' judicial exceptions (*i.e.*, the wet lab steps) was routine and conventional in the prior art, and importantly, required examiners to substantiate a finding of 'routine and conventional' with evidence, such as prior art publications.

That unofficial approach provided some clearer basis for challenging an eligibility rejection but the rubric seems to have been unevenly applied within the examining corps, and convincing a particular examiner of even the need to substantiate the rejection with evidence, much less how that evidence should be applied according to this rubric, sometimes required the intervention of a subject matter specialist. All of which increased the unpredictability of the outcome as well as the time and transaction costs of prosecution.

Fortunately, at least the requirement that examiners substantiate a finding of 'routine and conventional' with evidence was recently formalized in another memo following the Federal Circuit's decision in *Berkheimer v. HP Inc*. 881 F.3d 1360 (Fed. Cir. 2018). In Berkheimer, the court held that the question of whether the elements of a claim 'in addition to' those reciting judicial exceptions represent 'well-understood, routine, conventional activity' raises a disputed issue of fact. The *Berkheimer* memo expressly provides that a conclusion of 'routine and conventional' can only be reached where the elements are "widely prevalent or in common use in the relevant industry". The memo goes on to provide explicit guidance regarding the kind of factual evidence that must be found to support this conclusion.

The recent *Vanda Pharma* memo goes even further toward easing the path to patent eligibility by acknowledging that methods of treating are eligible under the first step of the Mayo inquiry. This means that time and related costs addressing eligibility rejections should go way down for these types of claims because an examiner can now find them eligible on their face, without the need to address whether or not there are steps 'in addition to' those reciting judicial exceptions that represent 'well-understood, routine, conventional activity'. This streamlined approach should lead to the withdrawal of many standing rejections and is likely to reduce the incidents of new rejections of claims linking diagnostic or similar methods with treating patients.

It bears mentioning that these positive developments reflect the remarks given by Director Andrei Iancu to the US Chamber of Commerce's Patent Policy Conference back in early April. Director Iancu promised that the USPTO would do 'everything we can' within its mandate to increase the clarity and predictability of the eligibility requirements, noting that they are "actively looking for ways to simplify the eligibility determination for our examiners through forward-looking guidance" and further promising that "[t]hrough our administration of the patent laws . . . the USPTO can lead, not just react to, every new case the courts issue." Those remarks were made on April 11, 2018, and already we have seen two very helpful memos in the form of the *Berkheimer* memo (April 19th) and the *Vanda Pharma* memo (June 7th). Pending some further action by the Federal Circuit to cloud the presently clearing skies, the future is indeed looking very bright.

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