

The Vanda Decision is Good News for Personalized Medicine Applications

By: Fatih Mercan, Ph.D.

After the Supreme Court's *Mayo* decision¹, overcoming the patent eligibility (35 U.S.C. §101) barrier for patent applications in the personalized medicine field became more challenging. However, the recent Federal Circuit *Vanda* decision² provides a welcome clarification on what is patent-eligible in this field. Following *Vanda*, the USPTO recently released a memo³, emphasizing that while the invention in *Vanda* recognizes the natural "relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation," the claims were not directed at the relationships, but rather were directed to "an application of that relationship."

Prior to *Vanda*, some Examiners' patent-eligibility analysis resembled an anticipation/obviousness analysis. Some Examiners were routinely rejecting medical treatment claims reciting "administering" steps because additional "administering" steps were allegedly "routine and conventional." The *Vanda* memo is good news as it confirms the patent eligibility of personalized method of treatment claims, and provides guidance to the Examiners on how to evaluate claims for eligibility. Based on *Vanda*, the Examiners are instructed to evaluate claims as a whole when determining whether they are "directed to" a judicial exception. In addition, the memo emphasizes that Examiners do not need to consider whether the recited steps are "routine or conventional" when determining whether claims are directed to a judicial exception (*Alice* step 2A). Furthermore, the memo states that if the claims are not directed to a judicial exception in the step 2A (as in *Vanda*), there is no need for the Examiner to further analyze whether the steps are "routine or conventional" (*Alice* step 2B). Hopefully, this guidance will decrease the number of rejections of personalized method of treatment claims based on *Mayo*, and will lead to more allowances in this field.

¹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 132 S. Ct. 1289 (2012)

² *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)

³ <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF>