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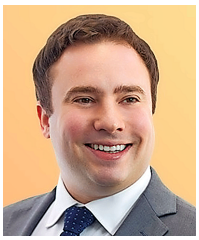
INSIGHT: Big Pharma Should Watch SCOTUS After Circuit Court Finds New Drug Uses Patentable



By Evan D. Diamond, Vanessa Yen, and Jesse D.H. Snyder

The U.S. Supreme Court created uncertainty seven years ago about whether some discoveries regarding the use of drugs in new disease treatments can be patented. In March, a federal circuit court found such inventions patent-eligible-- but pharmaceutical companies need to watch a circuit split and see if the high court takes it up again.

In the the 2012 decision, *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the Supreme Court noted in *dicta* that ''patent[s] on . . . a new way of using an existing drug'' are a ''typical'' example of patentable subject matter under 35 U.S.C. § 101. In the wake of *Mayo*, however, courts have struggled with applying the Supreme Court's patent-eligibility case law to claims that, like those struck down in *Mayo*, recite method steps involving assessment of biological phenomena in the context of pharmaceutical treatment.

Recently, several Federal Circuit decisions have upheld the patent-eligibility of pharmaceutical ''method of treatment'' claims (*i.e.*, administering a drug to patients to achieve a desired therapeutic effect).

As exemplified by *Endo Pharmaceuticals v. Teva Pharmaceuticals USA Inc.* (decided March 28 by the U.S. Court of Appeals for the Federal Circuit), these decisions have explained that ''method of treatment'' claims are generally patent-eligible, even when they touch upon ''natural laws'' or involve elements of biological/diagnostic testing. These decisions have also cabined *Mayo* to its facts, including the peculiar drafting of the challenged method claims in *Mayo*.

The Federal Circuit's recent approach towards ''method of treatment'' claims might be taken up in a potential Supreme Court review of the Federal Circuit's decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.* But, as the law stands, properly-drafted ''method of treatment'' claims appear to be safe from the section 101 challenges faced by claims to ''diagnostic'' inventions.

Patent Eligibility and ''Method of Treatment'' Claims

In *Mayo*, the Supreme Court concluded that claims ''directed to'' a biological ''natural law'' are not patentable under section 101 unless the invention ''amounts to significantly more than a patent upon the natural law itself.''

The *Mayo* Court struck down the challenged claims in that case, which were styled as a ''method of optimizing therapeutic efficacy for treatment'' of a specific medical condition, but included a ''wherein'' step that the Court described as instructing doctors to ''consider'' a ''natural'' relationship between blood levels of a drug metabolite (measured in a prior ''determining'' step) and the drug's safety and efficacy.

The Supreme Court's decisions in *Mayo* and *Alice Corp. v. CLS Bank International* established a two-part test to assess patent eligibility. ''Step one'' asks whether the claim is ''directed to'' a patent-ineligible category. If so, ''step two'' asks whether the additional claim elements amount to an ''inventive concept.''—i.e., something ''significantly more'' than the ineligible concept itself.

Recently, the Federal Circuit has used *Mayo*/*Alice* ''step one'' to find that ''methods of treatment'' claims are not ''directed to'' a natural law, and are generally patent-eligible under section 101. In last year's 2-1 *Vanda* decision (involving claims with a genetic testing step), and a March 15 precedential decision in *Natural Alternatives International Inc. v. Creative Compounds LLC*, the Federal Circuit has explained that ''method of treatment'' claims are generally not ''directed to'' natu-

ral laws because they require a doctor or patient to ''affirmatively administer a drug to alter a patient's condition from their natural state.''

The *Endo* Decision In *Endo*, the Federal Circuit panel reversed the District of Delaware's finding of patent-ineligibility for claims that the panel found were ''directed to'' a new method of treatment. Similar to the claims in *Vanda*, the *Endo* claims were styled as a ''method of treating'' a specific condition in patients, and included a diagnostic ''measuring'' step (assessing ''creatine clearance rates'' indicating degree of kidney impairment) followed by a step of ''administering'' a specific drug (oxymorphone) to the identified patients in an amount dependent on the diagnostic assessment (administering lower dosages to patients with higher degrees of impairment).

Citing *Vanda* and *Natural Alternatives*, and relying on the language of the claims and the specification, the *Endo* panel concluded that the challenged claims were ''directed to'' a patent-eligible ''method of treatment'' – specifically, the discovery of a new way of treating pain in patients with impaired kidney function. The Federal Circuit panel distinguished *Mayo* on its facts, explaining that the ''wherein'' clause in the *Mayo* claims failed to ''recite the steps of carrying out a dosage regimen based on the results of'' the prior ''determining'' (*i.e.*, diagnostic) step.

Implications of Endo As the *Endo* panel noted, ''[the Federal Circuit's] precedent leaves no room for a different outcome.'' In *Vanda* and the decisions that followed, the Federal Circuit's prevailing view is that a patent describing and claiming its invention as a ''method of treatment'' involving administration of a specific drug to specific patients, in a specific dose or dosage range, to treat a specific condition, will be considered patent-eligible under section 101—even if the claim involves steps of assessing biological phenomena.

If the Supreme Court decides to take up *Vanda* for review, however, the status quo very well may change. The pharmaceutical industry should watch the *Vanda* appeal closely, including for the Solicitor General's views, which the Supreme Court invited on this matter.

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