

INTELLECTUAL PROPERTY & *Life Sciences*

Drafting Method-of-Treatment Claims

Patenting *how* a product is used
as well as the product itself

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For most patents, claims directed to composition of matter are of the utmost importance. Infringement of a composition patent can typically be established when another party makes, uses or sells the claimed composition, regardless of what use is made of the composition. However, the increased breadth of composition-of-matter claims tends to make them more susceptible to invalidation.

In order to minimize the threat of invalidation, it is advised to also obtain claims directed to methods of utilizing the composition. Although infringement of a method claim can only be established if

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the composition is employed in the manner recited in the claims, the range of prior art that is available to anticipate the method claim will also be more narrow.

In the biotech and pharmaceutical arena, having a method-of-treatment claim directed to an FDA-approved therapeutic indication is critical, because in most situations, an infringer will be copying the labeling of an approved product with the intent to market the product for the same indication. In specific situations where both composition-of-matter and method-of-treatment claims are infringed, the method claims are arguably more valuable due to the decreased risk of invalidation. Also, in certain situations it may only be possible to obtain method-of-treatment claims if the molecular entity has been disclosed in the prior art, thereby barring patent protection for the composition of matter.

Method-of-treatment patents are also invaluable tools in protecting exclusivity for drug products subject to the provisions of the Hatch-Waxman Act, as they are listable in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the Orange Book. Patents listed in the FDA

Orange Book are available to provide a potential 30-month stay in the FDA's approval of a bioequivalent product to the listed drug.

Whatever the reason method claims are being pursued, the most important consideration is that the claims be properly drafted, not only to avoid the prior art, but also to ensure that there will be a clear determination of whether the claim is infringed. As is the case with composition claims, every limitation of a method claim must be met in order to prove infringement. Consider the following hypothetical method claim for a method of treating a patient suffering from diabetes:

- determining an initial dose of insulin for a patient;
- administering the initial dose of insulin to the patient;
- measuring the patient's blood sugar level; and
- administering an adjusted dose of insulin based on the patient's blood sugar level.

In order to infringe our hypothetical claim, a single party or joint parties must directly perform the recited determining, administering and measuring steps. A question then arises as to which party would be found to infringe this claim — the doctor who diagnoses and oversees the treatment of the patient, the patient himself or perhaps both? If the doctor determines

the initial dose of insulin for the patient, administers the dose, tests the patient's blood sugar level and then administers the adjusted dose, the doctor can certainly be found to infringe our hypothetical claim. However, what happens in the typical scenario in which the doctor determines the initial dose of insulin but the patient self-administers the dose, measures his or her own blood sugar and self-administers the adjusted dose? Although all steps have been performed, they are being performed by two separate parties. Would the doctor and the patient in this scenario be liable for joint infringement, or would neither be liable?

Because it is not advisable for the patentee to sue doctors or patients for patent infringement, the typical remedy is to go upstream to the drug manufacturer that supplies the drug product and provides instructions on the subsequent diagnosis and administration on the theory of inducement. Induced patent infringement is indirect infringement where a party instructs, directs or advises an underlying direct infringement, i.e., a single party or joint parties directly infringe each and every limitation of a claim. Thus, the determination of whether there is joint infringement between the doctor and patient in the hypothetical claim above still must be determined to establish inducement of infringement.

In *BMC Resources*, the court addressed the issue of joint infringement, showing that a mere relationship between two infringing parties was insufficient to establish a showing of joint infringement. Rather, the court held that joint infringement is established when one party is controlling or directing the activities of another party, or provides instructions or directions to the accused joint infringer. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007). Going back to our hypothetical claim, according to the court in *BMC Resources*, would the two parties be found liable for joint infringement if the doctor determined the initial dose and controlled or directed the patient to perform the remaining steps?

The court in *Akamai* addressed any discrepancies regarding the controlling or directing test applied in *BMC Resources*, including the notion that providing instruc-

tions may result in a finding of joint infringement. In *Akamai Techs., Inc. v. Limelight Networks, Inc.* 629 F.3d 1311 (Fed. Cir. 2010), the court stated that:

[W]hile the 'control or direction' test of *BMC Resources* established a foundational basis on which to determine liability for direct infringement of method claims by joint parties, it left several questions unanswered including the question of whether the furnishing of instructions is sufficient to attribute the actions of the instructed party to the accused.

The court clarified any confusion and held that:

[T]he performance of a method step may be attributed to an accused infringer when the relationship between the accused infringer and another party performing a method step is that of principal and agent, applying generally accepted principals of the law of agency as explained by the Supreme Court and the Restatement of Agency.

Thus, joint infringement is established only "when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps."

Applying this holding to our hypothetical claim, it can certainly be argued that under most circumstances, there is no agency or contractual relationship between a doctor and a patient. Therefore, regardless of whether the doctor provides the patient with instructions or direction, absent an agency or contractual relationship, there would be no joint infringement of our hypothetical claim if the doctor performed the determination step and the patient carried out the remaining steps.

Notwithstanding the *Akamai* decision, the *BMC Resources* court set forth the best guidance for method claims: "the concerns over a party avoiding infringement...can

usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by a single party." *BMC Resources*, 498 F.3d at 1381. It is therefore critical that method claims be drafted with careful consideration of how the claim might be infringed, and by whom. Recited steps should be capable of only being performed by a single party.

Going back again to our hypothetical claim, assuming that the determination step is not necessary for patentability, an alternative recitation could be, for example, a method of treating a patient suffering from diabetes comprising:

- administering a predetermined initial dose of insulin to a patient;
- measuring the patient's blood sugar level; and
- administering an adjusted dose of insulin based on the patient's blood sugar level.

In this alternative claim recitation, there would be an infringement even with the same fact pattern described above in which the doctor is determining the initial dose and the patient is carrying out both administration steps and the measurement step. As seen in the redrafted claim, the determination step of the doctor has been omitted and woven into the first administration step (i.e., the initial dose is now a "predetermined" initial dose) such that it is no longer a separate and distinct step that needs to be performed in order to establish infringement. Written in the revised format, issues associated with joint infringement are avoided and a direct infringement can be easily determined. Such a scenario is necessary to establish that a drug manufacturer is liable for inducement of infringement.

In situations where a biotech or pharmaceutical company does not have composition claims covering their product, or even when they do, but the claims are at risk for invalidation, the exclusivity of the company's product may rely solely upon method-of-administration patent claims. In these instances, the survival of the product (and in extreme situations the company itself) may very well depend on the careful drafting skills of a patent attorney. ■

