Avoiding Divided Infringement in Method of Treatment Claims

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Pharmaceutical companies often enforce patents involving methods of treatment under a theory of inducement. This typically requires a showing that a single party performed all the method steps, thereby directly infringing the claim(s), and that the inducing party provided instructions to perform the claimed method. Complications arise when the method involves the administration of multiple drug components at different times and possibly by different parties. In some cases an accused inducer may avoid liability altogether where there is divided infringement. Although exceptions exist and liability can still attach even where a single party does not perform every method step, it is best to draft claims with the aim of avoiding divided infringement where possible.

To find inducement of a method claim, the Federal Circuit in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 116 U.S.P.Q.2d 1344 (Fed. Cir. 2015) (en banc) stated that "[d]irect infringement under §271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity." *Id.* at 1022. The Federal Circuit examined the circumstances where a single entity may be held responsible for direct infringement when more than one party performs the steps of a method claim and held that "an entity [is] responsible for others' performance of method steps in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise." *Id.* In *Akamai*, the Court concluded that "a single entity directs or controls the acts of another" so that "liability under §271(a) can … be found when an alleged infringer [1] conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and [2] establishes the manner or timing of that performance." *Id.* at 1023.

Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 121 U.S.P.Q.2d 1277 (Fed. Cir. 2017) involved divided infringement of method claims in U.S. Patent No. 7,772,209, which claimed administering multiple therapeutic compounds at different times by different parties when treating cancer. More specifically, the claim method in the '209 patent involved administering a chemotherapy drug (pemetrexed disodium) to a cancer patient, preceded by the patient self-administering one or more doses of a vitamin prior to receiving the drug to

reduce toxic side effects. This resulted in divided infringement as illustrated by claim 12 of the '209 patent:

12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
13. a) administration of between about 350 µg and about 1000 µg of folic acid prior to the first administration of pemetrexed disodium;
14. b) administration of about 500 µg and about 1500 µg of vitamin B12, prior to the first administration of pemetrexed disodium; and
15. c) administration of pemetrexed disodium.

In this case, a healthcare professional administered pemetrexed disodium and vitamin B12 and the patient was instructed to self-administer folic acid for several days before receipt of the cancer drug. *Id.* at 1362. On appeal, the parties agreed "that no single actor performs all steps of the asserted claims; rather, the steps are divided between physicians and patients. Though physicians administer vitamin B12 and pemetrexed, patients self-administer folic acid with guidance from physicians." *Id.* The issue before the Court was whether all the steps were attributable to the treating physician even though folic acid was self-administered by the patient.

The Federal Circuit applied the *Akamai* test to determine whether physicians "direct or control" the performance of patients. *Id.* at 1364. The court framed the issue as (1) whether the physician conditions receipt of the cancer treatment upon performance by the patient of self-administering folic acid and (2) whether the physician established the manner or timing of such performance. *Id.* at 1365. The court held that physicians do in fact condition treatment with the cancer drug on the patient self-administering folic acid prior to receiving the drug. *Id.* at 1365-1366. Under the facts of the case, the outcome turned on how the drug was labeled and in view of expert testimony.

One interesting point is that even though the patient performed one of the method steps,

inducement was found nonetheless because the treating physician and patient tougher followed instructions for performing the steps of the claimed method. Therefore, one way to avoid divided infringement is to include, where possible, at least one claim in which the patient performs all of steps and at least one other claim where the physician performs all the steps. An example claim where the patient performs all the steps might recite:

1A. An improved method for treating a patient in need of chemotherapeutic treatment with pemetrexed disodium, wherein the improvement comprises:

1. a) the patient receiving about 350 µg to about 1000 µg of folic acid prior to first receipt of pemetrexed disodium;
2. b) the patient receiving about 500 µg to about 1500 µg of vitamin B12 prior to the first receipt of pemetrexed disodium; and
3. c) the patient receiving pemetrexed disodium.

Recognizing that such a claim may arguably lack a direct nexus between instructions provided by an inducing drug company and the patient (*i.e.*, where the inducer of patient performance is the physician rather than the drug company), the claim may recite involvement by a physician where such a nexus with the drug company does exist:

1B. An improved method for treating a patient in need of chemotherapeutic treatment with pemetrexed disodium, wherein the improvement comprises:

1. a) under the direction or control of a physician, the patient receiving about 350 µg to about 1000 µg of folic acid prior to first receipt of pemetrexed disodium;
2. b) under the direction or control of a physician, the patient receiving about 500 µg to about 1500 µg of vitamin B12 prior to the first receipt of pemetrexed disodium; and
3. c) under the direction or control of a physician, the patient receiving pemetrexed disodium.

An example claim where a physician or healthcare entity performs all the steps may recite:

1C. An improved method for treating a patient in need of chemotherapeutic treatment with pemetrexed disodium, wherein the improvement comprises:

1. a) prescribing the patient to self-administer, and verifying that the patient has self-administered, about 350 µg to about 1000 µg of folic acid prior to first administration of pemetrexed disodium;
2. b) administering about 500 µg to about 1500 µg of vitamin B12 to the patient prior to the first administration of pemetrexed disodium; and
3. c) administering pemetrexed disodium to the patient.

In the unlikely scenario that a court were to determine that the foregoing claim is primarily directed to the organization of human activity, another approach might be to claim:

1D. An improved method for treating a patient in need of chemotherapeutic treatment with pemetrexed disodium, wherein the improvement comprises:

1. a) after the patient has recieved about 350 µg to about 1000 µg of folic acid prior to first administration of pemetrexed disodium, administering about 500 µg to about 1500 µg of vitamin B12 to the patient prior to the first administration of pemetrexed disodium; and
2. b) administering pemetrexed disodium to the patient.

A possible weakness of the foregoing claim is the argument that there may be no active step of administering or receiving the prescribed amount of folic acid. This and the previous examples highlight the fact that there will likely be no single fool-proof way to ensure liability under a theory of inducement and that a variety of claims should be employed, whether in a single patent or in one or more continuation applications.