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Life Sciences Patents: Method Claims—United They Stand, Divided Do They Fall?

By Dr. Erica J. Pascal

Patent protection for methods claims can be tricky. Particularly for medical devices, diagnostics and even drugs, methods claims can present dilemmas for enforcement. It can boil down to the key question of ''who''—who performs each of the required steps?

Direct infringement is most easily demonstrated when a single party carries out each step of the claimed method. However, life science patents often involve more than just the manufacturer in the performance of the claimed steps. While indirect infringement theories (inducement and contributory infringement) provide some assistance, they do not always provide a vehicle for making a strong infringement case.

Under the recent rulings in *Akamai*, there must be a direct infringer on which to predicate claims of indirect infringement.[1] Performing a subset of the steps while encouraging or instructing another party to perform the others is on its own not sufficient for direct infringement. When more than a single party is involved, the law now requires that ''the acts of one are attributable to the other such that a single entity is responsible for the infringement.''[2] Responsibility may be created where one party directs or controls the actions of the other or when the parties form a joint enterprise.[3] The directing or controlling may be shown where one party ''conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance.''[4]

What does this look like when applied to patent claims in the life sciences? Here are some hypothetical methods claims and how they might fare in an infringement analysis.

Hypothetical medical device claim

A method of cutting a vein comprising:

a) Obtaining an electrically powered surgical cutting device having a clamping tool and a cutting blade;

b) Positioning the vein in the center of the clamping tool;

c) Applying pressure to the cutting blade such that the blade moves towards the clamping tool wherein the vein is compressed between the clamping tool and the cutting blade;

d) Applying the power for no more than 3 seconds, wherein the cutting tool bisects the vein.

In this claim, the manufacturer supplies the device for step a). Step c) can also be considered a function of the device as supplied. Steps b) and d) are not carried out by the device itself but are most likely based on the surgeon's discretion in using the device. The surgeon selects what type of tissue or blood vessel to cut and where to place it relative to the clamping surface. The surgeon may also dictate the duration for which power is applied, whether it be no more than 3 seconds required by step d) or a greater amount of time.

What if the instructions for the device recommend positioning the vein in the center of the clamp and applying power for less than 3 seconds—is this sufficient to demonstrate direct infringement? Probably not. Simply providing instructions without requiring the selection of the specified variables is likely not enough to be the control or direction required to attribute direct infringement to the manufacturer.[5] On the other hand, the situation could be reversed if the manufacturer required the user to apply the device in the manner dic-

[1] *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014); *Akamai Techs, Inc., v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015).

[2] *Akamai*, 797 F.3d at 1022–23.

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[3] *Id.* at 1022.

[4] *Id.* at 1023.

[5] *Akamai*, 797 F.3d at 1025.

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tated by steps b) and d). For example, a company could require performance of the two steps in the claimed manner for the device to remain under warranty. With these facts, the manufacturer could be attributed to directing ''the manner and timing of its customers' performance,'' rather than customers simply having guidance but making their own independent decisions.

For another look, below is a hypothetical diagnostic claim covering an app for assessing health status.

Hypothetical diagnostic claim

A method of diagnosing an individual's health status comprising:

a) Using a fitness device to measure at least one variable selected from the group consisting of heart rate, respiration rate and perspiration rate;

b) Inputting data into said device, said data comprising diet, nutrition, physical activity and sleep time;

c) Transmitting the measurement from step a) and the data from step b) to a central processing unit;

d) Outputting an analysis by said processing unit to a medical practitioner; and

e) Assigning a health status rank based on said analysis and recommending a health plan based on said rank.

In this claim, there may be several parties involved—the fitness device manufacturer, the individual whose health status will be assessed, the company that processes the data (e.g., the app company may be a separate entity from the device maker) and perhaps the medical practitioner (if this is the source of the rank assignment or health plan recommendation).

For each of these steps, to prove infringement against the fitness device manufacturer or alternatively the app provider, evidence of direction and control over the other parties is essential. This may prove to be difficult if, for example, the patient can select which variables to be measured and there is no requirement by the app or the device to select one of the attributes specified by step a). The final step could also be tricky to attribute to a device manufacturer or app company. However, if the app itself assigns a health rank and a health plan, rather than a physician with her independent judgment, this step may attach more easily to an accused infringer.

Given these complexities, a series of simpler claims may help capture potential infringers. While this is a viable suggestion in theory, claims with only a subset of the steps may run into more issues with prior art. Other issues, such as subject matter eligibility, may also come into play. For instance, Section 101 challenges may arise where the claimed steps are viewed as collecting or correlating data and the software and device operate simply as tools to more efficiently carry out the steps in an automated manner.[6]

In contrast to the above examples, methods for administering drugs often involve an interaction of physician and patient and thus have a tendency to lean more heavily to providing the direction and control necessary for direct infringement.

Hypothetical drug administration claim

A method of administering a combination medication for treating acne comprising:

a) Administering prescription drug A;

b) Administering vitamin supplement B;

c) Wherein B is administered by mixing 1 teaspoon of B with 1 cup of water; and

d) Administering said mixture orally once per day no more than 6 hours after the administration of drug A.

In the claim above, the prescribing physician may administer drug A (for example as an injection or an intravenous treatment) and the remainder of the steps may be performed by the patient. However, it is likely that the physician directs the patient to obtain the vitamin supplement and provides explicit instructions with the prescription on the dosage, mixing and timing with which the patient should take the supplement to obtain the benefit of the treatment. This level of direction coupled with the resulting benefit of treatment may be sufficient to demonstrate direct infringement by the physician.

Can claim construction be determinative for divided infringement?

In the above example, could the interpretation of ''administering'' determine the ''who'' for the steps of the claim? For example, drug A is a pill and although it is prescribed by the physician, the patient physically swallows it. Can this action be attributed to the physician?

At least a few courts have suggested that this claim construction might not matter.[7] The individual that physically carries out the administration is not the question but rather ''whether the physician sufficiently directs or controls the acts of the patients in such a manner as to condition participation in an activity or receipt of a benefit,'' namely treatment with the drug to achieve the desired effects.[8] Absent some independent judgment by the patient for at least one of the steps, the direction and control is likely to fall to the physician.

While drug administration methods may not be particularly sensitive to claim construction issues, other types of method patents may be more susceptible. Diagnostic methods and health-care software applications may turn more closely on the meaning of claim terms. For example, in the hypothetical diagnostic claim discussed above, the final step could lie within the province of a physician or be performed by the app (or both) depending on the meaning of ''assigning'' and ''recommending.''

In sum, keeping the ''who'' in mind can be key for a patent infringement action. ''Who'' may determine:

- the parties to be named in the suit,
- the party to identify as the direct infringer to form the basis for direct and indirect infringement claims,

[6] *See e.g.*, *Enfish, LLC v. Microsoft Corp.*, No. 2015-1244 at *11 (Fed. Cir. May 12, 2016); *Takeda Pharm. Co. v. Actavis Labs.*, No. 15-451-RGA, at *8, n.4 (D. Del. June 6, 2016).

[7] *Takeda*, No. 15-451-RGA, at *8, n.4.

[8] *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 126 F. Supp.3d 1037 (S.D. Ind. 2015).

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- the scope of discovery needed to show direction and control, and
- claim construction for terms that will be crucial to attributing each step to the identified direct infringer.