

# A Chance To Clarify Medical Device Patent Indefiniteness

By **Joe Bird and Sarah Daley** (August 5, 2019)

Claims in medical device patents can be less precise than in pharmaceutical or biotech patents because the latter are tied to a chemical structure, nucleotide and/or amino acid sequence. Medical devices, however, use mechanical means and energy forms not defined by the rigors of biochemistry, and therefore patent strategy and claims for devices can leave more to the imagination and creativity of the patent prosecutor.

Another aspect of uncertainty is that medical device patents in a given category use similar terms, so patent lawyers must try to use novel ways to describe improvements. For example, an “electrode” is an old concept even though novel electrodes will work in new ways, so practitioners must do all that is possible to distinguish the subject invention from prior art.

Neuromodulation devices are a subcategory of medical devices that can be even more challenging to claim than other medical devices, especially when a perception by the patient is an aspect of the claimed invention. For example, many neuromodulation devices are aimed at reducing pain, restoring vision or hearing or even changing a mood. Patient perception then is one way in which neuromodulation devices may be differentiated, and claims incorporating perception are becoming more common.

For example, a visual prosthesis patent claims a method of stimulating a retina in a predetermined pattern, “wherein the pattern results in interrupting each electrode for a period shorter than the threshold of perception...” (U.S. Patent No. 9,757,563). Another recent patent claims an external device to stimulate a nerve “without the electrical therapy signal causing paresthesia.” (U.S. Patent No. 10,328,256). These kinds of claims arise in all sorts of neuromodulation patents. Patient perception of pain is built squarely into the patent claims of Nevro Corporation’s many patents covering its kilohertz frequency spinal cord stimulators to reduce pain.

The claims construction in *Nevro Corp. v. Boston Scientific Corp.*, currently before the U.S. Court of Appeals for the Federal Circuit, presents a very interesting issue about patient perception in the context of indefiniteness under 35 U.S.C. Section 112. Nevro has a broad array of patents protecting neuromodulation within a range of 1.5-100 KHz, and it also has U.S. Food and Drug Administration clearance to market SCS devices which generate pulses at 10 KHz. Previous SCS clearances by the FDA were for much lower frequencies.

A little background about the device is necessary. After implantation of an SCS, a “user” such as a clinician or a manufacturer’s sales representative uses the operating system of the device to choose settings for the patient. The settings provide a set of preprogrammed choices for patients in general, which a user then selects for a specific patient after implantation.

In November 2016, Nevro sued Boston Scientific for patent infringement in the U.S. District Court for the Northern District of California, alleging that Boston Scientific had begun trying to copy Nevro’s high-frequency SCS. Nevro lost partially in the trial court on grounds that



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its system/device claims were indefinite, but the trial court found that the related method claims were definite. Both rulings are now on appeal.

A representative device claim at issue in the Nevro case is:

A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising:

an implantable signal generator configured to generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of 10 kHz, and at a current amplitude in a current amplitude range from 0.1 mA to 20 mA; and

an implantable signal delivery device electrically coupled to the implantable signal generator and configured to deliver the therapy signal to the patient's spinal cord.[1]

The Northern District of California ruled that this and other similar device claims are indefinite. One of the grounds for the holding of indefiniteness was that "non-paresthesia producing therapy signal" is indefinite for system or device claims. The court reasoned:

Whether a signal produces paresthesia depends on a patient's response to a signal; the same signal that produces paresthesia in one patient may not produce paresthesia in another patient. ... In other words, paresthesia is not a signal parameter; it is a signal effect. Thus, depending on the characteristics of the patient who uses a spinal cord stimulation system, the same system would either infringe or not infringe the asserted system patents. Because of this variability, a skilled artisan cannot identify the bounds of these claims with reasonable certainty.

The California court, in effect, held that a device manufacturer would not know whether its device would cause paresthesia in a given patient. Lack of knowledge about the effect of its own product on a patient's perception would render Nevro's patent claim indefinite, as the court ruled.

The parties disagree whether "non-paresthesia producing" is a functional element. Nevro says yes, even if the function is not always performed. Boston Scientific disagrees, saying this phrase is only an effect that varies greatly among patients, and citing evidence of variation among patients along with lack of predictability.

For method claims, however, the court in the Nevro/Boston Scientific case reached a different result on indefiniteness: "[B]ecause an artisan could quickly ascertain whether a signal generates paresthesia in a patient, the non-paresthesia-producing signal limitations would not prevent a skilled artisan from being able to determine whether she was practicing a claimed method with reasonable certainty." That is, a clinician using the device on a given patient would know whether the device produces paresthesia.

The war over high-frequency SCS seems to have only just begun. Although Boston Scientific stated in July 2018 that it has postponed entering the high-frequency SCS market in the U.S., Nevro has more than 100 U.S. patents which have yet to be litigated, and in February 2019 Nevro filed suit in Delaware against StimWave Technologies Inc., alleging infringement of five Nevro patents not involved in the suit against Boston Scientific.

On July 24, 2019, Nevro obtained a preliminary injunction against StimWave. The Delaware court did not adopt the California court's ruling of indefiniteness based upon patient

perception, and Nevro was able to provide evidence from StimWave's documents and witnesses that StimWave understood the meaning of "non-paresthesia producing therapy signal." The Delaware court also relied on evidence that "non-paresthesia producing" was uniform among patients at the high frequency.

If the Federal Circuit resolves the patient perception issue squarely in the Nevro/Boston Scientific case, this will provide greater clarity. Patient perception is now a common part of neuromodulation patents. At least one of Boston Scientific's own patents claims a device and method for "subperception modulation" of a patient, the "patient-perception threshold being a boundary below which a patient does not sense generation of the modulation field..." (U.S. Patent No. 10,342,979). This seems similar to "non-paresthesia producing therapy signal" in that the threshold could vary among patients.

Meanwhile, patent lawyers prosecuting claims with a patient perception should consider the following.

1. Allowability or validity could differ between a method and a device or system claim, so be mindful of including disclosure in an application for a method and a device.
2. A patent prosecutor should include evidence, if available, that all patients perceive a sensation at a given level. Evidence in the alleged infringer's own documents about use of "patient perception" would be most persuasive to counteract the argument of indefiniteness.

Given Nevro's aggressiveness and the high stakes involved, litigation involving neuromodulation patents will likely become even more interesting.

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[1] U.S. Patent No. 8,712,533, Claim 3.