THOMSON REUTERS
Westlaw®

District Court takes another logical step to expand the safe harbor

By Sara W. Koblitz, Esq., *Hyman Phelps & McNamara**

AUGUST 21, 2018

With one paragraph in a Summary Judgment Order issued July 24, the Northern District of California further expanded the patent safe harbor under 37 U.S.C. § 271(e)(1).

Though not a huge leap from previous safe harbor decisions, the Order in *Nevro Corp. v. Boston Scientific Corp.* held that use of a patented invention in clinical trials falls within the safe harbor provision "even after the patients have completed their participation in the trial." Docket No. 16-cv-06830 (N.D. Cal., July 2018).

In this case, Nevro sued Boston Scientific alleging infringement of its patents relating to Nevro's Senza and HF10 spinal cord stimulation systems.

The Senza is a spinal cord stimulator using high-frequency pulses rather than low-frequency, approved for marketing by FDA in May 2015 with labeling stating that the device is superior to conventional spinal cord stimulators using low-frequency therapy.

Boston Scientific manufactures a competing spinal cord stimulator, the Spectra WaveWriter, as well as the Precise with Multiwave system.

Nevro sued Boston Scientific for patent infringement in 2016 asserting that Boston Scientific infringed its patents covering methods for delivering spinal cord stimulation therapy at frequencies between 1.5 kHz and 100 kHz in its use of high-frequency therapy with Boston Scientific's spinal cord stimulation devices. Both parties filed cross-motions for summary judgement with respect to these patents.

Because Boston Scientific used high-frequency spinal cord systems only in a clinical trial, the Court determined that its use of Nevro's patented technology was protected by the patent safe harbor codified in 35 U.S.C. § 271(e).

The safe harbor protects the use of patented technology in the development and approval of a drug:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

In *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661 (1990), the Supreme Court read the safe harbor to include all inventions rather than only drug-related inventions because the safe harbor must be read in conjunction with the patent term restoration provisions in 35 U.S.C. § 156.

In time, the standard for the applicability of the safe harbor extended to any use of the patented technology as long as it is "reasonably related" to FDA approval. *Abtox v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997).

Use of information obtained under the exemption — even if not related to regulatory approval — is also protected under the safe harbor as long as the initial use is related to regulatory approval. *See Telectronics Pacing Sys. v. Ventritex, Inc.,* 982 F.2d 1520, 1523-24 (Fed. Cir. 1992).

In 2012, the Federal Circuit explained that the safe harbor will still protect use even if a non-infringing alternative exists. *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.,* 686 F.3d 1348 (Fed. Cir. Aug. 3, 2012), the Federal Circuit explained that the safe harbor will still apply even if a non-infringing alternative exists.

Building from this safe harbor framework, *Nevro v. Boston Scientific* explained that use of the patented invention in a clinical trial is clearly reasonably related to the development and submission of information to FDA for device approval.

Continued use of the invention *after* the clinical trial ends is necessarily included in the safe harbor because FDA "specifically approved a trial plan" that allowed patients to continue using the treatment protected by the safe harbor even after the relevant data for FDA submission was obtained and the trial concluded.

Further, international standards for medical research require trial sponsors to allow participants to access the studied treatment even after the trial's conclusion.

Thomson Reuters is a commercial publisher of content that is general and educational in nature, may not reflect all recent legal developments and may not apply to the specific facts and circumstances of individual transactions and cases. Users should consult with qualified legal counsel before acting on any information published by Thomson Reuters online or in print. Thomson Reuters, its affiliates and their editorial staff are not a law firm, do not represent or advise clients in any matter and are not bound by the professional responsibilities and duties of a legal practitioner. Nothing in this publication should be construed as legal advice or creating an attorney-client relationship. The views expressed in this publication by any contributor are not necessarily those of the publisher.

the answer company™
THOMSON REUTERS®

The Court here marginally extends the safe harbor to include the continued use of a patented invention even after the trial has ended and no further data will be submitted to FDA since it is still "reasonably related" to an FDA submission.

This makes sense: the safe harbor is clearly intended to protect *research* and encourage innovation; denying clinical trials protection from a safe harbor is therefore nonsensical.

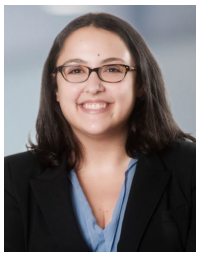
While continued use *after* the clinical trial may seem like more of a reach, denying such protection would preclude the continued treatment of the studied population — a consequence that would inherently deter other patients from participating in clinical trials down the line.

Given the congressional intent to encourage innovation and the safe harbor cases preceding *Nevro v. Boston Scientific*, this result is only logical.

This article first appeared in the August 21, 2018, edition of Westlaw Journal Medical Devices.

* © 2018 Sara W. Koblitz, Esq., Hyman Phelps & McNamara

ABOUT THE AUTHOR



Sara W. Koblitz in an associate at **Hyman Phelps & McNamara** in Washington, where she advises FDA-regulated clients on a range of issues with a focus on Hatch-Waxman patent and exclusivity, biosimilars, and the Orange Book. She helps drug and device manufacturers in various stages of product development and guides clients through the applicable regulatory requirements with respect to applications and submissions, device classification, potential exclusivities, promotional issues, and post-marketing requirements. She can be reached at skoblitz@hpm. This expert analysis was first published July 30 on the firm's FDA Law Blog. Republished with permission.

Thomson Reuters develops and delivers intelligent information and solutions for professionals, connecting and empowering global markets. We enable professionals to make the decisions that matter most, all powered by the world's most trusted news organization.

This publication was created to provide you with accurate and authoritative information concerning the subject matter covered, however it may not necessarily have been prepared by persons licensed to practice law in a particular jurisdiction. The publisher is not engaged in rendering legal or other professional advice, and this publication is not a substitute for the advice of an attorney. If you require legal or other expert advice, you should seek the services of a competent attorney or other professional. For subscription information, please visit legalsolutions.thomsonreuters.com.