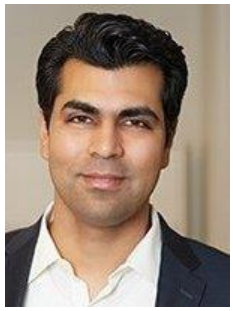
Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

# How Therapeutic Formulations Affect Medical Device Patents

By **Vern Norviel, Charles Andres and Prashant Girinath**
(July 6, 2020, 5:30 PM EDT)

Vern Norviel

Charles Andres



Prashant Girinath

Medical devices that (1) are configured to deliver a therapeutic formulation and (2) are packaged with a preloaded dose of the to-be-delivered formulation are becoming more common.

For patients, these medical devices can conveniently provide a predetermined dose — for example, a unit dose — of the therapeutic formulation. This can help ensure patients receive the correct dose or amount of the formulation, and that the dose or amount is correctly administered, thereby reducing the occurrence of dosage and administration associated adverse effects.

Preloaded devices can also increase patient compliance with a therapeutic regimen, and depending on the device, provide convenience to health care professionals.

Given the above-mentioned advantages, these medical devices are increasingly becoming the subject of patent applications and patents. Within these, the presence or absence of claims drawn to the device containing the therapeutic formulation can have far reaching impact on patentability, Orange Book listing eligibility, product life cycle management and potential antitrust liability.

This piece highlights two appeal cases, one from the U.S. Patent Office, the other in the U.S. Court of Appeals for the First Circuit, which collectively address these four points, and provide important considerations for the path forward.

**Ex Parte Ferreyro**

The first case, Ex Parte Ferreyro, is a decision from an appeal in the Patent Office. The patent examiner rejected various claims as being anticipated, and one claim as being obvious, all in view of the same reference. Claim 6, which is representative, is drawn to a "device for delivering viscous bone cement material under fluoroscopy to a site in a patient." Among other claim features, the device as described in claim 6 comprises "an injection part ... having a chamber loaded with a viscous bone cement."

The patent examiner construed claim 6 such that a viscous bone cement was not positively recited. Put differently, the patent examiner interpreted claim 6 to not require, in the device, the presence of a viscous bone cement.

Based on that interpretation of claim 6, the patent examiner then argued claim 6 was not patentable over a reference that was asserted to provide all of the remaining limitations in claim 6, in addition to stating the reference's device was "capable of delivering a viscous bone cement material" and could "be loaded with and inject viscous bone cement material."

On appeal, the patent applicant argued that there "is no reasonable way to read 'a chamber loaded with viscous bone cement'" as not requiring the presence of viscous bone cement because doing so "simply changes the claim language to something other than what it is."

The appeals board agreed with the applicant, determining that "'an injection part ... having a chamber loaded with viscous bone cement' positively requires an amount of bone cement that is loaded in the chamber" and that the patent examiner's claim 6 interpretation is unreasonable.

The appeals board reversed the patent examiner's findings on all rejections. Thus, in this instance, the presence of a formulation — viscous bone cement — was an important claim limitation that helped distinguish over prior publications asserted by the Patent Office and ultimately overcome the patent examiner's rejections.

**Observations on Ex Parte Ferreyro**

We provide three observations stemming from Ferreyro. First, when a device is intended to deliver a therapeutic formulation, it is advantageous to present at least some claims in the device patent application and ultimately issued patent that require the presence of the therapeutic formulation in the device. These claims, as shown by Ferreyro, can help to prevent or overcome rejections in the Patent Office, smoothing the way to issuance of a patent.

Second, requiring the presence of a therapeutic formulation in at least some claims in a device patent can also render these claims more resistant to challenge in the Patent Office and federal courts. The inclusion of a therapeutic formulation can make it less likely that a patent challenger will find a reference, containing all claim limitations, that may serve as basis for challenging claims of an issued patent.

Finally, claims to devices which require the presence of the therapeutic formulation can be employed as a tool to extend a therapeutic or other composition patent franchise. This point is illustrated in the second case, Castillo v. Sanofi-Aventis.

**Castillo**

Castillo is a case that relates largely to antitrust and competition law, but implicates a medical device patent, insulin glargine and drug life cycle management. Briefly, earlier in time, the U.S. Food and Drug Administration approved Sanofi SA's new drug application, or NDA, for insulin glargine — a long-lasting form of insulin for use in the management of diabetes.

Later, Sanofi filed a supplemental NDA to sell insulin glargine in a disposable injector pen medical device.

Previously, insulin glargine was sold in vials, or in cartridges for reusable injectors.

The FDA approved Sanofi's supplemental NDA, and Sanofi listed a medical device patent in the Orange Book. Orange Book listing is important. A generic manufacturer who wishes to sell a generic version of a branded drug in the U.S. must submit an abbreviated new drug application, or ANDA, to the FDA.

If the generic manufacturer wishes to sell its drug before expiration of an Orange Book listed patent protecting the branded drug franchise, the generic must, among other things, provide notice of this intent to sell early to the branded drug manufacturer. If the branded drug manufacturer timely sues the generic after receiving notice, the FDA is stayed from approving the ANDA for an adjustable period of 30 months.

The patent that Sanofi listed in the Orange Book contains claims drawn to drive mechanisms that were part of its disposable injector pen device. Per the court, the patent "did not include a claim for an injector pen more broadly" and the patent did "not mention insulin glargine ... at any point." The problem is that only certain types of patents are listed in the Orange Book, and Castillo and the other plaintiffs argued that Sanofi's patent did not meet the criteria for being listed.

It was alleged that by listing the patent in the Orange Book, Sanofi artificially restricted competition by "impermissibly extending its monopoly over insulin glargine products" and that Sanofi's listing of the patent in the Orange Book was a sham "initiated merely to trigger the [30 month] automatic stay of FDA's approval" of a competing product.

Claims were therefore brought under Section 2 of the Sherman Act, based on an "unlawful scheme to monopolize and an attempt to monopolize the market for insulin glargine products."

The trial court dismissed these claims. On appeal, the First Circuit vacated the trial court's dismissal. Initially, the First Circuit assumed, and Sanofi did not challenge, that Sanofi possessed monopoly power in the relevant market. The court's analysis then turned on whether Sanofi's submitting of the patent for listing in the Orange Book was an "'improper means' of maintaining that [monopoly] power."

Sanofi presented several arguments in its defense. We present the court's analysis of Sanofi's two primary arguments. First, Sanofi argued, based on the legal definition of a drug, that the medical device components claimed in its patent listed in the Orange Book were drugs. And because the medical device components were drugs, the patent was properly listed in the Orange Book. This argument was not found persuasive by the First Circuit.

The First Circuit held that "because the claims of the ... patent do not mention the drug for which the [supplemental NDA] was submitted, the patent does not 'claim the drug,' and it was improper for Sanofi to have submitted [the patent] for listing in the Orange Book."

The First Circuit, in any case, pointed out that even if the claimed medical device components somehow were drugs, the claimed components were not the approved drug. And Orange Book regulations limit listing to patents claiming the approved: drug, formulation, and methods of treatment employing these.

Sanofi separately argued that submitting its patent for listing in the Orange Book was "reasonable, and that Sanofi cannot be held liable under antitrust laws for a reasonable mistake." The plaintiffs argued, in contrast, that "the Orange Book listing statues was sufficiently unambiguous so as to render Sanofi's filing unreasonable as a matter of law."

The court concluded that "neither side is quite correct, and that further proceedings ... are necessary to determine whether Sanofi should be held liable under the Sherman Act." The court considered Sanofi's argument that it was required, by law and regulation, to "submit any patent that claims the drug for which it seeks approval" and that failure to comply "could itself arguably have an anticompetitive effect by depriving potential competitors of notice and other procedural benefits that result from an Orange Book listing."

To bolster this argument, Sanofi pointed to an earlier complaint where a patent was not listed in the Orange Book, and competitors "alleged that they were damaged by the defendant's failure to [Orange Book] list the patent because they spent money developing a potential generic competitor they would not have developed had they know of the original patent through an Orange Book listing."

The court determined that Sanofi has a fair point but also that "this does not mean that Sanofi gets a free pass from antitrust scrutiny." The court therefore determined that Sanofi, on remand, should be allowed to make its case that its listing in the Orange Book "was taken as part of a good faith, reasonable attempt to comply with a regulatory scheme;" and that this is a legitimate antitrust defense.

**Observations on Castillo**

Requiring the presence of a drug or therapeutic formulation, in at least some medical device patent claims, can decrease the chance that a plaintiff raising antitrust questions can successfully argue that the medical device patent was improperly listed in the Orange Book. This, in turn, can decrease the potential for antitrust liability.

Also, when faced with a judgement call about whether to list, or not list, a medical device patent in the Orange Book, it is may be beneficial to obtain an opinion of counsel. The opinion may aid in the decision to list in the Orange Book and may also be useful in mounting a defense to a charge of engaging in illegal monopolistic behavior.

Finally, requiring the presence of a drug or therapeutic formulation, in at least some medical device patent claims, and timely listing the patent in the Orange Book, can be a way to extend a therapeutic drug franchise. This approach, if employed, should be undertaken as part of a comprehensive life cycle management strategy.

---

*Vern Norviel is a partner and head of the patents and innovation strategies group at Wilson Sonsini Goodrich & Rosati PC.*

*Charles Andres is senior counsel at the firm.*

*Prashant Girinath is a senior associate at the firm.*

*Wilson Sonsini patent agent David Mata contributed to this article.*