Getting The Most Out of Your Method of Use Claims and Use Codes

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Patent Information Submitted Upon And After Approval of an NDA or Supplement

"[T]he brand company has every incentive in the world to ensure they don't make [use code description] mistakes."

When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the innovator pharmaceutical manufacturer is required to submit a Form FDA 3542. Form FDA 3542 requires the innovator to select a use code that describes one or more of the uses approved for the product and described in the product's label.

The innovator also is required to submit patent information to the FDA. The FDA allows innovators to draft use codes which are then entered into the Orange Book without FDA review.

The applicant is allowed to describe the scope of the patent to be listed in terms of whether the patent claims "one or more approved methods of using the approved drug product"; the patent claims that claim "an approved method of use of the approved drug product"; and the "indication or method of use information as identified specifically in the approved labeling".

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Form FDA 3542, Section 4

4. Method of Use		
Sponsors must submit the information in section 4 for each approved method of using the approved drug product claimed by the patent. For each approved method of use claimed by the patent, provide the following information:		
4.1 Does the patent claim one or more approved methods of using the approved drug product?		☐Yes ☐ No
4.2 Patent Claim Number(s) (as listed in the patent)	Does (Do) the patent claims referenced in 4.2 claim an approved method of use of the approved drug product?	☐Yes ☐ No
4.2a If the answer to 4.2 is "Yes," identify the use with specific reference to the approved labeling for the drug product.	*Use: (Submit indication or method of use information as identified specifically in the approved labeling.)*	
4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (*Submit the description of the approved indication or method of use that you propose FDA include as the "Use Code" in the Orange Book, using no more than 240 total characters including spaces*.)	

The Generic Applicant's Choices

If a generic applicant seeks FDA approval to market a copy of a branded drug product before all of the patents listed in the Orange Book for that drug product have expired, it must either challenge the unexpired patents by filing a Paragraph IV certification or, in the case of method of use patents, attempt to carve out a patented use from its label by filing a "section viii" statement. 21 U.S.C. §355(j)(2)(A)(viii).

A paragraph IV certification requires that the generic applicant provide notice of its FDA to the innovator drug holder and the patent owner. If suit is filed by the innovator within 45 days of receiving notice from the generic applicant, the FDA will automatically stay approval of the generic application for 30 months.

On the other hand, if the generic applicant can file a section viii statement, there is no requirement to provide notice to the innovator and no opportunity for an automatic 30 month stay of the generic's application.

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The Generic Applicant's Choices cont'd

A generic applicant that seeks to carve out a method of use for which one or more method of use patents have been identified to the FDA, must provide the FDA with a proposed label that omits the information that is described in the patent use code.

The FDA must then decide whether (1) the generic drug product is as safe and effective as the innovator drug for all remaining approved uses sought by the generic applicant that are not designated as protected by patents, and (2) there is any overlap between the uses that are designated as protected by patents the uses proposed in the generic applicant's label.

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Caraco Pharmaceutical Labs., Ltd v. Novo Nordisk A/S:

One of the patents to Novo (the " '358 patent") claimed the use of repaglinide in combination with metformin. The original use code submitted for the '358 patent was for "use of repaglinide in combination with metformin to lower blood sugar."

There were three approved uses for repaglinide: monotherapy treatment (repaglinide alone); treatment in combination with thiazolidinediones; and treatment in combination with metformin.

Caraco initially made a Paragraph IV certification as to the '358 patent (repaglinide and metformin), but amended its ANDA to switch to a section viii statement and carve out all "metformin" combination information.

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Caraco Pharmaceutical Labs., Ltd v. Novo Nordisk A/S: cont'd

During the time of the litigation, the FDA required Novo to change its label description to "improving glycemic control in adults with type 2 diabetes mellitus." Thereafter, Novo amended the use code to correspond with the label.

As a result, the FDA refused Caraco's section viii statement. Caraco then Amended its counterclaim and requested that the Court issue an injunction requiring Novo to delist the new use code (improve glycemic control in adults with type 2 diabetes mellitus) and replace it with the former (use of repaglinide in combination with metformin to lower blood sugar).

The District Court agreed with Caraco, and directed Novo to change its use code listing accordingly. Chief Judge Rader for the Federal Circuit reversed stating that Caraco does not have a statutory basis to assert a counterclaim requesting such relief, because the Act allowed the innovator to claim "any" approved use of the drug product.

Caraco Pharmaceutical Labs., Ltd v. Novo Nordisk A/S: cont'd

The Hatch-Waxman Act enables a generic manufacturer in a Paragraph IV suit to assert a counterclaim challenging the accuracy of the "patent information" submitted to the FDA on one of two grounds:

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the [ANDA] applicant, **the [ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder** under subsection (b) or (c) **on the ground that the patent does not claim either** —

(aa) the drug for which the application was approved; or

(bb) **an** approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I). (Emphasis added).

Caraco Pharmaceutical Labs., Ltd v. Novo Nordisk A/S: cont'd

Chief Judge Rader stated:

"The Hatch-Waxman Act provides a limited counterclaim to a generic manufacturer in a Paragraph IV infringement action. The Act authorizes the generic manufacturer to assert a counterclaim "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I) ."

"[T]he Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug."

"Accordingly, to preserve the Act's careful balance and to enforce the language of the statute, the explicit definition of 'the patent information' as 'the patent number and the expiration date' controls."

What Do You Need To Know?

Putting aside the outcome of Caraco:

When preparing a patent application, and drafting claims, you need to know your product's label and FDA approved uses for that product.

Conform pending patent claims (and specification if possible) to the proposed label, taking care to conform with the requirements of 35 U.S.C. § 112, ¶ 1, as appropriate.

Make sure the individual filling out the Form FDA 3542 for submission to the FDA is in communication with the prosecuting attorney. Preferably, to avoid errors, the prosecuting attorney would fill out and submit the Form FDA 3542.

Of course, if you do consider submitting an amended FDA Form 3542, make sure that you do it in consultation with your regulatory counsel.

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Practical Applications For The Prosecuting Attorney

The USPTO gives terms their "broadest reasonable interpretation" during prosecution of a patent application.

What if your product is approved for a use that employs a term that the USPTO just does not like, such as "preventing…", or "reducing….", or "restoring…"? Suppose you get a rejection that states that the application has not enabled the full scope of a particular term, and the examiner tells you to change the phraseology employed in your claims.

Considerations include:

making sure that you can appropriately encompass the approved indication(s) with your claims; avoiding the patent appeal process which can take a long time; and thinking ahead to litigation and allegations of obviousness – the statements that you make in response to an enablement rejection will be used against you.

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Practical Applications cont'd

Examples of what you can do:

Ideally, you have plenty of examples to support the full scope of your claims to overcome the rejection.

Assuming you have few or no examples:

- remember that the standard is "broadest reasonable interpretation" not "broadest interpretation";
- cite to patents issued in the field containing the particular term that you recite BUT avoid using art that employs your particular drug product;
- interview the examiner to explain your position;
- consider a declaration by one of skill in the art to explain the ordinary understanding of the term;
- if you have to amend the term employed, make sure that the record is clear that you are only giving up the furthest reach of the claim term that the examiner has focused upon.

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In re Cortright, 165 F.3d 1353 (Fed. Cir. 1999)

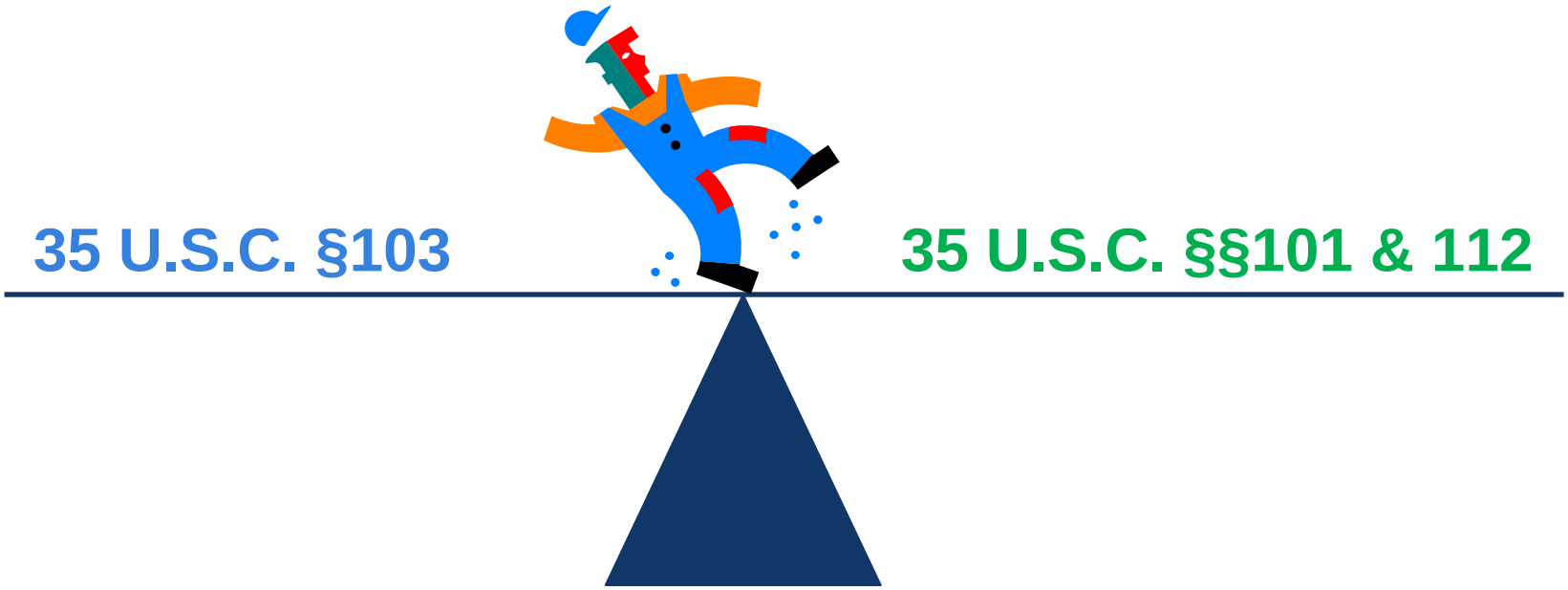
Claim 1 recites a method of "treating scalp baldness with an antimicrobial to restore hair growth, which comprises rubbing into the scalp the ointment wherein the active ingredient 8-hydroxy-quinoline sulfate 0.3% is carried in a petrolatum and lanolin base."

The board explained that claim 1 is not enabled because it claims "restor[ing] hair growth," which the board interpreted as requiring the user's hair "to return to its original state," that is, a full head of hair. Thus, the board's rejection was not based on complete non-enablement, as the original decision had implied, but on the claim not being commensurate with the scope of the disclosure.

Although the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach.

Accordingly, the PTO's interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art. "[c]onsistent with Cortright's disclosure and that of other references, one of ordinary skill would construe this phrase as meaning that the claimed method **increases the amount of hair grown on the scalp but does not necessarily produce a full head of hair**."

Straddling the Balance



Enablement and Utility

35 U.S.C. §112, ¶ 1 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

If the written description of the specification fails to set forth a credible utility, the PTO may make both a section 112, ¶ 1 rejection for failure to teach how to use the invention and a section 101 rejection for lack of utility, because the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.

Thus, an applicant's failure to disclose how to use an invention may support a rejection under either section 112, ¶ 1 for lack of enablement as a result of the specification's failure to disclose adequately to one ordinarily skilled in the art “how to use” the invention without undue experimentation, or section 101 for lack of utility when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.

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Avoiding The Enablement/Obviousness Seesaw

While it is important to have broad claims, it is equally as important to have tight claims that track your label.

To avoid a world of problems, make sure you have at least one claim to:

- The specific active;
- The specific route of administration (*e.g.*, oral);
- The specific subject (*e.g.*, human, treated);
- The specific dosage to be administered; and
- The specific dosage form to be administered (*e.g.*, tablet, solution).

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Cases That You Need to Know In Rebutting a Lack of Enablement/Utility Argument

In re Brana, 51 F.3d 1560 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *Id*. at 1566 (citing *In re Bundy*, 642 F.2d 430, 433 (CCPA 1981)).

Eli Lilly & Co. v. Actavis Elizabeth LLC, 2011 WL 3235718 (Fed. Cir. July 29, 2011)(unpublished)(compare *In re '318 Patent Infringement Litigation*, 583 F.3d 1317 (Fed. Cir. 2009)).

Ortho-McNeil Pharmaceutical, Inv. v. Mylan Laboratories, Inc., 520 F.3d 1358 (Fed. Cir. 2008)(Further, even if clinical trials informed the anticonvulsively effective amount, this record does not show that extensive or "undue" tests would be required to practice the invention.) at 1365-1366.

Cases That You Need to Know In Rebutting a Lack of Enablement/Utility Argument cont'd

U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1252 (Fed. Cir. 1989)(Markey, Chief Judge)("The court's section 101 finding must be affirmed because we affirm, infra, the court's infringement finding. *See* Raytheon Co. v. Roper Corp., 724 F.2d 951, 959, 220 USPQ 592, 598 (Fed. Cir. 1983) ("correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under § 101"), cert. denied, 469 U.S. 835, 83 L. Ed. 2d 69, 105 S. Ct. 127 (1984).")

MPEP §2107.03 (8th ed. 2008) ("Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.")

This Has Been a LOEB & LOEB LLP Presentation

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