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New U.S. Supreme Court Decision Addresses Pharmaceutical "Use Codes"

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The U.S. Supreme Court recently issued a decision that provides generic pharmaceutical manufacturers with the ability to challenge the "use codes" listed by brand name manufacturers in filings made with the U.S. Food and Drug Administration ("FDA"). The decision in *Caraco v. Novo Nordisk* illustrates the impact that these "use codes" can have on the generic drug approval process, and will likely open up a new area of litigation between brand name and generic manufacturers in the U.S. Specifically, a dispute can arise where a brand name manufacturer has a "method of use" or similar patent protecting its drug, and a generic manufacturer – in an attempt to avoid those patents – seeks to bring its generic drug to market for limited uses allegedly not covered by those patents. In some cases, the breadth of the "use code" chosen by the brand name manufacturer could impact the timing of generic entry.

Briefly, under the U.S. drug approval process provided for in the Hatch-Waxman Act (the "Act"), a brand name manufacturer must submit, among other things: (a) a list of patents that cover its drug, and (b) for each such patent that covers a "method of use" for the drug, a description of the approved method of use or indication covered by such patent (called a "use code"). This may seem an obscure requirement, but the "use code" language can potentially have a significant impact on the timing of generic entry because it may affect which approval procedure is available to the generic manufacturer. Under the Act, when a generic manufacturer seeks FDA approval for a generic drug, it generally must state whether it seeks to enter the market prior to the expiration of the patents that the brand name manufacturer listed for the drug. If it does seek to enter prior to expiration of a patent, then it generally must submit a certification (called a "Paragraph IV" certification) that argues that the generic drug either does not infringe such patent, or that the patent is invalid. In response to this certification, the brand name manufacturer is entitled to commence patent litigation against the generic company and obtain an automatic 30-month stay on FDA approval of the generic product.

The Act provides a different procedure, however, which is often used where the generic manufacturer seeks to market its product after the expiration of the patent protecting the drug compound itself, but before the expiration of patents that may cover some (but not all) approved "methods of use" for the drug. If a brand name drug

is approved for two uses, for example, only one of which is covered by a patent, then a generic manufacturer can submit a "Section VIII statement" seeking FDA approval for only the non-patented uses (and to use a drug label that excludes language relating to the patented uses). This Section VIII statement procedure is only available, however, if the generic manufacturer can identify approved uses for the brand name product that are outside the scope of the use codes provided for the patents listed by the brand name manufacturer. In such a case, the Act does not require a Paragraph IV certification with respect to those patents, and there is no authorization under the Act for the brand name manufacturer to file suit on such patents and obtain a 30-month stay on generic entry.

In *Caraco*, Caraco (the generic company) alleged that Novo Nordisk used an excessively broad use code for its patent that defeated Caraco's attempt to avoid the patent with a Section VIII statement. Specifically, Novo's drug was approved for three uses relating to the treatment of diabetes, one of which involved the use of the drug by itself, and two of which involved the use of the drug in combination with one or more other drugs. Caraco argued that Novo's patent covered only combination therapies, and sought limited approval under Section VIII for monotherapy. Novo ultimately adopted a use code for its patent that described the "indication" treated by the drug ("[a] method for improving glycemic control in adults with type 2 diabetes mellitus"), and was not limited to the specific uses claimed by the patent (i.e., combination therapy). The FDA rules do permit an "indication" to be used as a use code description – and Novo also argued that its description was submitted in response to prior related guidance that it had received from FDA. But Caraco objected to the fact that this language encompassed all of the approved uses for Novo's drug, including the monotherapy for which Caraco sought approval. This prevented Caraco from making use of the Section VIII statement procedure, and required Caraco to seek approval for its generic drug with a Paragraph IV certification (and with a label that included all approved uses, including combination therapy) – which then provided Novo with the ability to bring patent litigation and obtain a 30-month stay on approval (which it did).

The Supreme Court's decision in *Caraco* analyzed the relevant statutes and concluded that generic companies should be permitted to assert counterclaims under the Act against brand name manufacturers that have sued them for patent infringement to seek a court order compelling the brand name manufacturer to adopt a different use code. This potentially expands significantly the issues that are in play in the patent litigation, and opens up the door to potential claims by the generic company in the litigation that the brand name manufacturer has acted anticompetitively in submitting an overly broad use code. On the other hand, the ability of a generic to challenge the use code in court potentially makes it harder for the generic company to argue that the brand name manufacturer's use code had an anticompetitive effect – i.e., because the generic company now has the opportunity to challenge the use code at the early stages of the patent litigation. It is also worth noting that narrow use codes that avoid the Paragraph IV process (which allows patent litigation to be brought prior to generic entry) also have the potential for unfair results for the brand name manufacturer– e.g., where a generic product is approved for a limited use, but in practice it is known that once the product is released, it will be used by customers for the unapproved, patented, use, without any compensation paid to the brand. Finally, another issue

mentioned by the Court is the possibility that a brand name manufacturer may use a broad use code and then initially decline to sue the generic manufacturer – which would result in no 30-month stay, and in FDA approval of the generic product with a label that includes the infringing as well as non-infringing uses. The use of this broad label would potentially leave the generic manufacturer highly vulnerable to a later lawsuit for contributory patent infringement.

After *Caraco*, there is sure to be further litigation between brand name and generic pharmaceutical companies in the U.S. relating to these "use codes" and the effects that they can have on the generic approval process and the brand name manufacturer's ability to enforce its patents.

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This entry was posted on Tuesday, June 12th, 2012 at 4:19 am and is filed under Intellectual property (IP), Pharmaceuticals, United States of America
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