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Federal Circuit Vacates Injunction Against Generic Drug Manufacturer, Determining That A Settlement Agreement Term Is Ambiguous

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On December 22, 2010, the Federal Circuit vacated an injunction preventing Sun Pharmaceutical Industries, Ltd. and Caraco Pharmaceutical Laboratories, Ltd. (collectively "Sun") from manufacturing and selling a generic oxaliplatin product. *Sanofi-Aventis v. Sandoz, Inc.*, No. 2010-1338 (Fed. Cir. Dec. 22, 2010). Read the decision here. The district court's injunction was based on the entry of a contested "consent judgment" resulting from a settlement agreement between Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Debiopharm S.A. (collectively "Sanofi") and Sun. In vacating the injunction, the Federal Circuit ruled that the term "decision(s) enjoining" in the settlement agreement was objectively ambiguous, and that the district court erred in entering a contested "consent judgment" without first determining the parties' obligations under the terms of the settlement agreement after a full and fair hearing.

Background

In 2007, Sanofi brought suit against multiple generic pharmaceutical companies, including Sun, based on their ANDAs for generic versions of oxaliplatin. *Sanofi-Aventis*, slip op. at 3. In June 2009, Sanofi settled with Sun with an agreed launch date for a licensed oxaliplatin product that could be accelerated by an at-risk launch by one of the other generics prior to a final court decision. *Id*. at 3-4. Significantly, that at-risk launch provision included language that "[s]hould Sun exercise such an option [to launch at-risk] and a Court subsequently enters a ***decision(s) enjoining*** each such At-Risk Launch product(s), Sun agrees [that it will cease sales until the Launch Date]." *Id*. at 4 (*emphasis added*).

Two days after "Sanofi and Sun reached a settlement agreement," the district court granted summary judgment of noninfringement. *Id*. at 5. Sanofi then refused to send an executed set of the settlement papers to Sun, and challenged the enforceability of the settlement agreement. *Id*. But, the district court found that the parties had reached a binding settlement agreement and it was enforceable. *Id*. at 5-6. In August 2009, other generic companies launched at-risk their own generic oxaliplatin products, and subsequently, Sun launched its own licensed generic oxaliplatin product pursuant to the settlement agreement. *Id*. at 6.

Sanofi was able to settle with the other generics that launched their oxaliplatin products at-risk, but each of those settlement agreements included a provision where each generic company agreed to a consent judgment that would enjoin them from further at-risk sales as long as Sun would be enjoined

from marketing its generic oxaliplatin product by June 30, 2010. *Id*. at 6. Sanofi then sent several letters to the district court requesting entry of a revised version of the Consent Judgment (with respect to Sun) that "***clarifie[d]***" Suns obligations under the settlement agreement. *Id*. at 7. The language requiring that each at-risk launcher be enjoined via a "***decision***" was absent from this clarified version of the parties' agreement. *Id*.

Sun objected to the entry of Sanofi's revised version of the ***consent*** judgment to which it did not, in fact, ***consent*** to. *Id*. at 7-8. Despite Sun's objection, the district court entered the revised consent judgment to which Sun appealed.

The Term "Decision(s) Enjoining" Was Found To Be Objectively Ambiguous

The Federal Circuit held that the district court erred in entering the contested consent judgment over Sun's objections. With respect to Sanofi's argument that the original consent judgment was unambiguous and included injunctions entered voluntarily by the other at-risk generics via consent judgments in the definition of "***decision(s)***," the Court observed that:

> Sanofi has repeatedly challenged its settlement agreement with Sun. Just days after reaching a binding settlement, Sanofi refused to return fully-executed settlement documents to Sun. After losing that battle, Sanofi challenged the enforceability of the settlement agreement. It lost that battle as well. Undeterred, however, Sanofi set out on a course to rewrite the proposed Consent Judgment and Order. Regarding its justification for altering the agreed-upon Consent Judgment, Sanofi represented to the district court that "most important, it ***clarifies*** Sun's obligations under the Settlement Agreement and License Agreement as incorporated into the Consent Judgment." Sanofi then received what it desired: A Consent Judgment entered by the district court—under protest by Sun—enjoining Sun from marketing generic oxaliplatin based on Sanofi's negotiated settlement agreements and injunctions entered into with other defendants. With its victory at hand, Sanofi now represents to this court that the license agreement is clear and unambiguous, despite its earlier need to "clarif[y] Sun's obligations." Sanofi's own recognition that the agreement required clarification is itself powerful evidence of ambiguity.

Id. at 12-13 (citations omitted) (emphasis in original).

As a result, the "consent" judgment entered by the district court was vacated with instructions that the court resolve the meaning of the objectively ambiguous term "decision(s) enjoining" in the settlement agreement through discovery and an evidentiary hearing. *Id*. at 14-15.

Conclusion

The *Sanofi-Aventis* decision is just one example where contested terms of a settlement agreement can be of great significance. In this matter, it meant the difference between preventing and allowing at-risk sales of one or more generic products. Perhaps the "objective ambiguity" found by the Federal Circuit could be avoided if such settlement provisions are drafted to require a "court order" enjoining an at-risk launch as opposed to a "decision."

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