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Defendant's Clinical Trial Found to Constitute Invalidating Public Use of Asserted Patents

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In a case of first impression, Southern District of New York Judge John G. Koeltl found that a defendant innovator drug company's clinical trial resulted in an invalidating public use of the plaintiffs' asserted formulation patents. Read the Court's decision here.

Plaintiffs Dey, L.P., Dey, Inc., and parent Mylan Inc. filed suit against Sunovion Pharmaceuticals Inc., alleging that Sunovion's Brovana® (a nebulized arformoterol solution indicated for treatment of COPD) infringed seven related Dey formulation patents in two patent families. Sunovion moved for summary judgment that all five of the second family patents were invalid because Sunovion had used formulations within the scope of the asserted claims in a clinical trial more than one year before the effective filing date of those patents.

The parties did not dispute that the clinical trial subjects received up to three weeks of the study medication at a time and used that medication in their homes over the course of the twelve week clinical trial, and that the study medication used by the trial subjects met all the limitations of the asserted claims. Nor was there any dispute that the study medication was "ready for patenting" at the time of the clinical trial. Therefore, the only issue in dispute was whether the use of the study medication in the clinical trial was "public" within the meaning of § 102(b).

Plaintiffs argued that use during Sunovion's clinical trial could not be public, relying on several cases refusing to find a patentee's own clinical trials to be public uses. Judge Koeltl carefully analyzed the cited cases and found that this case was different.

The decision noted that the clinical trial cases cited by plaintiffs were in the context of a patentee's ostensible public use. In those instances, experimental use by the patentee can negate the applicability of the public use bar. But in this case, the public use was not that of the patentee, Dey, but of a third party, Sunovion, so experimental use does not negate Sunovion's public use as to Dey's patents. (*Id*. at p. 21-23). The decision also recognized that the amount of control exercised by the patentee is important in determining whether the use is deemed public under § 102(b). In this case, none of the individuals involved in Sunovion's clinical trial was under the control of the patentee, Dey, or had any obligations to Dey. (*Id*. at p. 20, 23-24).

Because of the distinctions between the prior cases involving a patentee's own clinical trials, and this case, where Sunovion's clinical trial was relied upon against plaintiffs' asserted patents, the use during Sunovion's clinical trial was found to be public as to Dey's patents. Accordingly, the five second family patents were invalid under § 102(b).

In addition to finding the five second family patents invalid, Judge Koeltl also found that the two first family patents had been substantively amended during recent reexaminations, thus triggering absolute intervening rights under 35 U.S.C. 252 and wiping out all of plaintiffs' alleged damages through the issuance of the reexamination certificates in October 2011 -- a period of four and a half years.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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