At the nexus of commercial success and non-obviousness

Dr. Gregory K. Bell recently testified in three challenges to abbreviated new drug applications (ANDA) on behalf of pharmaceutical manufacturers seeking to protect patents covering their products. A key factor in each challenge was how to demonstrate commercial success of the product and the nexus between that success and the patents-in-suit with respect to the issue of non-obviousness of the patents-in-suit.

Kowa Co. Ltd. and Livalo
Kowa sought a permanent injunction restraining and enjoining Amneal Pharmaceuticals, LLC (Amneal) and Apotex Inc. (Apotex) from infringing on valid Livalo® patents through the commercial manufacture and sale of generic pitavastatin. Dr. Bell evaluated the level and growth of Livalo sales, market share, and the extent to which the product filled a need in local and global markets. Critically, he concluded that the patents-in-suit enabled Livalo to be differentiated from other cholesterol-lowering statins in its application to certain types of patients, such as those with type II diabetes or those who are on protease inhibitors or multiple medications. He concluded that Livalo was indeed a commercial success with respect to the issue of non-obviousness regarding the patents-in-suit.

The US District Court for the Southern District of New York found the patents-in-suit to be valid and infringed. The Court decision cited Dr. Bell’s testimony regarding advantages for certain patient subpopulations in concluding that Kowa had successfully presented objective secondary considerations of non-obviousness. The US Court of Appeals for the Federal Circuit affirmed the decision in January. Dr. Bell was supported by a team of CRA consultants including Cavay Ip and Natalie Nah.

Endo and Opana ER
CRA consultants supported Endo International plc (Endo) in its successful challenge of products that infringed on its patents covering Opana® Extended Release (ER). Dr. Gregory K. Bell assessed the commercial success of Opana ER. He testified with respect to the issue of non-obviousness regarding the patents-in-suit, as the patents-in-suit enabled a long-lasting controlled release formulation of the painkiller. The District Court relied on secondary considerations of non-obviousness, including Dr. Bell’s testimony demonstrating the commercial success of Opana ER and the nexus of the patent claims and market success. Dr. Bell was supported by a team including Dr. Andrew Tepperman and Dr. Justin Ho.
Shire, Sanofi-Aventis and Firazyr

CRA consultants advised counsel to Shire Orphan Therapies, LLC (Shire) and Sanofi-Aventis Deutschland GMBH (Sanofi-Aventis) in their challenge of an ANDA filed by Fresenius Kabi USA, LLC (Fresenius). Fresenius sought to manufacture and sell a generic version of Firazyr®, an anti-inflammatory drug to treat hereditary angioedema (HAE). Dr. Bell testified for the plaintiffs as to the commercial success of Firazyr. The US District Court for the District of Delaware decision noted Firazyr outperformed other HAE treatments as it is the only acute treatment that can be administered subcutaneously. The Court also found the defendants had failed to establish that Firazyr’s commercial success is due to factors other than those enabled by the patents-in-suit. Dr. Bell was supported by a team that included Dr. Andrew Tepperman and Archan Ruparel.

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