



# CRA Insights:

## Life Sciences

**CRA** Charles River  
Associates

May 2019

### At the nexus of commercial success and non-obviousness

*CRA expert testifies in three successful ANDA challenges*

**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,<sup>®</sup> 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](#).

## About CRA and the Life Sciences Practice

CRA is a leading global consulting firm that offers strategy, financial, and economic consulting services to industry, government, and financial clients. Maximizing product value and corporate performance, CRA consultants combine knowledge and experience with state-of-the-art analytical tools and methodologies tailored to client-specific needs. Founded in 1965, CRA has offices throughout the world.

The Life Sciences Practice works with leading biotech, medical device, and pharmaceutical companies; law firms; regulatory agencies; and national and international industry associations. We provide the analytical expertise and industry experience needed to address the industry's toughest issues. We have a reputation for rigorous and innovative analysis, careful attention to detail, and the ability to work effectively as part of a wider team of advisers. To learn more, visit [www.crai.com/lifesciences](http://www.crai.com/lifesciences).

## Contact

### Dr. Gregory K Bell

Group Vice President and Global Practice Leader

+1-617-425-3357

[gbell@crai.com](mailto:gbell@crai.com)



The conclusions set forth herein are based on independent research and publicly available material. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any of the organizations with which the authors are affiliated. Any opinion expressed herein shall not amount to any form of guarantee that the authors or Charles River Associates has determined or predicted future events or circumstances and no such reliance may be inferred or implied. The authors and Charles River Associates accept no duty of care or liability of any kind whatsoever to any party, and no responsibility for damages, if any, suffered by any party as a result of decisions made, or not made, or actions taken, or not taken, based on this paper. If you have questions or require further information regarding this issue of *CRA Insights: Life Sciences*, please contact the contributor or editor at Charles River Associates. Detailed information about Charles River Associates, a registered trade name of CRA International, Inc., is available at [www.crai.com](http://www.crai.com).

Copyright 2019 Charles River Associates