

Onyx Pharmaceuticals, Inc. v. Bayer Corp. et al.

Overview

Cooley delivered a significant win for longtime client Onyx Pharmaceuticals, Inc. in a dispute with its partner, the international pharmaceutical company, Bayer.

Results

Bayer will pay Onyx a royalty of 20% of future worldwide net sales of regorafenib in cancer. Onyx will have no obligation to pay past or future development and commercialization costs of regorafenib.

Onyx secured the right to co-promote regorafenib in the United States.

The "change of control" clause in the original collaboration agreement was removed. As a result, Onyx's rights to Nexavar (profit sharing, co-development and co-promotion) and regorafenib royalties (but not the right to promote regorafenib) would remain unchanged should Onyx be acquired.

Bayer paid Onyx a one-time lump sum of \$160 million and Bayer will have no obligation to pay royalties to Onyx for sales of Nexavar in Japan for any period after December 31, 2011. Bayer could also make future payments to Onyx of up to an aggregate of \$15 million in 2012-2013 based on future Nexavar pricing in Japan.

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In April 1994, Bayer and Onyx entered a collaboration agreement to discover cancerfighting drugs in the Ras Pathway, a cellular pathway responsible for many cancers. After years of joint research, the collaboration discovered sorafenib, a member of a new class of anti-cancer compounds. Sorafenib is marketed under the name Nexavar® and is FDA-approved for treatment of kidney cancer and liver cancer.

In 2009, Onyx learned that Bayer was developing and claiming as its own a drug, known as DAST (later regorafenib), which has the chemical structure of sorafenib except for a single atom change.

Onyx filed suit seeking rights to DAST as a Collaboration Compound in the spring of 2009. Later, Onyx amended its complaint to add a damages claim based on the allegation that Bayer had blocked clinical trials of sorafenib to minimize conflicts with DAST.

Cooley defeated Bayer's motion for summary judgment in May 2011 and defeated numerous subsequent Bayer motions, ensuring that all of Onyx's claims would go to the jury. Trial began in San Francisco federal court in October 2011. In parallel with the litigation, Cooley business attorneys began negotiating a settlement agreement. In a complex set of agreements announced mid-way through trial, Onyx obtained its principal litigation objective—a significant stake in DAST—together with additional benefits that could not have been achieved even with a favorable jury verdict.

Perspectives

"Without Cooley's keen insights and dogged determination in building and sustaining a fabulous case, we wouldn't be here. But, most importantly I appreciate what you've done for patients. They're the real winners here, because Onyx and its partner, Bayer, can be more focused on getting both these drugs to as many people as possible and, for that, I am grateful for your advice, counsel and help."

– N. Anthony Coles, MD, President, CEO and Member of the Board, Onyx Pharmaceuticals, Inc.

"I was impressed with Cooley's creativity and effectiveness in putting on a clear, compelling case on behalf of Onyx in the courtroom. Through a combination of tutorials, historical evidence, and testimony (including mine), the Cooley team taught lay jurors the science behind cancer, the hunt for cancer treatments and Bayer's breach of the Collaboration Agreement. I thank Cooley for their tireless efforts in achieving a fantastic result for Onyx, and more importantly, for the patients who ultimately benefit from the repair of this collaboration."

– **Frank McCormick, PhD, FRS, DSc**, Co-founder of Onyx Pharmaceuticals, Director of the UCSF Helen Diller Family Comprehensive Cancer Center, and Associate Dean of the UCSF School of Medicine. McCormick was the first witness at trial. His groundbreaking research in the Ras Pathway was at the heart of the Onyx-Bayer Collaboration.

"I want to commend counsel for an excellent job in presenting this case; not an easy case to present, in terms of all of the technology and the terminology...it was an enjoyable experience."

– **The Honorable Edward M. Chen**, United States District Court, Northern District of California

"I wish that it would have gone to deliberation. I was leaning towards the side of Onyx. All of the information and diagrams that [the Cooley team] showed were so helpful, especially for me not knowing a lot of the medical and scientific terms. They were excellent and had an ease and confidence about them. I really liked the whole team."

– **Juror No. 1**

"Bayer had a very high hurdle to get over after Cooley's presentation of the case."

– **Juror No. 2**

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