



CRA Insights

Intellectual Property

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CRA Insights: Intellectual Property is a periodic newsletter that provides summaries of notable developments in IP litigation

The Washington University in St. Louis v. Wisconsin Alumni Research Foundation C.A. No. 13-2091 (JFB)

Overview

On November 26, 2018, visiting Judge Bataillon in the District of Delaware issued a judgment in favor of The Washington University (WashU) and against Wisconsin Alumni Research Foundation (WARF) for breach of contract. WashU was awarded damages of \$31.6 million for underpayment of royalty income under the parties' inter-institutional license agreement (IIA). The litigation, described below in greater detail, arose from a dispute between WashU and WARF about the relative value of different patents and allocation of royalties to those patents under the terms of the IIA.

Background

In the late 1980s, University of Wisconsin (UW) researchers invented the 19-Nor Vitamin D analog known as paricalcitol. WARF, the independent nonprofit technology transfer organization serving the UW-Madison, worked with the UW researchers to obtain a portfolio of patents including US Patent No. 5,587,497 claiming the new chemical entity paricalcitol (the '497 patent) and US Patent No. 5,246,925 claiming a method of using paricalcitol to treat secondary hyperparathyroidism (the '925 patent).

In January 1993, WARF and Abbott¹ entered into a license agreement (the 1993 Abbott License) in which Abbott obtained exclusive rights to the '497 and the '925 patents and nonexclusive rights to a number of additional paricalcitol-related patents that were referred to in the WARF-Abbott license as the "Ancillary Patents." Under the 1993 Abbott License, Abbott agreed to pay a royalty of 7% of net sales based on the exclusively licensed '497 and '925 patents and a 5% royalty on the ancillary patents, with Abbott's royalty obligation capped at 7%. AbbVie's paricalcitol product, Zemplar®, was approved by the US Food and Drug Administration on April 17, 1998. To date, AbbVie has paid WARF royalties totaling \$428 million under this license agreement.

¹ Abbott's branded pharmaceutical business was spun-off in 2013 and formed AbbVie.

In the early 1990s, collaborating researchers at UW and WashU discovered a new method of using paricalcitol to treat renal osteodystrophy and filed an application that issued as US Patent No. 5,597,815 (the '815 patent). On November 1, 1995, WARF and WashU entered into the IIA, which gave WARF the exclusive right to manage patent prosecution and licensing activities related to the collaboration. WashU also agreed to pay WARF a 15% administration fee and to accept a 33.3% share of the revenues derived from licensing the '815 patent, after deducting certain expenses. The net effect of these provisions was that WashU would receive no more than 28.33% of the revenues attributable to licensing the '815 patent.

The IIA also included a clause stating that WARF might license the co-owned intellectual property subject to the IIA along with intellectual property owned solely by WARF. This clause further stated that "WARF shall have the authority to assign relative values to Patent Rights and/or Property Rights, and other patent and/or other proprietary rights as are included in any such license and the portion of the gross receipts from royalties and other fees received by WARF... shall be determined in accordance with such relative values assigned to Patent Rights and/or Property Rights in proportion to the total value represented by all patent rights and/or proprietary rights which are included within such license."

On July 28, 1998, WARF and Abbott entered into an amendment to the 1993 Abbott License adding the '815 patent to the existing list of ancillary patents. The royalty obligations remained the same as the 1993 Abbott License.

In 1998, WashU requested a copy of WARF's agreement with Abbott. WARF responded that it could not do so because of confidentiality obligations, but it would provide "full details regarding the calculation used to determine [WashU's] distribution." In 2001, WARF sent a letter to WashU explaining its royalty allocation which stated that it allocated 70% of the total royalties received under the 1993 Abbott license to the '497 and '925 patents and the remaining 30% to the 31 ancillary patents, including the '815 patent, or 0.968% to each Ancillary Patent. The letter further stated that it was WARF's policy to allocate evenly among the ancillary patents "regardless of whether or not the patent is actually currently being used by the Licensee... because, in many cases, it is difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time."

In 2011, Abbott listed the '815 Patent in the Orange Book for Zemplar. The following year, WARF asserted the '815 patent against eight generic drug companies. WashU subsequently requested that WARF provide it with related information, including the valuations assigned to the Zemplar Orange Book-listed patents that were licensed to Abbott and whether any calculations for the Abbott licensed patents had changed since WARF's 2001 letter to WashU. On February 7, 2013, WARF responded "[i]t is the compound patent that is the gatekeeper patent; without a license to it, the other patents directed to methods of using paricalcitol are meaningless and largely irrelevant." WARF further explained that no further valuations had been done and that nothing had changed since WARF's 2001 letter to WashU.

Litigation

WashU sued WARF on December 26, 2013, alleging breach of contract, breach of implied covenant of good faith and fair dealing, and breach of fiduciary duty with respect to the IIA. WashU claimed that WARF's breach resulted from WARF's failure to assign a proper value to the '815 patent which resulted in underpayments to WashU.

The case proceeded to a bench trial on March 26, 2018. WashU presented alternative relative value allocations that attributed a relative value of 27.1% to 33% to the '815 patent, versus the 0.968% WARF had assigned it. WARF presented an analysis of the incremental value of the '815 patent through its inclusion in

WARF's paricalcitol patent portfolio license and argued that WashU received more in royalties than the incremental value attributable to the '815 patent.

Although Judge Bataillon's opinion is currently under seal, a judgment was entered in favor of WashU on November 26, 2018 with damages assessed in the amount of \$31,617,498, the same amount which WashU attributed to the '815 Patent under a relative value allocation of 27.1%.

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