

On October 27, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent Nos. 9,168,304 and 9,168,305. On February 5, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Teligent for patent infringement of U.S. Patent No. 9,220,784. All three patents, U.S. Patent Nos. 9,168,304, 9,168,305, and 9,220,784 are listed in the Orange Book and have claims that cover PENNSAID 2%.

The Company entered into a settlement and license agreement with Teligent (the “Teligent settlement agreement”), effective May 9, 2016, relating to the patent infringement litigation against Teligent. In accordance with legal requirements, the Company and Teligent submitted the Teligent settlement agreement to the FTC and DOJ for review, and no issues have been raised by the FTC and DOJ. The Company and Teligent have also filed stipulations of dismissal with the district court regarding the litigation, with these dismissals having been entered by the district court on May 2, 2016. The Teligent settlement agreement provides for a full settlement and release by both the Company and Teligent of all claims that were or could have been asserted in the litigation and that arise out of the issues that were subject of the litigation or Teligent’s generic version of PENNSAID 2%.

Under the Teligent settlement agreement, the Company granted Teligent a non-exclusive license to manufacture and commercialize Teligent’s generic version of PENNSAID 2% in the United States after the license effective date (as defined below) and to take steps necessary to develop inventory of, and prepare to commercialize, Teligent’s generic version of PENNSAID 2% during certain limited periods prior to the license effective date.

Under the Teligent settlement agreement, the license effective date is January 10, 2029; however, Teligent may be able to enter the market earlier under certain circumstances. Such events relate to the resolution of any other third-party PENNSAID 2% patent litigation, the entry of other third-party generic versions of PENNSAID 2% or certain substantial reductions in the Company’s PENNSAID 2% shipments over specified periods of time.

Under the Teligent settlement agreement, the Company also agreed not to sue or assert any claim against Teligent for infringement of any patent or patent application owned or controlled by the Company during the term of the license granted in the Teligent settlement agreement based on the manufacture, use, sale, offer for sale, or importation of Teligent’s generic version of PENNSAID 2% in the United States.

In certain circumstances following the entry of other third-party generic versions of PENNSAID 2%, the Company may be required to supply Teligent PENNSAID 2% as an authorized distributor of generic PENNSAID 2%, with the Company receiving specified percentages of any net sales by Teligent. The Company also agreed that if it enters into any similar agreements with other parties with respect to generic versions of PENNSAID 2%, the Company will amend the Teligent settlement agreement to provide Teligent with terms that are no less favorable than those provided to the other parties.

The Company received from Amneal Pharmaceuticals LLC (“Amneal”) a Paragraph IV Patent Certification dated April 2, 2015 against Orange Book listed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, 8,741,956, and 8,871,809 advising that Amneal had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On May 15, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal seeking an injunction to prevent the approval of the ANDA. The lawsuit alleged that Amneal has infringed U.S. Patent Nos. 8,217,078, 8,252,838, 8,546,450, 8,563,613, 8,618,164, and 8,871,809 by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of certain of the Company’s patents listed in the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Amneal’s ANDA for 30 months or until an earlier district court decision that the subject patents are not infringed or are invalid.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,066,913. On August 11, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,101,591. On September 17, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Amneal for patent infringement of U.S. Patent No. 9,132,110. All three patents, U.S. Patent Nos. 9,066,913, 9,101,591, and 9,132,110 are listed in the Orange Book and have claims that cover PENNSAID 2%.