



Press release

Orexo appeal Zubsolv® US district court decision

Uppsala, Sweden, December 8, 2016 - Orexo AB (publ.) announces that it has appealed the decision rendered by the United States District Court for the District of Delaware on November 15, 2016 regarding the validity of Orexo's US Patent No. 8,940,330 protecting Zubsolv.

The decision was rendered in the patent litigation regarding Actavis's generic Zubsolv 1.4/0.36 mg and 5.7/1.4 mg buprenorphine/naloxone products, and Orexo's US Patent Nos. 8,454,996 (expiring in September 2019) and 8,940,330 (expiring in September 2032). In the decision, the district court held that Orexo's '996 patent is valid and infringed by Actavis, and that Orexo's '330 patent is invalid.

Orexo believes that the District Court committed reversible legal and factual errors in reaching its decision on the validity of the '330 patent. Orexo has therefore appealed the District Court's decision relating to the validity of the '330 patent to the Court of Appeals for the Federal Circuit. Generally, the Federal Circuit takes about one year from the district court decision to render a ruling on the appeal.

Besides the possibility to reverse the district court's decision relating to the validity of the '330 patent on appeal, Orexo has two other patents protecting Zubsolv in the US until September 2032, namely US Patent Nos. 9,259,421 and 9,439,900. These two patents are not addressed in the decision by the District Court. The '421 and '900 patents are currently the subject of separate litigations against Actavis in the District Court of Delaware.

"We appreciate the district court's decision that the '996 patent is valid and that Actavis is infringing our intellectual property rights. However, the decision relating to the validity of the '330 patent came as a surprise. We have now closely reviewed and analyzed the decision and identified several reasons for why the decision should be reversed by the Federal Circuit. We remain confident in our IP protecting Zubsolv, not only in the US, but on a global basis. Besides the appeal process, we will continue to defend Zubsolv through the '421 and '900 patents and remain optimistic for IP protection of Zubsolv until 2032." says Nikolaj Sørensen, CEO and President of Orexo AB.

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About Orexo

Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. Zubsolv is an advanced formulation of buprenorphine and naloxone using Orexo's unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo's share is listed on Nasdaq Stockholm Exchange Mid Cap (STO:ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo's global headquarters and R&D are based in Uppsala, Sweden.

For more information about Orexo, please visit www.orexo.com or follow us on [Twitter](#) or [LinkedIn](#). For further information about Zubsolv in the US, please visit www.zubsolv.com.

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 AM CET on December 8, 2016