

Corporate Release

U.S. court issues decision in Trintellix patent litigation upholding active ingredient patent

Valby, Denmark, 1 October 2021 - H. Lundbeck A/S (Lundbeck) announces that the U.S. District Court for the District of Delaware (the 'Court') has issued its decision upholding the validity of Lundbeck's patent covering the active ingredient in Trintellix, vortioxetine (U.S. Patent No. 7,144,884) in patent litigation proceedings against six generic manufacturers challenging Lundbeck's patent rights to Trintellix (vortioxetine) in the U.S.

Lundbeck and its partner, Takeda Pharmaceutical Company Limited (Takeda), filed the infringement actions against the six generic manufacturers Alembic, Lupin, Macleods, Sandoz, Sigmapharm, and Zydus (each referred to as an 'ANDA Filer' and collectively as the 'ANDA Filers') in response to their filing of Abbreviated New Drug Applications (the 'Filed ANDAs') with the FDA seeking to obtain marketing approval for generic versions of vortioxetine in the U.S.

Lundbeck and Takeda asserted a total of eight Lundbeck patents, namely U.S. Patent No. 7,144,884 (the '884 Patent) covering the active ingredient in Trintellix, vortioxetine, and seven other U.S. patents, which cover, *inter alia*, specific forms of vortioxetine, methods of using vortioxetine, and manufacturing processes for vortioxetine (collectively, the 'Other U.S. Patents').

The Court's ruling on the '884 Patent

The Court found that the '884 Patent is valid. The '884 Patent expires on 17 June 2026, with an expected six-month pediatric exclusivity period extending to 17 December 2026. Assuming the ruling is affirmed on potential appeal, final approval will not be granted to the relevant ANDAs until after expiration of the '884 Patent, including any extensions or additional periods of exclusivity.

The Court's ruling on the Other U.S. Patents

The Court's ruling on the validity and infringement of the Other U.S. Patents (and the '884 Patent) is summarized below. The Court's decision, which is subject to appeal, prohibits final regulatory approval of any of the six Filed ANDAs found to infringe a valid Other U.S. Patent(s) until after expiry of that patent. Unless and until the Court's ruling is reversed on appeal, the patents found not infringed by a particular ANDA Filer will not prevent that ANDA Filer from receiving final approval.

U.S. Patent No.	Expiry date*	Court decision on validity of the patent	Court decision on infringement
8,476,279	2 October 2022	Valid	Patent only challenged by Sigmapharm and Zydus. Infringement not disputed.
9,090,575	2 October 2022	Valid	Patent only asserted against Zydus. Infringement not disputed
7,144,884	17 June 2026	Valid	Patent only challenged by Sigmapharm and Zydus. Infringement not disputed
9,101,626	15 June 2027	Validity not disputed	Patent only asserted against Lupin. Infringed
9,861,630	15 June 2027	Validity not disputed	Not infringed by Alembic, Lupin, Macleods, Sigmapharm, or Zydus
9,125,910	15 June 2027	Valid	Not infringed by Alembic, Lupin, Macleods, Sigmapharm, and Zydus
8,722,684	30 June 2031	Validity not disputed	Not infringed by Alembic, Lupin, Macleods, Sigmapharm, or Zydus
9,278,096	21 March 2032	Valid	Not infringed by the six ANDA Filers (Alembic, Lupin, Macleods, Sandoz**, Sigmapharm, and Zydus)

(*) an additional six months of pediatric exclusivity is also expected for the '279, '884, '630, '684, '910, and '096 Patents, which are listed in the FDA Orange Book.

(**) Sandoz only challenged the '096 Patent at trial.

Appeal

The Court's decision may be appealed to U.S. Court of Appeals for the Federal Circuit. Unless and until changed on appeal, the Court's decision stands.

About Brintellix/Trintellix

Vortioxetine was discovered by Lundbeck researchers in Copenhagen, Denmark. Depending on the market, vortioxetine is known as Trintellix® or Brintellix®. In the United States, vortioxetine is sold under the tradename Trintellix®.

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About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

Millions of people worldwide live with brain diseases, and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement, and other unnecessary consequences.

Our approximately 5,600 employees in more than 50 countries are engaged in the entire value chain throughout research, development, production, marketing, and sales. Our pipeline consists of several R&D programs, and our products are available in more than 100 countries. We have research centers in Denmark and the US, and our production facilities are located in Denmark, France, and Italy. Lundbeck generated revenue of DKK 17.7 billion in 2020 (EUR 2.4 billion; USD 2.7 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com, and connect with us on Twitter at @Lundbeck and via LinkedIn.

Safe Harbor/Forward-Looking Statements

This corporate release contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance. Forward looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain words like "believe", "anticipate", "expect", "estimate", "intend", "plan", "project", "will be", "will continue", "will result", "could", "may", "might", or any variations of such words or other words with similar meanings. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.

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