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Dr. Reddy's Labs announces favorable outcome in patent litigation

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This decision vacates the District Court's preliminary injunction that had prohibited Dr. Reddy's from selling its generic version of Suboxone (buprenorphine and naloxone) sublingual film.

Dr. Reddy's Laboratories Ltd. along with its subsidiaries together referred to as Dr. Reddy's has announced that the United States Court of Appeals for the Federal Circuit issued a decision in favor of Dr. Reddy's Laboratories Inc. concluding that Indivior had not shown that it is likely to succeed on the merits of its infringement case on U.S. Patent No. 9,931,305. This decision vacates the District Court's preliminary injunction that had prohibited Dr. Reddy's from selling its generic version of Suboxone (buprenorphine and naloxone) sublingual film. As a result of this ruling, Dr. Reddy's will resume its launch activities as soon as permitted.

A company spokesperson stated, "We are pleased with the decision of the appellate court in Dr. Reddy's favor, vacating the preliminary injunction that had prevented Dr. Reddy's from bringing this important drug to the public. We are committed to providing affordable and innovative medicines that address the unmet and under-met needs of patients around the world and in particular look forward to taking the lead in helping to fight Opioid Use Disorder."

In June, the U.S. Food and Drug Administration (USFDA) approved Dr. Reddy's Buprenorphine and Naloxone Sublingual Film, in four strengths including 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, for sale in the U.S. market. The product was launched immediately after approval, with sales and commercialization activities halted as a result of a court-imposed temporary restraining order (TRO) against Dr. Reddy's. The TRO did not include a prohibition on commercial manufacturing of the product.