

9TH NALSAR JUSTICE B.R. SAWHNY MEMORIAL MOOT COURT COMPETITION, 2015

NALSAR UNIVERSITY OF LAW, HYDERABAD

- OCTOBER 1-4, 2015 -

MOOT PROBLEM



ZAYER INDIA

V.

KIPLA AND ANR.

The Lebola epidemic has claimed about 12,000 victims world over, since its outbreak in December 2013. Although there are about 30,000 patients suffering from this viral haemorrhagic fever, victims of this deadly virus are largely in West Africa and the countries in the south-Asian peninsula. In India alone, there are about 2500Lebola patients.

In March 2014, Zayer Inc., a multi-national company, patented its recently developed drug formulation and the only known cure for the haemorrhagic fever caused by the Lebola virus, in the United States of America. The drug, sold by the commercial name Lebin X, was classified as an Orphan Drug in the USA, owing to which 50% of the R&D costs of Zayer were reimbursed by the Government.

Zayer went on to obtain a patent on its drug in over 45 countries. In October 2014, Zayer was granted a patent in India too, pursuant to its application in April that year. This patent was worked by Zayer India Ltd., a wholly owned subsidiary of Zayer Inc, and Lebin X was sold at Rs. 36,000 for 60 tablets per month.

Kipla Pvt. Ltd, one of the largest pharmaceutical companies in India, had also undertaken R&D to produce a drug molecule, after the Lebola outbreak in 2013. In November 2014, Kipla sought to enter into a license agreement with Zayer India to manufacture and sell its drug formulation, stating the growing public need and the unaffordability of Lebin X in India. It sought to sell the drug at a price of Rs. 600 per month, for the same dosage of 60 tablets. Negotiations however never took off, and ultimately, the license was refused by Zayer India.

In February 2015, Kipla introduced Lebocin, its generic variant for treatment of Lebola, at a price of Rs. 600 per month, in the Indian market. It also sought to patent its formulation on the footing that it possessed therapeutic efficacy over existing drugs in the market. Zayer India however was swift to move the High Court of Delhi, in an original suit against Kipla, seeking protection against infringement of its patent in the drug formulation of LebinX, and an interim injunction against manufacture and sale of Lebocin by Kipla.

Aggrieved by such action, Kipla moved the Competition Commission of India ("CCI"), arguing that Zayer India's refusal to license the drug to it, and the subsequent effort to injunct Kipla from manufacturing and selling the drug, amounted to a gross abuse of its dominant position, especially in light of the growing number of deaths caused by the Lebola virus. However, the CCI found that there was no prima facie case made out against Zayer India. In appeal proceedings before the Competition Appellate Tribunal ("COMPAT"), Kipla argued that the CCI ought to have, as a regulatory body, recognised the disparate public health impact caused to Indian patients, by Zayer India's abuse of

¹ This moot problem has been drafted by Malavika Prasad (Nalsar alumnus). Any attempt to contact her on matters relating to this problem or the 9th Nalsar Justice BR Sawhny Memorial Moot Court Competition, 2015 shall result in immediate disqualification.

dominant position. The COMPAT set aside the order of the CCI, finding that there were heavy social costs to permitting Zayer India to violate its obligations towards public health, keeping in mind the fundamental right to health recognised under Article 21 of the Constitution of India. It noted particularly that the public would be solely and absolutely dependent on Zayer India for access to life-saving drugs, should Kipla be injuncted, even as a willing licensee. Such conduct by Zayer India was found to squarely fall within the prohibition of Section 4 of the Competition Act.

Mr. Thomas Ali, a member of the Board of Directors of Zayer India and shareholder, moved the High Court of Delhi under Article 226 of the Constitution of India, against the order of the COMPAT, raising several grounds of challenge. Chief among them was that the order of the COMPAT was a nullity for lack of jurisdiction to enforce fundamental rights. Other substantive grounds of challenge were also raised, including, inter alia, the violation of the fundamental right under Article 19(1)(g). The High Court however dismissed the petition, finding that the cost to public health was irreparable as against the monetary losses incurred by Zayer.

Zayer India then sought special leave to appeal against this judgment of the High Court, before the Supreme Court of India. When the SLP came up for admission, the Court issued notice to Kipla, and also directed that notice of the proceedings be given to the Attorney General for India, to represent the views of the Union Government.

The special leave petition has been listed for final disposal on 4th October, 2015.

[Parties are expected to raise issues outside of those delineated in the proposition, but are required to ensure that they are integrally constitutional law issues.]