

PGDM, Batch 2015 -17
Business Laws
Subject Code DM 302
Batch 2015 -17
Trimester III; End Term Examination: *March - 2016*

Time allowed: 2.5 Hours

Maximum marks: 50

Roll No. _____

Instruction: Students are required to write their Roll No. on every page of the question paper; writing anything except the Roll No. will be treated as **Unfair Means**. In case of rough work please use answer sheet

Section A: Attempt any three out of the following five questions (5 marks each)

- 1) What does the Prevention of Money Laundering Act state? Give examples.
- 2) What do you understand by horizontal agreement under the Competition Act? What does granting of Compulsory License mean?
- 3) What does the FEMA state with reference to authorized dealers and current account transactions?
- 4) What is the relevance of Industrial Disputes Act in terms of ease of doing business?
- 5) How do you look at the process of environmental clearances?

Section B: Attempt any two out of the following three questions: (10 marks each)

1. How do you justify that the proposed GST Act would be a "win-win situation to all stake-holders in an economy such as government, consumers and business"?
2. How does the Company Act, 2013 address the issues revolving around increasing number of corporate frauds?
3. Analyze whether the Rehabilitation and Resettlement Act, 2013 is a business friendly law. What were the measures initiated since mid- 2014 by the incumbent government to resolve these issues?

Section : C [Case Study]

(15 marks)

Give your answers for the following case.

A division bench of the Delhi High Court sided with Roche against Indian firm Cipla, upholding the Swiss drug maker's patent claims on key lung cancer drug erlotinib hydrochloride, branded Tarceva. The ruling is the second in a month to have upheld patent rights of an overseas drug company and sets a key precedent with regard to intellectual property, experts said.

The court, however, rejected Roche's plea for an injunction on Cipla's product, considering the patent expires in March 2016. Roche, which was granted a patent for Tarceva in 2007, sued Cipla in 2008 after the Indian company launched cheaper version Erllocip. Cipla said it hadn't infringed the innovator's patent as it sold a polymorphic form of the drug.

Legal experts noted that Cipla may appeal against the decision of the division bench to the Supreme Court but this could not be confirmed from the company. In its latest order, the court directed Cipla to pay Rs 5 lakh while adding that it will be liable to render accounts concerning the manufacture and sale of Erllocip "to record evidence pertaining to the profits made by Cipla concerning the offending product."

In a statement to ET, Roche said it welcomed the decision of the court, which has upheld the patent covering erlotinib hydrochloride (Tarceva) and found Cipla to have infringed it.

The latest decision sets aside a 2009 verdict by a single judge in the same court that had rejected Roche's arguments and allowed the Indian drug firm to continue selling its product.

Roche and Cipla then cross appealed against that decision and last year, on directions from court, the two had agreed to discuss a settlement via a mediation exercise. However, an amicable settlement remained elusive and the case moved back to court. In a 106-page order, Justices Pradeep Nandarajog and Mukta Gupta outlined contentions of the two sides. The court was clear about nature of infringement.

"This (the patent claim) is a sufficiently broad claim that is clearly not limited to any polymorphic version of erlotinib hydrochloride, but to erlotinib hydrochloride itself," it said. "This compound may exist in several polymorphic forms, but any and all such forms will be subsumed within this patent. Therefore as Cipla's Erllocip is admittedly one particular polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will clearly infringe IN'774 patent."

Roche had said its patent covered all polymorphs and derivatives of erlotinib while Cipla contended its product (polymorph B) didn't infringe Roche's intellectual property. Cipla had also demanded Roche's patent be revoked under Section 3(d) of the Indian Patent Act that essentially bars incremental innovations unless significant efficacy is proven.

Bringing clarity to Section 3(d), the judges wrote: "We understand Section 3(d) as a positive provision that in fact recognizes incremental innovation while cautioning that the incremental steps may sometimes be so little that the resultant product is no different from the original. The inherent assumption in this is that infringement of the resultant product would therefore be an infringement of the original i.e. the known substance and by no stretch of imagination can Section 3(d) be interpreted as constituting a defence to infringement." Last month, Merck had won a crucial case related to anti-diabetes drug sitagliptin against Indian drug maker Glenmark.

- 1) With regards to the above case discuss the provision in the Patent Act due to which Roche won the case against Cipla in the Delhi High Court. What are the three categories of Patent that you can apply for?
- 2) What does the Trademarks Act, Copyright Act and Geographical Indicators pertain to?