

NATIONAL LAW UNIVERSITY, DELHI

LL.M. (Professional), Semester-II (Batch of 2020)

End Semester Examinations, July-2021

Paper: Patents, Plant Variety Protection and Trade Secrets

Total Marks: 100

Instructions:

1. All three questions are compulsory.
 2. No clarification shall be sought on the question paper.
 3. Please do not repeat the facts unless they are extremely relevant in answering the questions.
 4. Answer every main question in less than 3000 words (max.) in total.
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X is a company that has invented and manufactured a vital complex molecule required for producing an important lifesaving drug called Genvir that produces antibodies for seasonal influenza virus. It was granted a patent in February 2020 in India, just before the first wave of the pandemic. Genvir has been licenced to seven different manufacturers in India at zero royalties, which have the full capacity to produce upto 1.10 crore doses per month. However, it requires 4-5 weeks' time to produce on a full scale (i.e. from zero to full scale) and requires deep secret technical know-how to produce the drug on a mass scale. The seven licencees have priced Genvir anywhere between Rs. 800/- to Rs. 3500/- per dose considering the seasonal demand for flu treatment.

Incidentally, during the first wave of the Covid-19 pandemic in March-April 2020, it was found that the administration of Genvir in some patients saved some lives. But the correlation between Genvir and Covid-19 patent is not fully known through clinical trials or scientific data. During the second wave of the pandemic in April-June 2021, there was a sudden demand for Genvir since doctors started administering Genvir to Covid-19 patients in sheer desperation to save their lives. Thus the demand grew from 5000 doses a month to 1.50 crore doses a month.

Another big generic company Y, which is not among the licencees of X, has received a marketing approval to produce Genvir by the Drugs Controller. However, to understand the know-how in manufacturing Genvir on a large scale, it hired two top scientist working with X by paying them five times their current salary in order to help scale-up production through disclosure of deep secret know-how that they had acquired during their employment with X. Y has a singular capacity to produce upto 1.0 crore doses a month. But it is not willing to enter into the market fearing patent infringement law suit by X. However, producing the Genvir drug at full scale by Y would also mean that there could be over production by at least more than twice based on the current demand, without which Y is not interested in production since it needs economies of scale to price the drug at competitive price of Rs. 500/- per dose. Thus Y is thus interested in selling the drug to neighboring countries too, where Covid-19 second wave is spreading rapidly and there is continuing demand for Genvir.

While the Government of India is relieved that a big generic manufacturer is willing to enter, it is anticipating a much brutal third wave in the month of September 2021 and is interested in

diversifying manufacturing through the entry of more number of generic players, importing Genvir from different countries and stockpiling of the drug. However, it is concerned that other generic companies (other than Y) may not be able to produce Genvir due to lack of know-how even if a compulsory licence was granted on grounds of national emergency or situations of extreme urgency. In this regard, the GoI wants to explore what provisions can be used to force X to reveal its trade secrets within the current framework of compulsory licenses under the Patent Act, 1970 since it is of the opinion that the patent specification on Genvir ought to have made full disclosure of the know-how in the patent application involving manufacturing of the same and thus the quid-pro-quo of the patent grant was not complied by X. It also wants to explore revoking the patent for lack of adequate disclosure if X fails to openly disclose its know-how to any successful compulsory licence applicant. While X is willing to scale up production by giving more voluntary licences, it wants to oppose any requirement to disclose its trade secrets.

Q. I. What are the options for Y? (35 Marks)

- a) For challenging the invalidity on the ground that there is a new use of the patent on Genvir in relation to Covid-19.
- b) For launching Genvir directly in the market and to contest a potential suit against the grant of an injunction.
- c) To successfully apply for a compulsory license for the Genvir patent under any provision on the chapter concerning compulsory licences in the Patents Act, 1970.
- d) To be able to sell a predominant portion of Genvir in neighboring countries under the compulsory licence, if granted.
- e) The legal defence for trade secret violation by the act of hiring the two scientists and subsequent disclosure of manufacturing know-how belonging to X.

Q. II. What are the options for X? (35 Marks)

- f) For defending the invalidity challenge by Y on the ground that there is a new use of the patent on Genvir in relation to Covid-19.
- g) For preventing the launch of a generic copy of Genvir by Y without seeking a license through an injunction.
- h) To defend the application for compulsory license for the Genvir patent under any provision on the chapter concerning compulsory licences.
- i) To be able to stop the export of Genvir in neighboring countries under the compulsory licence, if granted.
- j) The legal challenge in placing liability on Y for trade secret violation by the act of hiring the two scientists and subsequent disclosure of manufacturing know-how.
- k) Legal defence against potential forcible disclosure of trade secrets along with the compulsory licence or as a ground for revocation.

Q. III. What are the options for the Indian Government? (30 Marks)

- l) To invoke provisions under the Patents Act, 1970 to import and stockpile the drug in India.
- m) To declare national emergency and explore how trade secrets belonging to X can be forced as a condition for grant of compulsory licences.
- n) To revoke the patent for non-disclosure of technical know-how required in manufacturing Genvir.