NATIONAL LAW UNIVERSITY, DELHI

LL.M., Semester-II (Batch of 2021)

End Semester Examinations, April-2022

Paper: International Intellectual Property, Health Innovation and Access in India

Time: 3 Hours **Total Marks: 50**

Instructions:
1. All questions are compulsory.
2. No clarification shall be sought on the question paper.

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1) There are several related upstream patents on mRNA technologies in India which is blocking the development of mRNA technologies during COVID-19. This is due to foreign patent holders, who are current not working their patents in India, having refused to licence such patents to Indian vaccine developers engaged in the development of mRNA vaccines. The Government of India wants to acquire such patents under section 102 of the Patents Act, 1970. Examine the TRIPs consistency Section 102 and its potential use by the Government of India. **(Marks: 10)**

2) Taking inspiration from the success of the Australia- plain packaging dispute at the WTO, the Government of India is considering amending its Trademark law that will completely prohibit the use of brand names as trademarks in the context of medicines. While companies will be allowed to use the Company name (e.g. CIPLA, Dr. Reddy's, Roche etc.), as manufacturers of the medicines, the use of brand names (e.g. Crocin/Dolo for paracetamol) will be replaced by a requirement to use only therapeutic indications (e.g. Paracetamol). Some other drug regulatory laws will also be amended to require the doctors to only prescribe drugs using therapeutic indications. It is believed that such a prohibition on branding will allow pharmacists to engage in generic substitution in case of prescription drugs. Prepare an advisory for the Government of India on the current proposal and its consistency with the Australia- plain packaging dispute so that India's chances of winning at the dispute, if challenged, are higher. Suggest amendments to the current proposal if necessary. **(Marks: 10)**

3) The Government of India is considering the formation of a Comprehensive mRNA Patents Pool (CMPP) of all patents which are essential for the production of mRNA vaccines in India. It is expected that CMPP would allow all mRNA vaccine developers in India to have a single licence and pay a single joint royalty to all patent holders. The CMPP norms states that such royalties would be distributed among the patent holders based on the number of patents declared. The Government of India is of the opinion that the CMPP would reduce the threat of litigation and royalty burden against mRNA vaccine developers in India. However, due to complexity of the technology, the Government of India and the vaccine developers in India are unable to identify which patents are essential for the production of mRNA vaccines.

In this regard, the Government of India is considering an amendment related to Section 10 of the Patents Act, 1970 by adding clause (7) of it. The proposed Clause (7) will make it mandatory for all patent holders to declare in their patent application that their patent is essential to the production of mRNA vaccine. Clause (7) further states that if and when such essential patents are not declared, but such a patent holder files a suit for patent infringement against mRNA vaccine developers in India, the Government of India will revoke such patents under Section 66 of the Patents Act, 1970 on account of lack of adequate disclosure and strategic litigation as it is generally prejudicial to the public. Examine the TRIPS consistency of:

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a) The proposed amendment of Section 10 by adding clause (7) that requires disclosure of all essential patents required for mRNA vaccine production.

b) Formation of CMPP and the determination of royalty rates

c) Section 66 revocation of patents for lack of adequate disclosure and strategic litigation as it is generally prejudicial to the public. **(Marks: 5x 3= 15)**

4) Critically examine the leaked text of the TRIPs waiver proposal tentatively agreed by India, South Africa, United States and the European Union in the light of original proposal jointly made by India and South Africa in October 2020. **(Marks: 5)**

5) The Government of India is considering a law to guide the judiciary in tailoring injunction by requiring the judiciary to use the principle of proportionality by limiting the grant of injunctions for violations of trade secrets against any individual or business entity which is involved in the production of Covid-19 vaccines, drugs and diagnostics. Alternatively, the remedy of damages in the form of on-going royalties is explicitly allowed by the law. In this regard, prepare any opinion for the GoI on the potential TRIPS consistency issues and challenges. **(Marks: 10)**