QUESTION-A: REPORT ON INDIA

Emergence of Competition Law in the Indian Market:

1. Asia has emerged as a promising and attractive economy. Out of all the Asian countries which are responsible for this positive development, India has played a vital role.

2. India was under the colonial rule of the British for a very long period of time and this had a deep-rooted impact on its subsequent development in various sectors. India has been blessed with a great range and variety of climates, soils and natural resources throughout its territory. Its unique location and diverse conditions has contributed in it containing rich raw materials. These unique characteristics have always led to India being a very tempting market for carrying out trade and business.

3. Even today, after 69 years of India having attained its independence, it remains a very tempting market to carry on trade and exchange with. However, it is interesting to note that India was not always open to trade and commerce with the outside world and its policies were restrictive in nature. It was only in the 1990s that the Indian economy opened up due to entirely new policies being framed and as a result of India becoming a signatory to various international treaties.

4. This opening up of the Indian market broadened the scope of trade and commerce and has since then only seen upward movement. This phenomenon combined with industrialisation was a recipe fit for growth of the Indian market and has today made it one of the most significant markets in Asia.

5. Opening up to global trade and multi-faceted growth of the Indian market meant that issues pertaining to Competition Law were bound to arise sooner or later. These concepts arose in the legal jurisprudence owing to the industrialisation and globalisation of the Indian economy. Initially, the statute which governed the concepts of Competition in India was known as the Monopolies and Restrictive Trade Practices (MRTP) Act, 1969.

The Monopolies & Restrictive Trade Practices (MRTP) Act, 1969:

6. As the name of the statute itself suggests, this particular enactment was meant to protect the market from misuse of monopolies and also to keep a check on restrictive trade practices.

7. In April, 1964 the Government of India appointed the Monopolies Inquiry Commission under the Chairmanship of Justice K.C. Das Gupta, a Judge of the Supreme Court, to inquire into the extent and effect of concentration of economic power in private hands, and also the prevalence of monopolistic and restrictive trade practices in important sectors. The statute was a result of the recommendations and Bill prepared for enactment by the said Monopolies Inquiry Commission.

8. However, the scope of the MRTP Act was limited to the private sector and keeping a check on concentration of economic power in private hands.

9. Since it was the very first statute of its kind, it did suffer from shortcomings and flaws, which came to light with the passage of time. Also, anti-competitive activities increased in variety and scope over the period of time. This paved the way for enactment of the new statute known as the Competition Act, 2002.

The Competition Act, 2002:

10. As a result of globalisation and industrialisation, the Indian economy opened up to trade with the outside world. This led to the industries in India facing competition from not only within the country, but also from outside.

11. When the MRTP Act was no longer seen to be effective in curbing anti-competitive activities of all kinds, which emerged with the modernisation of the market, a High Level Committee on Competition Policy and Law was constituted by the Government of India which submitted its report on 22nd May, 2002. The Central Government consulted the concerned persons, which included the trade and industry associations and the public. After considering the suggestions which came from the concerned persons, it was decided to enact the Competition Act.

12. Under the Competition Act, 2002 the following three types of activities are prohibited or regulated:
    (i) Anti-competitive agreements – under Section 3
    (ii) Abuse of dominant position – under Section 4
    (iii) Regulation of combination – under Section 6

13. The Competition Act, 2002 under Section 7, provides for establishment of the Competition Commission of India (CCI), which is a quasi-judicial body. The CCI has wide powers under the Act to prevent appreciable adverse effect on competition in the Indian markets, including the power to impose penalties under various provisions contained in Chapter VI of the Act. The CCI plays a vital role in investigating and keeping a check on various anti-competitive practices prevalent in the Indian market.

14. Section 53A of the Competition Act, 2002 provides for the establishment of the Competition Appellate Tribunal (COMPAT). Appeals from the decisions of the CCI can be made to the COMPAT under Section 53B of the Act.

15. Further, an appeal can be filed against the decision of the COMPAT before the Supreme Court of India, under Section 53T of the Act. Therefore, as far as the Competition Act, 2002 is concerned, there is a three-tier system in place which comprises the CCI, COMPAT and the Supreme Court of India.

Pharmaceutical Industry and Competition Law in India:

16. In India the pharmaceutical industry has a substantial presence and India is a major global supplier of generic drugs. The Indian pharmaceutical industry has 3 types of substitutable drugs, i.e. originator drugs (patented or newly innovated) having a brand name, branded generic drugs and generic-generic drugs[1].

[1] "Competition Law and Indian Pharmaceutical Industry", Centre for Trade and Development (Centad), New Delhi, 2010

17. The Pharmaceutical companies spend vast sums of money on drug promotion, by way of practices like sales representatives, samples, advertisements etc. Drug promotion is also viewed to be closely linked with unfair trade practices.[2]

18. Regulatory issues are at the core of the competition in the pharmaceutical market in India. Intellectual property law principles are also closely linked to the pharmaceutical market. Patents form a major source of market power in the absence of effective competition in the market. The entry of generic drugs into the market after the expiry of patents is a major reason for the fall in prices of such drugs. The Patent Act, 1970 from the very beginning did not provide for product patents, owing to the experience with aggressive monopolies being formed in the pharmaceutical sector. Two expert studies conducted by the Government resolved in the favour of withdrawal of the product patent regime from pharmaceuticals. However, subsequently India became a signatory to the TRIPS Agreement (1995) and it mandated product and process patent in all fields of technology. Hence, the Patent Act, 1970 was amended in 2005 and the product patents were re-introduced for pharmaceuticals.[3]

19. Section 3(d) of the Patents Act, 1970 is a major public health safeguard and a lot of litigation on the subject has revolved around this particular provision. Section 3(d) of the Patents Act, 1970 plays an important role in preventing the "evergreening" of pharmaceutical inventions.[4]

20. The Patents Act also provides for compulsory licensing in certain cases. The Act provides for a three year rule for compulsory licensing, which is also in line with the Paris Convention. The only difference being that the Paris Convention states that in the case of non-working of a patent a compulsory license shall be issued only after the expiry of three years; whereas the Patents Act, 1970 makes the rule applicable in all cases, except in cases of emergency.[5]

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[2] Ibid
[3] Ibid
[4] Ibid
[5] Ibid

21. Apart from the aforesaid provisions of the Competition Act, 2002 which directly keep a check on the anti-competitive activities in the pharmaceutical sector in India, provisions of certain other statutes are of great importance in the Indian market.

22. One such enactment is the Drugs and Cosmetics Act, 1940. Section 3(b) of the said Act defines "drug" as including *"all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes"*.

23. The Drugs and Cosmetics Act, 1940 was introduced with the objective to establish a comprehensive measure for the uniform control of manufacture, distribution and imports of drugs.

24. Chapter III of the Act deals with Import of Drugs and Cosmetics. Section 10 of the Act, which forms part of aforesaid Chapter III gives the Central Government the power to prohibit imports and Section 10A further gives them the power to prohibit imports based on public interest.

25. Chapter IV of the said Act which deals with the manufacture, sale and distribution of drugs and cosmetics, provides for a similar power to the Government under Section 26A and 26B, wherein the Government is empowered to prohibit and regulate or restrict, respectively, the manufacture of a drug in public interest.

26. It is interesting to note that not all drugs are brought under the scanner of the Government under the Act. The Drugs and Cosmetics Rules, 1945 were framed under the Drugs and Cosmetics Act, 1940 and these Rules provide for the procedure and methodology for enforcement of the various powers provided under the Act. The drugs are categorised into various Schedules under the said Rules and the standards and methodologies prescribed vary from one category of drugs to another.

27. Another important legislation in this regard is the Essential Commodities Act, 1955. This Act was enacted in public interest to provide for the control of the production, supply and distribution of, and trade and commerce in certain commodities. Section 2A

of the said Act provides that *"For the purposes of this Act, "essential commodity" means a commodity specified in the Schedule."*

28. The 'essential commodities' under the Essential Commodities Act, 1955 are enlisted in the Schedule to the Act and the said commodities are brought under the purview of control in public interest. The Schedule, as aforesaid, provides as follows:-

"(1) drugs.
Explanation – For the purposes of this Schedule, "drugs" has the meaning assigned to it in clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940".

29. Hence, the Schedule to the Essential Commodities Act relates back to the definition of "drugs" as provided in the Drugs and Cosmetics Act, 1940.

30. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) issued an Order, popularly known as the Drug Price Control Order dated 15th May, 2013[6]. The said Order was issued and imposed under the Essential Commodities Act, 1955, and it was aimed at primarily creating a ceiling price for essential and life-saving drugs, so as ensure accessibility of the same to the public at large. This was a very significant event as far as the pharmaceutical industry is concerned. This made it difficult for the pharmaceutical industry to fix prices as per its own discretion and created a system of check on them.

Conclusion:

31. All of the aforesaid legislations, i.e. the Competition Act, the Drugs and Cosmetics Act as well as the Essential Commodities Act are all complementary to each other. They all function with one common goal, i.e. to secure the interest of the consumers.

32. Under these legislations the Government has wide powers to keep a check on issues pertaining to Competition Law in the Indian pharmaceutical market. The ground of public interest runs as a common stream through all these enactments which empowers the Government to take steps accordingly for the best interest of its people. These broad

[6] http://www.nppaindia.nic.in/DPCO2013.pdf

powers act as a deterrent on the manufacturers and corporate houses and ensure that they are not able to indulge in any kind of anti-competitive activity or misuse their positions in the economy.

33. However, apart from keeping a check on manufacturers and corporate houses, it is important to keep in mind that the back-bone of the pharmaceutical industry is research and development. Till research and development is not encouraged and given its due importance, newer and more efficacious medicines will not be discovered. As diseases and ailments take numerous forms, the research and study of medicines has to keep pace with it. Manufacturers who spend huge amounts of money on research and development need to have proportionate incentive to be able to profit from their discoveries.

34. Therefore, if these legislations and the Government are allowed to completely over-shadow this industry, it will result in the industry as well as the consumers suffer irreparable harm and injury.

35. Hence, it is essential to strike a balance between public interest and encouraging research and development of medicine in the economy to enable a harmonic and symbiotic growth which is truly sustainable in all its forms.

36. The principle of 'compulsory licensing' is an example of such a balancing measure. It ensures that the holder of the intellectual property right has the exclusive ownership of the rights for a limited period of time, after which the rights have to be compulsorily available to other manufacturers to purchase. This ensures that the crop is reaped exclusively by the originator of the intellectual property right for a limited period of time, after which it is open for other players to again access to it as well and this in turn ensures fair competition for the said drug in the market.

37. The judiciary has also taken positive and proactive steps in the form of judgments, like in the case of *Novartis*[7], wherein an important role was played in preventing the evergreening of pharmaceutical inventions. Also, judgments like in the case of *K.S.*

[7] (2013) 6 SCC 1

Gopinath (2003) play a crucial role, wherein directions were issued to the Government to ensure that essential and life-saving drugs do not fall out of price control.

38. As a way forward, it is essential that the legislature, executive and the judiciary work hand in hand towards a more balanced regime where not only is public interest safeguarded, but also due importance, protection and incentive is given to the pharmaceutical companies. This would pave the way for a viable commercial environment in the market and bring about stability.