IN THE HIGH COURT AT CALCUTTA

ORIGINAL SIDE

COMMERCIAL DIVISION

Present:

The Hon'ble Justice Krishna Rao

IPDPTA No. 121 of 2023

ITC Limited

Versus

The Controller of Patents, Designs & Trademark

Mr. J. Sai Deepak, Sr. Adv.
Mr. Paritosh Sinha
Mr. Manosij Mukherjee
Mr. Samik Chakraborty
Ms. Mitul Dasgupta
Ms. Amrita Majumdar
Mr. K. K. Pandey
Mr. Gyan Prakash
Mr. T. Das
Ms. Mallika Bothra
Ms. Pooja Sett

... For the appellant.

Mr. Amit Chakraborty
Ms. Sanjukta Gupta

... For the respondent.

Hearing Concluded On : 08.04.2025

Judgment on : 30.04.2025

Krishna Rao, J.:

1. This is an appeal under Section 117A of the Patents Act, 1970 against the order passed by the Controller of Patents and Designs, Kolkata, dated 26th June, 2023 under Section 15 of the Patents Act, 1970 wherein the application filed by the appellant being Indian Patent Application No. 685/KOL/2015 dated 10th June, 2015 was rejected.

2. The application filed by the appellant before the Controller is for invention titled *"A Device and method for generating and delivery of a Nicotine Aerosol to a user"*.

3. Mr. J. Sai Deepak, Learned Senior Advocate representing the appellant submits that the device does not have any electrical/electronic components or like arrangement. The device consists of a tube enclosing at least two components. One of the components holds at least one aerosol generating substance i.e. nicotine/alkaloids and another component holds at least one aerosol promoting substance, i.e. pyruvic acid. He submits that the two components are arranged parallel to each other in a novel configuration. During inhalation, the aerosol generating substance reacts with the aerosol promoting substance at a particular location to generate the nicotine salt-based aerosol to be delivered to the user.

4. Mr. Sai Deepak submits that the subject invention disclosed in the application is not an e-cigarette nor does it belong in the category of Electronic Nicotine Delivery System (ENDS). He submits that since it does not use electrical or electronic or like sources of heat to generate aerosol. He submits that the device is activated by a process wherein nicotine salt aerosol is generated by a chemical reaction without any deployment of heating/ electrical/ electronic element. He submits that the subject invention is, therefore, able to generate aerosol through a novel design configuration when combined with an effective and productive process based solely on a chemical reaction without the deployment of any heating or electronic means/ method.

5. Mr. Sai Deepak submits that the respondent has cited new documents in the impugned order which were not a part of the First Examination Report. He submits that no documents in support of the ground of Section 3(b) were cited in the First Examination Report. The documents in support of objection under Section 3(b) were cited for the very first time in the hearing notice. The document which was cited is an online newspaper article.

6. Mr. Sai Deepak submits that in the impugned order found reference to a White Paper titled *"White paper on Electronic and Nicotine Delivery System"* dated 29th May, 2019 by the Indian Council of Medical Research (hereinafter referred as "ICMR") and several statutes and portions from the same were relied upon. He submits that the ICMR White Paper dated 29th May, 2019 was neither cited in the First

Examination Report or Hearing Notice nor was served upon the appellant prior to passing of the impugned order. In support of his submissions, he has relied upon the judgment reported in the case of ***Ssangyong Engineering and Construction Company Limited Vs. National Highways Authority of India (NHAI)*** reported in ***2019 SCC OnLine SC 677***.

7. Mr. Sai Deepak submits that the subject invention is not an electronic cigarette, the reliance on the News Paper Article dated 31st May, 2019, the ICMR White Paper dated 29th May, 2019 and the contents therein and the e-cigarette Prohibition Act is completely misplaced and unjustified.

8. Mr. Sai Deepak submits that the respondent has failed to appreciate that the term *"serious prejudice"* in Section 3(b) of the Patents Act, 1970 has to be read together with the rest of the provision which uses the words *"primary or intended use"*. In support of his submissions, he has relied upon the judgment in the case of ***Balsinor Nagrik Co-op. Bank Ltd. Vs. Babubhai S. Pandya*** reported in ***AIR 1987 SC 849***.

9. Mr. Sai Deepak submits that as per PowerPoint presentation by Shri DPS Parmar, the then Deputy Controller of Patents and Designs available on the website of World Intellectual Property Organization, providing explanation with examples on what constitutes a fit case for attracting Section 3(b) of the Act. He submits that none of the examples

provided Section 3(b) exclusion mention tobacco, smoking or nicotine or inventions relating thereto.

10. Mr. Sai Deepak submits that if patentability of an invention is denied merely because its commercial exploitation is prohibited, it would violate of Article 27(2) of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Article 4quarter of Paris Convention for the Protection of Industrial Property (Paris Convention). He submits that the Patent Office is not empowered to decide on policy issues regarding incentivizing/ disincentivizing innovation in a particular filed of invention which exclusively lies within the realm of the Government/ Executive.

11. Mr. Sai Deepak submits that Section 83(e) of the Patents Act further reinforces the fact that grant of a patent does not necessarily mean that the claimed invention can be commercially exploited. He submits that the fundamental aspect of Patent Law that "grant of patent" is distinct from "commercialization" and that the grant of patent does not result in a consequential right to sell the product.

12. Mr. Sai Deepak submits that the Patent office has granted several tobacco related inventions. He submits that recently by an order dated 18th April, 2024, granted patent of such invention but the application of the appellant is rejected arbitrarily. In support of his submissions, he has relied upon the judgment in the case of ***Manganese Ore (India) Ltd. vs. Regional Asstt. CST*** reported in ***(1976) 4 SCC 124***.

13. Mr. Amit Chakraborty, Learned Advocate representing the respondent submits that the invention claimed by the appellant falls under Nicotine Replacement Therapy (NRT) which uses nicotine for replacement of smoking. He submits that as per the Drugs and Cosmetics Act, 1940, Nicotine Replacement Therapy is not approved and the present invention uses 90 microliters of nicotine each in three channels. The 90 microliters are equivalent to 90 mg. of nicotine, which is way beyond permissible limit as per Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945.

14. Mr. Chakraborty submits that the present device uses salt of nicotine which is 60 microlitre or 60 mg to 90 microlitre or 90 mg. in each tube. Nicotine is a known addictive substance that can have serious health effects. He submits that any device that could potentially promote or facilitate nicotine addiction might be seen as against public health policies.

15. Mr. Chakraborty submits that nicotine even in therapeutic use, has health risk. Inhaling nicotine-based aerosols could have adverse effects on the lungs and cardiovascular system. He submits that the device delivers aerosolized nicotine directly to the lungs, as such, it is harmful, especially given increasing global concerns about vaping and e-cigarette related lung deceases.

16. Mr. Chakraborty submits that as per the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945 permit the use of nicotine upto 2 mg

and 4 mg in gums, lozenges and strips. He submits that such a product should be adhere to the provisions of chapter IV of the Drugs and Cosmetics Act and Rules made thereunder, which requires them to manufactured under a valid Drug manufacturing license and valid sales license for products containing more than 2 mg of nicotine.

17. Mr. Chakraborty submits that the Controller has satisfied that the application filed by the appellant does not comply with the provisions of Section 3(b) of the Patents Act, 1970 and accordingly, the same was rejected.

18. Mr. Chakraborty submits that the notice of hearing was given to the appellant on 1st May, 2023, an opportunity of hearing was given to the appellant on 30th May, 2023. The appellant attended the hearing and submitted his reply on 14th June, 2023 and thereafter, the Assistant Controller has passed the order dated 26th June, 2023, thus the appellant cannot say that the respondent has violated the principles of natural justice.

19. Mr. Chakraborty submits that the documents and statutes relied by the Assistant Controller are available in the Government website and statutes books. The ICMR report is mentioned in the hearing notice dated 1st May, 2023. He submits that the appellant had the knowledge about all the documents relied by the Assistant Controller but the appellant has not dealt with the said documents either in the reply or at the time of hearing of the application.

20. Mr. Chakraborty submits that the final product of Electronic Nicotine Delivery System and NRT are *"Nicotine Based Aerosol"* which is same as that of the ICMR Report. He submits that Vapes, NRT and ENDS have common properties and all three are designed to deliver nicotine to the user through *"Nicotine based aerosol".* All three generate nicotine based aerosols, which are inhaled and delivered to the lungs. He submits that unlike traditional cigarettes, vapes do not burn tobacco but instead create an aerosol by vaporizing the liquid. He submits that the aerosol contains nicotine, which is absorbed through the lungs into the bloodstream due to which the ICMR report and the advisory issued by the Government of India dated 20th August, 2018, are quoted in the order passed by the Assistant Controller.

21. Mr. Chakraborty submits that Article 47 of the Constitution of India provides duty of the State to raise the level of nutrition and the standard of living and to improve public health. He submits that in view of Article 47 of the Constitution of India, nicotine which causes serious prejudice to human, animal or plant life or health or to the environment cannot be permitted to use in the present device beyond the permissible limit for the purpose to protect and improve public health.

22. Mr. Chakraborty submits that it is a settled legal proposition that Article 14 of the Constitution of India is not meant to perpetuate illegality or fraud, even by extending the wrong decisions made in other cases. He submits that if some other similarly situated persons have

been granted some relief inadvertently or by mistake, such an order does not confer any legal rights on others to get the same relief as well. In support of his submissions, he has relied upon the judgment in the case of ***Basawaraj and Another Vs. Special Land Acquisition Officer*** reported in ***(2013) 14 SCC 81*** and ***Fuljit Kaur Vs. State of Punjab and Others*** reported in ***(2010) 11 SCC 455***.

23. The first issue raised in the present application whether the documents relied by the respondent was served upon the appellant or not or whether the appellant get an opportunity to deal with the documents relied by the respondent.

24. In the impugned order, the respondent has relied upon the following documents:

> *"i. ICMR White Paper on Electronic Nicotine Delivery System dated May 29, 2019.*
>
> *ii. Environment (Protection) Act, 1986.*
>
> *iii. The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989.*
>
> *iv. Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011.*
>
> *v. The Food Safety and Standards Act, 2006.*
>
> *vi. Information on Nicotine Sulfate as seen on https://pubchem.ncbi.nlm.nih.gov/compound/Nicotine-sulfate.*
>
> *vii. Government of India, Ministry of Health & Family Welfare order no. F.No.-P-16012/19/2017-TC dated 28/08/2018.*
>
> *viii. Insecticide Act 1968.*

ix. The Drugs and Cosmetics Act, 1940 & Rules, 1945.

x. Circulars purportedly issued by the State Governments of Punjab, Karnataka, Mizoram, Kerala, Jammu & Kashmir; Uttar Pradesh and Bihar;

xi. Promulgation of the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage And Advertisement) Ordinance, 2019.

xii. The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019, dated 5th December 2019.

xiii. Judgement related to Civil Writ Petition (PIL) No. /2022, Priyansha Gupta vs Union of India & others."

25. In the hearing notice dated 1st May, 2023, the respondent has mentioned about the documents which are as follows:

"Without prejudice to any other objections, prima facie it seems that the subject matter of amended claims 1-17 of the alleged invention discloses an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human animal or plant life or health or to the environment.

Hence the subject-matter of amended claims 1-17 as filed in the instant application prima facie development to a stimulant cigarette or e-cigarette and falls within the scope of clause (b) of section (3) of the Patents Act, 1970 (as amended). Therefore, the invention claimed in the said amended claims is not patentable.

Application fails to explain how to control the addition effect of the nicotine with controlled nicotine delivery, which is hazardous to the health

and therefore it cannot be allowed as per Section 3(b) of IPA-1970.

The Indian Council of Medical Research (ICMR) has released a paper on May 31, 2019, titled "Vaping Could Put You on Path from Womb to Tomb": ICMR Recommends Ban on E-cigarettes May 31, 2019 has recommended a complete ban on e-cigarettes and other electronic nicotine delivery systems (ENDS) and said that it "adversely" affects almost all the human body systems with impact….from womb to tomb". The ICMR noted that e-cigarettes could, in fact increase the possibility of nonsmokers turning to smoking, "Use of ENDS or e-cigarettes by non-smokers can lead to nicotine addiction and regular smoking, "it said and added that several studies have found that youth using ENDS or e-cigarettes were "more likely to use regular cigarettes later". Passive smoke from e-cigarettes or vapes is also harmful, it said "Passive exposure to vapors during pregnancy can severely affect the health of both mother and foetus". ICMR recognizes ENDS are devices that heat a solution to create an aerosol, which also frequently contains flavours, usually dissolved into propylene glycol and glycerin. There are various types of ENDS devices like e-cigarettes, heat-not-burn devices, vape, e-sheesha, e-nicotine flavored hookah among others. The most common type is an e-cigarette that produces an aerosolized mixture of the flavored liquids and nicotine, which is inhaled by the user. The release of the white paper comes amid a raging debate over the harm reduction aspects of ENDS with some organizations claiming that they held in smoking cessation and are less harmful alternatives to traditional cigarettes. Professor K Srinath Reddy, President, Public Health Foundation of India and a renowned cardiologist who chaired the ICMR expert group for this white paper said that the tobacco consumption, especially cigarette smoking has shown a decline in India in recent years, in response to several tobacco control measures that has already been initiated. "Thus, at this juncture, marketing of product like ENDS or e-cigarettes, with unproven benefit and high potential harm from addiction and health risks, is unwarranted as a tobacco control measure"."

26. The contention of the respondent is that the said documents are available in the Government Website, in other words it is admitted that the said documents were not supplied to the appellant. The respondent in the impugned order relied upon (i). The Environment (Protection) Act, 1986, (ii) the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989, (iii) The Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 under the Food Safety and Standards Act, 2006, (iv) The Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945, (v) Insecticides Act, 1968, and (vi) The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019. In the hearing notice dated 1st May, 2023, the respondent has not mentioned about the said Acts or informed the appellant that the respondent will consider the said Acts.

27. In the case of ***Ssangyong Engineering (Supra)*** wherein the Hon'ble Supreme Court held that:

> ***"73.*** *Given these parameters of challenge, let us now examine the arguments of the learned counsel on behalf of the appellant. There can be no doubt that the government guidelines that were referred to and strongly relied upon by the majority award to arrive at the linking factor were never in evidence before the Tribunal. In fact, the Tribunal relies upon the said guidelines by itself and states that they are to be found on a certain website. The ground that is expressly taken in Section 34 petition by the appellant is as follows:*
>
> > *"It is pertinent to mention here that no such guidelines of the Ministry of Industrial Development had been filed on record by*

> *either of the parties and therefore, the Tribunal had no jurisdiction to rely upon the same while deciding the issue before it. Accordingly, the impugned award is liable to be set aside."*
>
> ***74.*** *The learned counsel for the respondent also agreed that these guidelines were never, in fact, disclosed in the arbitration proceedings. This being the case, and given the authorities cited hereinabove, it is clear that the appellant would be directly affected as it would otherwise be unable to present its case, not being allowed to comment on the applicability or interpretation of those guidelines. For example, the appellant could have argued, without prejudice to the argument that linking is dehors the contract, that of the three methods for linking the New Series with the Old Series, either the second or the third method would be preferable to the first method, which the majority award has applied on its own. For this reason, the majority award needs to be set aside under Section 34(2)(a)(iii)."*

28. In the present case, the respondent in his argument as well as in the written notes of argument, it is mentioned that the documents and statutes, which were mentioned in the order by the Assistant Controller are available in the website. In the hearing notice also the respondent has not indicated that in terms of the Acts and the Rules as mentioned in *para 26 (supra)*, the appellant will not get patent.

29. This Court finds that the documents on the basis of which the respondent has refused to grant patent to the appellant, the appellant was denied an opportunity of hearing to deal with the said documents and the Acts relied by the respondent.

30. Section 3, 3(b) and 3 (d) of the Patents Act, 1970 are reads as follows:

> *"**3. What are not inventions.—**The following are not inventions within the meaning of this Act,—*
>
> *(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*
>
> *(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*
>
> ***Explanation.—**For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."*

31. In the impugned order, the respondent has cited that the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 (e-cigarette Prohibition Act) which is statute regulating and banning electronic cigarettes.

32. The appellant claims that the device as claimed in claims 1 or 2 or 3 or 4, wherein said aerosol promoting substance concentration is from about 10 microliters to 90 microliters and preferably in between 60 microliters to 90 microliters. It is the further case that the claim nos.1 or 2 or 3 or 4, wherein said aerosol promoting substance concentration

is from about 90 microliters to 10 microliters and preferably in between 120 microliters to 140 microliters. It is also that the device as claimed in 1 or 2 or 3 or 4 generates, nicotine aerosol concentration from about 0 microgram per puff to 50 microgram per puff and preferably from about 1.4 microgram per puff to 3.2 microgram per puff.

33. As per the case of the appellant, the present invention discloses a device (system), embodying a novel configuration (e.g. parallel configuration) to hold at least one aerosol generating substrate (e.g. tobacco, alkaloid, nicotine and the like) and aerosol promoting substance (e.g. acid), to generate and deliver the aerosol of a nicotine salt to the user. The present invention provides an efficient, parallel design device that delivers nicotine to the users without burning or heating of tobacco and/or nicotine. The figures are as follows:

As per Figure-1(a):

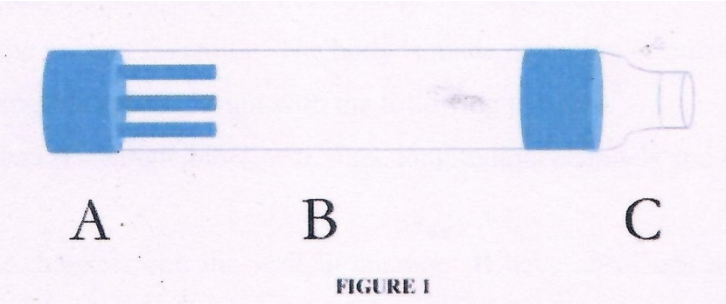


FIGURE 1

Nicotine -60 microliters each in two channels,

Pyruvic Acid -140 microliters in one channel,

Nicotine Delivery -1.4 to 9.2 microgram per puff.

As per Figure -1(b):

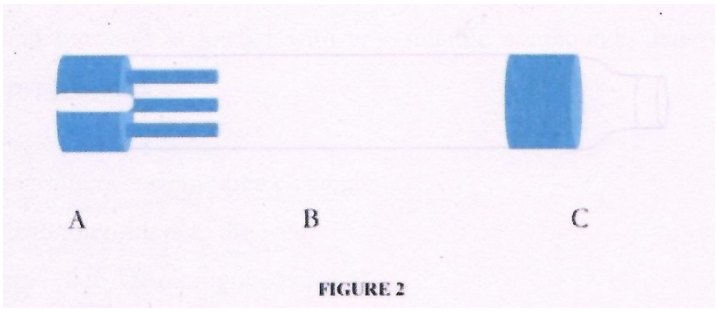


FIGURE 2

Nicotine -90 microliters each in three channels,

Pyruvic Acid – 140 microliters in the well,

Nicotine Delivery – 0 to 15 microgram per puff.

As per Figure -2:

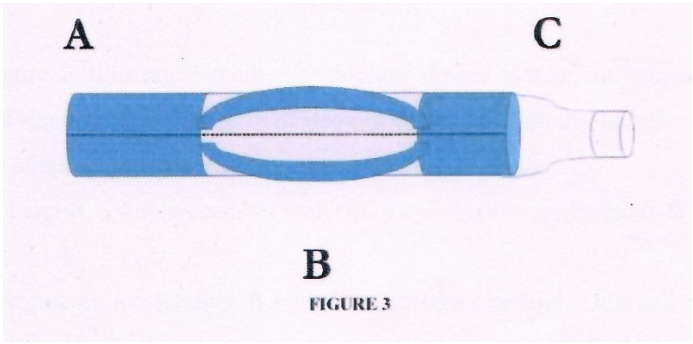


FIGURE 3

Nicotine -60 Microliters,

Pyruvic Acid-140 microliters,

Nicotine Delivery -2.9 to 3.2 microgram per puff.

34. Figure-1 relates to chemical evaluation of electronic cigarettes. The terms, electronic cigarette are broadly classified under *"Electronic*

Nicotine Delivery System" which does not involve burning or combusting of tobacco/nicotine to generate aerosol.

35. It is the case of the appellant that the present invention does not belong to electronic nicotine delivery system, thus it does not use electrical or electronic sources to generate aerosol. It uses chemical to generate nicotine aerosol wherein it is totally eliminate electrical or electronic components.

36. In the present case, the respondent by taking into the consideration of the ICMR White Paper publication, the Drugs and Cosmetics Act, 1940 and Rules, 1945 framed therein and considering the other Acts has come to the conclusion that the device is an e-cigarette but the respondent has not taken the said plea in the hearing notice and the appellant has been denied an opportunity to deal with the said contention of the respondent.

37. The respondent has applied the serious prejudice by referring Section 3(b) of the Patents Act. Section 3(b) is the *intent principle* and not the *effect or harm principle*. Shri DPS Parmar, the then Deputy Controller of Patents and Designs provided explanation with examples on what constitutes a fit case for attracting Section 3(b) of Patents At which are as follows:

Section 3 exclusions

Section 3(b)

Commercial exploitation or primary use of inventions, which is

- **Contrary to**
  - public order or
  - Morality

Examples

- Gambling machine,
- Device for house-breaking ,

Section 3 exclusions

Section 3(b)

Commercial exploitation or primary use of inventions , which

- **Causes serious Prejudice to**
  - health or
  - human, animal, plant life or
  - to the environment

Examples

- Biological warfare material or device, weapons of mass destruction
- Terminator gene technology,
- Embryonic stem cell

Checks and Balances

Section 3(b)

Excludes patents on

- GMOs – exploitation of which could be contrary public order or morality or prejudicial to human, animal or plant life or health or to the environment

Effect : Only genetically modified micro-organisms (GMOs) which do not fall under section 3 (b) are patentable.

In none of the examples provided above discussing Section 3(b) exclusions mention tobacco, smoking or nicotine or inventions relating thereto. In the *"Patents Manual"* does not include tobacco/smoking/ nicotine related inventions at the time of giving examples of inventions that fall within the ambit of Section 3(b) of the Patents Act.

38. Article 27.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), it is mentioned that:

> *"**27.2.** Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, **provided that such exclusion is not made merely because the exploitation is prohibited by their law.**"*

Article 4quarter of the Paris Convention read as follows:

> *"Patents: Patentability in Case of Restrictions of Sale by Law*
>
> *The Grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process **is subject to restrictions or limitations resulting from the domestic law.**"*

Taking into consideration, this Court finds that the grant of patent shall not be refused on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions and limitations resulting from the domestic law.

39. Section 83(d) and (e) of the Patents Act, 1970 reads as follows :

> ***"83. General principles applicable to working of patented inventions.—****Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—*
>
> ***(d)*** *that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;*
>
> ***(e)*** *that patents granted do not in any way prohibit Central Government in taking measures to protect public health."*

The patents are granted to encourage inventions and to secure that the inventions are works in India on a Commercial Scale and to the fullest extent that is reasonably practicable without undue delay. The patents granted do not in any way prohibit Central Government in taking measures to protect public health.

40. Considering the above, this Court finds that it is the fit case to set aside the order passed by the Assistant Controller of Patent at Kolkata dated 26th June, 2023 and remand the matter back to the respondent for considering of the matter a fresh within a period of six months from this date. It is directed that the matter shall be heard a fresh by any competent officer other than the officer who has passed the impugned order. It is made clear that the officer concern is free to take its decision without being influenced, if any, observation made in this order.

41. IPDPTA No. 121 of 2023 is **allowed**.

(Krishna Rao, J.)