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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\# **CNR No. DLHC010477572025**

\+ C.A.(COMM.IPD-PAT) 29/2025

PHILLIP MORRIS PRODUCTS S. A. .....Appellant

Through: Mr. Manish Aryan, Ms. Manisha Singh, Mr. Abhai Pandey, Mr. Nishant Rai and Ms. Yojana Sonkusare, Advocates.

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS .....Respondents

Through: Ms. Nidhi Raman, CGSC with Mr. Rishay Raj and Ms. Nikita Singh, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

O R D E R

% 09.09.2026

1. This appeal is filed on behalf of Appellant under Section 117A of the Patents Act, 1970 ('1970 Act') laying challenge to order dated 24.01.2025, passed by the Respondent, whereby Patent Application No. 202217021141 has been refused.

2. To the extent relevant, facts as pleaded in the appeal are that Appellant filed PCT International Application PCT/EP2020/086199 on 15.12.2020 for invention titled "*Aerosol-Forming Substrate with Nitrogen-Containing Nucleophilic Compound*" and on 08.04.2022, filed PCT National Phase Application no. 202217021141. The application was examined and First Examination Report ('FER') was issued on 19.10.2022, to which reply was filed by the Appellant on 16.03.2023. On 20.03.2024, Respondent

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issued hearing notice and after oral hearing on 30.08.2024, post-hearing written submissions were filed by the Appellant on 11.11.2024 with amended claims. By impugned order dated 24.01.2025, Respondent has refused to grant patent on grounds of lack of inventive step under Section 2(1)(ja) and non-patentability under Section 3(b) and (e) of 1970 Act.

3. To appreciate the controversy in the appeal, it will be useful to navigate through claim 1 of the subject invention which relates to aerosol-forming substrate comprising one or both of cellulose and cellulose derivatives, wherein one or both are present in an amount of 15 weight percent to 85 weight percent on a dry weight basis based on the total amount of aerosol-forming substrate and an aerosol-former, which is present in an amount of 20 weight percent to 58 weight percent on dry weight basis and a nitrogen-containing nucleophilic compound, which is present in an amount of 0.1 weight percent to 10 weight percent on a dry weight basis, wherein nitrogen-containing nucleophilic compound is selected from at least one of the amino acid, a tripeptide, urea or urea derivative or a combination thereof, a nitrogen-containing saccharide and polysaccharide, an inorganic ammonium compound and a nitrogen-containing plastic as also a disaccharide. Amended claim 1 is an independent claim and claims 2-14 are dependent claims.

4. Appellant avers that the aerosol-generating article including an aerosol-forming substrate, which comprises aerosol-formers such as polyhydric alcohols and nicotine are known in the art, however, they are associated with problems such as generation of unwanted aldehydes, particularly, formaldehyde in the aerosol produced. The aerosol-generating article is inserted into the heating chamber of an aerosol-generating device

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and heated to a temperature at which one or more components of the substrate are volatilized without burning the aerosol-forming substrate. These non-liquid articles may or may not comprise of tobacco. It is known that aldehydes, in particular unwanted formaldehyde can be formed, when burning tobacco in traditional cigarettes and aldehydes can also be formed when heating aerosol generating articles without burning the substrate. It was surprisingly, found that the aerosol-forming substrates not containing tobacco or that are substantially free of tobacco but comprising one or both of cellulose and cellulose derivatives may produce aerosol having high concentration of aldehydes and therefore, there was a need to reduce formation of the unwanted aldehydes in the aerosol produced by heating aerosol-forming substrate without burning.

5. It is stated that the aerosol-forming substrate of the present invention is substantially free of tobacco and addresses the need for reducing the formation of unwanted aldehydes. Additionally, the presence of disaccharide may enable the release of aerosol-former over a longer and extended period of time, allowing a user to enjoy an aerosol generated from the substrate after having taken more than 6, 7 or 8 puffs [lines 31-36 and 1-7 of specification]. Thus, the aerosol-forming substrate of the subject application aims to solve the problems associated with use of non-tobacco substitutes known in the art.

Submissions on behalf of the Appellant:

6. The subject application has been erroneously refused on grounds of lack of inventive step under Section 2(1)(ja) and non-patentability under Section 3(b) and (e) of 1970 Act. Respondent has reached a conclusion that amended Claims 1-14 lack inventive step owing to prior arts D1

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(GB1355865 A), D2 (US4195645 A) and D3 (US2018352856 A1), but has given no reason as to why a person skilled in the art would be motivated to combine D1-D3 to reach the present invention. Merely listing of prior art references without demonstrating any technical motivation is not enough to conclude that the claimed invention lacks inventive step. The only paragraph of the impugned order that deals with this objection reads *"In order to this, herein, it concluded that by teaching of the cited documents D1-D2, the composition disclosed in the present invention is obvious for person skill in the art. Hence, in view of the prior art documents D1, D2, and D3, adding a disaccharide such as sucrose, for the purpose of the aerosol generating system along with cellulosic materials (as a tobacco free or substantially free tobacco containing materials) is obvious for person skill in the art."* and this reasoning is insufficient to explain the relevancy of D1-D3 *qua* the claimed invention. It is also unclear whether D3 is even relevant in assessing the inventive step in the instant case and perhaps for this reason in the concluding part of the order Respondent has not even referred to D3. Evidently, the impugned order is not only unreasoned but also reflects non-application of mind. Importance of a reasoned and speaking order cannot be over-emphasized and for this proposition, the decision in ***Huhtamaki Oyj and Another v. Controller of Patents, 2023 SCC OnLine Del 3272,*** is instructive.

7. The order under challenge also stands vitiated owing to violation of principles of natural justice inasmuch as Respondent has taken into consideration three documents: (a) Report of the Standing Committee of Parliament 'Review of Intellectual Property Rights Regime in India' in Rajya Sabha on 23.07.2021 (Annexure-I); (b) Report on 'Economic Burden

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of Tobacco Related Diseases in India' (Annexure-II); and (c) WHO Report on 'Global Tobacco Epidemic, 2021' (Annexure-III), to uphold the objection under Section 3(b) without notifying the same either in the FER or in the hearing notice and thus Appellant had no opportunity to rebut them and/or address arguments with respect to these documents, resulting in grave prejudice.

8. The other glaring error in the order is that the Respondent has not followed the five-step test for determining the inventive step in the subject application or lack of it, contrary to the judgments of the Division Benches of this Court in ***F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2015 SCC OnLine Del 13619*** and ***Tapas Chatterjee v. Assistant Controller of Patents and Designs and Another, 2025 SCC OnLine Del 636*** as also Single Bench in ***Agriboard International LLC v. Deputy Controller of Patents and Designs, 2022 SCC OnLine Del 940,*** wherein it was held that when considering an application for determining inventive step, Controller is required to consider three elements: invention disclosed in the prior art; invention disclosed in the application under consideration; and the manner in which the subject invention would be obvious to a person skilled in the art. Respondent has failed to carry out this exercise and has instead adopted a hindsight approach to determine obviousness, which is legally impermissible as held by this Court in ***Bristol-Myers Squibb Holdings Ireland Unlimited Company and Others v. BDR Pharmaceuticals International Pvt. Ltd. and Another, 2020 SCC OnLine Del 1700.*** Respondent has wrongly held that claimed invention lacks inventive step and is obvious in light of prior arts D1-D3, without articulating how a person skilled in the art will be motivated to consult or combine them to

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reach the invention claimed. Respondent has observed that in view of D1, D2 and D3, adding disaccharide such as sucrose, for the purpose of aerosol-generating system along with cellulosic material (as a tobacco free or substantially free tobacco containing material) is obvious for person skilled in the art, without reasoning how this conclusion is derived from D1-D3, particularly, when D2 and D3 make no reference to use of disaccharides or sucrose, whether in the claimed context or otherwise. In order to prove obviousness, Respondent was required to show that each and every element of claim 1 is disclosed in the prior arts and there was motivation for the person skilled in the art to combine various prior arts without reasonable expectation of success. Respondent has refused the application citing D1, in particular Example 11, without analyzing whether each element of claim 1 is disclosed in the prior art *albeit* even this reliance is flawed for multiple reasons, the first being that Example 11 finds no mention in the hearing notice and hence, Appellant had no opportunity to address it. For ready reference Example 11 is as follows:-

The incorporation of urea into the composition is seen to cause a significant reduction in tar delivery.

EXAMPLE 11.

A tobacco replacement material was prepared by homogeneously blending the following ingredients in water and casting a film therefrom:

6.0 g sodium carboxymethyl cellulose
12.0 g dolomitic limestone
10.0 g diatomaceous earth
8.0 g burley tobacco dust
4.0 g bright tobacco dust
0.18g colorants
1.0 g humectant
0.3 g tobacco casing

The film was then shredded, formed into cigarettes and tested in the manner of Example 1. The "tobacco casing" is a mixture of flavouring ingredients including sugars, inverted sugars and gums. Cigarettes were also prepared from the same formulation additionally containing 0.5 g urea, i.e., 1.22% urea. Results obtained in testing of the two formulations are set forth in Table XI.

TABLE XI

% Urea in Dry Mix	Cigt. Wt. (grams)	Puff Count	Wet Tar (mg/cigt)	Dry Tar (mg/cigt)
0	1.3	7.0	11.2	9.4
1.22	1.35	7.2	10.9	9.4

A four-member smoking panel unanimously agreed that cigarettes prepared from the formulation containing urea delivered a higher nicotine impact and had less irritation than those which did not contain urea. These results indicate that similar compositions containing a lower concentration of added nicotine should deliver a mainstream smoke with a suitable physiological nicotine impact by the use of urea as an additive.

EXAMPLE 12.

A reconstituted tobacco in shred form was placed in a suitable container such that the material could be conveniently tumbled on ball milling rolls. A 10% aqueous solution of urea was used to apply to the tobacco as a spray a 2.5% add-on level of urea. The treated shred was made into cigarettes and tested in the manner set forth in Example 1. The results are presented in Table XII.

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9. Visibly, Example 11 teaches a tobacco replacement material consisting of eight ingredients, one of which is a 'tobacco casing' and additionally, urea is used for preparing the tobacco replacement material, which involves the use of '*burley tobacco dust*' and '*bright tobacco dust*' and thus Example 11 actually contains significant amount of tobacco component despite the objective of D1 being to provide a tobacco replacement material. Therefore, D1 teaches away from the subject invention. Moreover, Respondent has conflated the humectant used in Example 11 with aerosol-former of claimed invention. Example 11 of D1 does not disclose the identity of the humectant employed and Respondent appears to have inferred the same, basis Example 15 and statement in lines 26-27 of D1 i.e., "*plasticizers and humectants, such as butylene glycol, glycerol and propylene glycol",* that the humectant is glycerine, which is employed as aerosol-former in the subject application. Even if this extrapolation, which is wholly wrong, is accepted, D1 does not explicitly identify glycerine or any other aerosol-former as humectant in Example 11 and mere presence of 1g of humectant equals only 2.41 wt% of total formulation and is insufficient to function as an effective aerosol-former in the context of the present invention. In contrast, claim 1 of the present invention requires aerosol-former to be present in an amount ranging from 20 wt% to 58 wt% on a dry weight basis of the aerosol-forming substrate. Respondent has further erred in technically construing inverted sugar disclosed in Example 11 of D1 to be equivalent to the teaching of use of disaccharides in Claim 1. Person skilled in the art would appreciate that disclosure of inverted sugar is not equivalent to disclosure of sucrose. The disaccharide claimed in Claim 1 is used to facilitate conduction of heat from

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heating element to aerosol-former. It is well known in the art that inverted sugar is an equimolecular mixture of glucose and fructose, both of which are monosaccharides, as taught in two authoritative text books on organic chemistry by Morrison and Boyd and I L Finar, respectively.

10. Figure 2 depicts a column chart of the formaldehyde detected in the aerosol generated from the aerosol-generating article having heating element at a temperature of 350°C and shows that the amount of formaldehyde in the aerosol could be reduced by including a nitrogen-containing nucleophilic compound such as urea as a formaldehyde-scavenger. There is no such disclosure in D1 and instead the urea disclosed therein has been used in the context of higher nicotine impact for correcting odour and lessening irritation. No reasoning has been given by the Respondent as to why a skilled person will be motivated to combine teachings of D2 and/or D3 since D2 merely teaches a tobacco-substitute and no disclosure of nitrogen-containing nucleophilic compound and disaccharide and D3 is completely silent about the use of the disaccharide as claimed in Claim 1.

11. D2 discloses a tobacco-substitute smoking material comprising a polysaccharide as the combustible organic ingredient. A tobacco alkaloidal material such as nicotine or a derivative thereof is incorporated into the smoking material in the form of plurality of combustible microcapsules containing tobacco alkaloidal material and D2 does not overcome deficiencies of D1 and does not disclose use of a disaccharide or provide any teaching or suggestion to a person skilled in the art to modify the tobacco-substitute taught therein in order to arrive at the claimed substrate. D2 also does not anticipate that adding a disaccharide such as sucrose results in delay of release of aerosol-former like glycerine so that more glycerine is

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released at a later stage during use of the aerosol-generating article as happens in the claimed invention. Respondent has not considered these non-disclosures in D2, which shows the inventive step in the claimed invention. D3 discloses aerosol delivery devices, method of forming such devices and elements of such devices. Respondent lists the various embodiments of D3 stating that the filter in D3 comprises cellulose-containing material and also lists the examples of cellulose materials taught in D3, however, it is not stated how and why a person skilled in the art will find any motivation in the disclosure of D3, either alone or in combination with D1-D2, to modify the aerosol delivery device. D3 is silent on the use of disaccharide and hence, there is no disclosure that adding disaccharide results in delay of the release of aerosol-formers like glycerine. In fact, there is not a whisper in the order as to how D3 is of relevance in assessing the obviousness of the aerosol-forming substrate claimed in the subject application.

12. D1 and D2 are very old prior arts. D1 was filed on 30.07.1971 and published on 05.06.1974 and D2 was published on 01.04.1980. Despite these disclosures being available for several decades, no one has achieved the technical solution in these years as provided by the present invention. It is held in multiple cases by this Court that if there is a long time gap between the prior art document and the invention under consideration, invention is not obvious and to buttress this plea, reliance is placed on the judgments in ***Avery Dennison Corporation v. Controller of Patents and Designs, 2022 SCC OnLine Del 3659; Societe Des Produits Nestle SA v. Controller of Patents and Design and Another, 2023 SCC OnLine Del 582;*** and ***Brugger & others v. Medic-Aid Ltd. (Brugger), [1996] RPC 635.***

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13. Respondent has erred in refusing the application on ground of non-patentability under Section 3(e) of the 1970 Act. The first flaw in the order is that Respondent has given a reasoning, which is completely different from the objection raised in the hearing notice. Secondly, even on merit, the composition disclosed in claim 1 clearly establishes synergism amongst different components, which results in reduction of formaldehyde and helps in maintaining dense and stable aerosol for a longer period of time even after 7th or 8th puff. Respondent has wrongly concluded that invention is a mere admixture and lacks synergy. In the hearing notice, the objection was that Claim 1 concerns aerosol-forming substrate, which compositions are known in prior art and further the specific amounts of components are not mentioned in the composition and hence, it is a case of mere admixture. These findings are contrary to the actual facts inasmuch as claim 1 not only specifies the various components that make up the claimed aerosol-forming substrate but also provides specific weight percentages to combine the said components to facilitate the intended technical effect of delaying the release of aerosol-formers, which are not only novel as acknowledged in the FER, but also inventive. Data provided by the Appellant demonstrated: (a) delayed release of aerosol-former in presence of disaccharide; (b) increased formaldehyde levels when disaccharide content increases; and (c) reduction of formaldehyde upon addition of nitrogen-containing nucleophiles. A simple cellulose-replacement explanation cannot simultaneously account for the linked behaviours. The aerosol-forming substrate in the subject application employs a specific combination of components to obtain the desired effects and if any component is missing, the effectiveness and functionality of the substrate would be compromised

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and there will be no medium to hold and deliver the aerosol-former and optionally nicotine etc., undermining the structural integrity.

14. Respondent failed to appreciate that the synergistic effect afforded by the aerosol-forming substrate in the claimed invention was sufficiently demonstrated in the specification by way of data depicted in Figures 1-4 and corresponding description on pages 17-19. Broadly, Figure 1 demonstrates that nitrogen-containing nucleophilic compounds like urea and lysine react with formaldehyde, thereby eliminating formaldehyde from the aerosol. Figure 2 shows that the amount of formaldehyde could be reduced by 39% when including 1 weight percent of urea as formaldehyde-scavenger. Figure 3 shows presence of disaccharide such as sucrose, which increases formaldehyde and release of formaldehyde associated with the disaccharide can reliably be reduced by including the nitrogen-containing nucleophilic compounds in the substrate and Figure 4 shows that addition of sucrose results in delay of release in glycerine. Therefore, absence of any component would disrupt the synergistic balance resulting in a product that cannot deliver the intended benefit of delay in release of glycerine with reduction in unwanted aldehydes and hence, components of aerosol-forming substrate in the subject application have a synergistic effect and it is not a mere admixture.

15. Respondent has erroneously refused the application invoking Section 3(b) of the 1970 Act overlooking Claims 1-14 of the subject application filed with written submissions dated 11.11.2024, which do not attract provisions of the said Section. Section 3(b) prohibits patentability of invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious

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prejudice to human, animal or plant life or health or to the environment. The three documents relied on by the Respondent for purposes of Section 3(b) being *"Review of Intellectual Property Rights Regime in India"*; *"Report on the Economic Burden of Tobacco-Related Diseases in India"*; and *"The WHO Report on the global tobacco epidemic 2021"*, were for the first time cited in the impugned order and hence, opportunity to deal with them and/or rebut them was denied to the Appellant, which violates of principles of natural justice.

16. Respondent has refused the application for the reason that the claimed invention will cause serious prejudice to human life or health or environment, which is wholly misplaced since the claimed invention provides for an aerosol-forming substrate, commercial exploitation of which involves manufacture and supply of the substrate, which in isolation does not pose any inherent risk to health or environment and no material has been cited to prove otherwise. Additionally, the subject matter is not directed to e-cigarette and instead the intended use is to provide a substrate that is tobacco free with nitrogen-containing nucleophilic compounds aimed at reducing unwanted aldehydes and for delayed release of glycerine. In particular, subject application actually focuses on reducing harmful effects of smoking. The Manual of Patent Office Practice and Procedure provides guidance on what would fall within the scope of Section 3(b) and does not include the invention relating to aerosol-generating device or use of tobacco or nicotine and while the list is not exhaustive, it cannot include the claimed invention as Section 3(b) is based on intent principle and not the effect or harm principle.

17. Observation of the Respondent in the impugned order that the

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complete specification of the subject application and claim subject matter 1, 7, 8 and 14 directly form a composition with nicotine in significant amount does not come in the way of the application being granted. The present invention allows for optional inclusion of nicotine and makes it a non-mandatory component of the aerosol-forming substrate, however, even when nicotine is used, that *per se* cannot be a ground to refuse the application as it is not unknown that nicotine is widely recognized and utilized in medical treatments primarily as part of smoking cessation therapies, which help individuals quit smoking by reducing withdrawal symptoms and cravings. There are many Nicotine Replacement Therapies (NRT) approved by US Food and Drug Administration for quitting smoking. Nicotine patches, gums and lozenges are most common quit-smoking medicines that can be bought over the counter. In fact, Ministry of Health and Family Welfare has included NRT in the national list of essential medicines (NLEM)-2022 under the head "23.5-Medicines for disorders due to psychoactive substance abuse".

18. The observation that use of nicotine in India as an ingredient of food is prohibited under the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011 is also erroneous since the subject substrate does not relate to a food product and therefore, this Regulation and/or the Food Safety and Standards Act, 2006, are inapplicable. Moreover, provisions such as Section 3(b) exist in major IP jurisdictions including EPO, Albania, Argentina, Armenia, Croatia, Czech Republic, Ecuador, Finland, Guatemala, Italy, Japan, Mexico, etc. and as a matter of record inventions such as the present ones have been granted in several jurisdictions and it goes without saying that if they were intended to cause

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serious prejudice to human health, no Patent Office would have granted patent to cause damage to the health of people living in those countries. In some IP jurisdictions, provisions such as this have been clarified citing examples of what is likely to cause harm and would thus fall within the exclusion from patentability, such as processes for cloning human beings or modifying the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes and process of modifying the genetic identity of animals.

19. Impugned order has created an ambiguity in the scope of Section 3(b) and it is concerning that Controllers are exercising unfettered discretion and acting arbitrarily in allowing or refusing patents, where subject matter of applications relate to either aerosol generating devices or use of nicotine or tobacco. No doubt that decisions of Patent Controllers in other jurisdictions granting patents is not binding, however, it is in the interest of justice and to maintain uniformity that Controllers in Indian Patent Offices give due weightage to such grants when applications relate to the same inventions and particularly, when they involve issues such as prejudice to human or plant health etc. and questions of law and policy issues are involved. There is no gainsaying that invention which is not considered harmful to human health in one country is hardly likely to be harmful in another country.

20. As per Article4quater of Paris Convention, grant of patent shall not be refused on the ground that sale of the patented product or a product obtained by means of a patented process is subject to restrictions or limitations under domestic law. Similar provision exists in Article 27(2) of TRIPS Agreement, which recites that members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is

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necessary to protect *ordre 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 and India is a member of both the Treaties. Article 51(c) of the Constitution of India provides that State shall endeavour to foster respect for international law and treaty obligations.

21. Heavy reliance by the Respondent in the impugned order on WHO Report on Global Tobacco Epidemic, 2021 is misconceived for various reasons. Firstly, claimed invention is not directed towards e-cigarettes, which form the focus of WHO report and secondly, both Paris Convention and TRIPS Agreement direct that patentability of an invention should not be refused based on restrictions under domestic law and India is member of both the Treaties. Respondent has decided the objection under Section 3(b) influenced by the Government notification on ban of e-cigarette, overlooking that Patent Act is a complete Code and incorporates provisions for deciding patentability and Govt. policies/guidelines are not encompassed therein. Moreover, there is always a possibility of revocation of the ban in future and if that happens, refusal of the application at this stage will cause irreparable damage to the Appellant. Illustratively, before 01.01.2005, India was granting only process patent and not product patent, however, to safeguard the interests of the inventors, mailbox facility was provided and from 01.01.1995 to 01.01.2005 an application could be filed for a product patent which was subsequently examined post 01.01.2005 and those who comply with the requirements are being granted product patents. In any event, patent is a negative right and does not automatically give the patentee the right to use/sell the patented product or process or product by process, in

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India by virtue of Section 48 of the 1970 Act. Therefore, grant of patent at this stage will only confer a right on the Appellant to prevent third parties from using the invention without its permission. Instances are replete where IPO has granted patents in similar fields relating to smoking articles, wrapper material over a tobacco smoking material including nicotine and traditional cigarettes, but this factor also has been overlooked in the impugned order.

Submissions on behalf of the Respondent:

22. There is no infirmity in the impugned order, refusing the patent application under Section 15 of 1970 Act on grounds of lack of inventive step under Section 2(1)(ja) and non-patentability under Section 3(b) and (e). Impugned order is a speaking and well-reasoned order and reflects careful consideration of claims specifications, claims, FER and its reply as also arguments of the Appellant, both oral and written. All objections and their responses have been carefully analysed in accordance with applicable provisions of 1970 Act. Appellant's invention relates to specific composition of an aerosol-forming substrate which is the consumable component designed for use in an aerosol-generating system as defined in Claim 14 such as a heat-not-burn device. The core of the invention (Claim 1) is a specific admixture comprising: (a) cellulose and/or cellulose derivatives; (b) an aerosol-former; (c) nitrogen-containing nucleophilic compound such as an amino acid or urea; and (d) a disaccharide such as sucrose, all within specific and defined weight ranges.

23. Respondent's finding that claims 1-14 are obvious, is correct on a detailed and exhaustive analysis of prior arts D1-D3. Appellant's central claim of adding a disaccharide (sucrose) to a cellulosic material (tobacco-

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free or substantially tobacco-free) for use in an aerosol-generating system, is a combination of features which are fully taught and motivated by the prior arts. D1 discloses the core components, their functions and their advantageous effects, effectively anticipating the claimed invention. D1 discloses that '*many of these materials consist of a combustible material different from tobacco, e.g., cellulose, a cellulose ether or an oxidized cellulose*'. D1 also discloses '*a solid primary amino compound (equivalent to nitrogen-containing nucleophilic compound of the present invention)*', in amounts '*up to 5% of its weight*' and explicitly names '*urea, guanidine carbonate and lower amino acids*', the very class of compounds and particularly, the specific compound urea, claimed by the Appellant. Further, D1 discloses the same advantageous effects and ameliorates or even completely eliminates the smoke, which is an irritant or has a bad odour. Humectants such as butylene, glycol, glycerol and propylene glycol are also disclosed in D1 and in Example 11, it discloses 'tobacco casing' as a flavoring ingredient including sugars, inverted sugars and gums.

24. Appellant's contention that sucrose is not equivalent to 'inverted sugar' in D1 is without merit. The invention as per Claim 1 is an aerosol-forming substrate and as per Claim 14, the system involves heating this material to elevated temperatures to generate aerosol. Invert sugar results from hydrolysis of sucrose into glucose and fructose and does not require any aqueous media and the claimed high temperature combustion/heating conditions is enough to dry the thermal breakdown of sucrose into glucose and fructose. Therefore, under the claimed operating conditions, Appellant's sucrose inherently forms a composition which is functionally and chemically indistinguishable from the invert sugar taught in D1.

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25. Prior arts D2-D3 also make the invention obvious. D2 discusses a successful tobacco substitute product, which has substantially lower amount of undesirable components than tobacco smoke and provides a flavour impact and combustion rate acceptably similar to tobacco. Similarly, D3 discloses an aerosol delivery device with a heater configured to vaporize the liquid aerosol precursor composition and demonstrably all components in the solid composition are known and obvious for person skilled in the art to mix together.

26. Respondent's finding on non-patentability under Section 3(e) is also correct inasmuch as the provision bars patenting a substance obtained by mere admixture of ingredients and exception requires a synergistic effect, which the Appellant has failed to demonstrate. Appellant's entire argument of synergy rests on the data presented in Figure 4, which purportedly shows that addition of disaccharide results in delayed release of the aerosol-former (glycerine). Respondent correctly identified in his analysis of this data that far from proving synergy, it proves that the observed effect is predictable and non-inventive. Respondent notes that the graph denotes the release of glycerine from an aerosol-generating article containing 58 weight percent cellulose, 35 weight percent glycerine, 4 weight percent carboxy methyl cellulose and 3 weight percent cellulose fibers. Respondent has clearly highlighted the flaw in Appellant's experiment. Appellant has replaced the cellulose content with sucrose with respect to wt% and after examining, Respondent rightly deduced that the change in aerosol release was not due to any synergistic interaction but a function of reduced cellulose, which is corroborated by Appellant's own Figure 1. The findings are thus unassailable and are based on the material on record.

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27. Grant of patent on the claimed invention is barred under the provisions of Section 3(b) and thus the objection was sustained. Claimed invention's primary and intended use is contrary to public order and causes serious prejudice to human health. The aerosol-generating device, heating element and heating chamber, unambiguously constitute an e-cigarette or heat-not-burn device and claims and specifications confirm the inclusion of addictive substances, with Claim 8 explicitly claiming nicotine as component 'f'. Furthermore, the prior arts and specifications establish that tobacco up to 5 wt% can be added, which is a significant and not a trivial amount. Respondent correctly notes that nicotine is one of the most addictive substances, owing to the rapidity at which it introduces into the body, age of first exposure etc. and the flavors and attractive designs allure the young population and addiction is a disease which affects morality of human beings and the objection is fully supported by the guidelines in the Patent Manual.

28. Appellant's argument that invention is a safer alternative is irrelevant to Section 3(b) and misleading. Aerosol-generated smoking may be less harmful compared to conventional cigarettes but is by no means harmless as it continues to pose health risks due to nicotine exposure and chemical constituents, even if there is no tobacco or nicotine is in small amounts. Appellant's reference to Article4quater of Paris Convention or Article 27 of TRIPS Agreement is misplaced and an attempt to seek exemption from national laws, which cannot be granted and Respondent has correctly decided the issue within the framework of applicable domestic law i.e. The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019

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('ENDS Act').

29. There is no violation of principles of natural justice as alleged. Appellant's argument on this aspect in fact, conflates two types of documents i.e., prior arts citations on novelty or inventive step, which must be cited in the FER or hearing notice and supporting documents used to rebut/place legal arguments and policy guidelines. Report on Economic Burden (Annexure-II) as also WHO Report (Annexure-III) are not prior art citations and were rightly taken into consideration at the time of taking a decision. The sole purpose of using Annexure-II was to illustrate, how the claimed invention, which relates to products that create significant public health and economic burden, does not meet the socially useful standard and has no technical or scientific bearing on the claims. Similarly, WHO Report was not used as a technical prior art but was only referred to show that Article4quater and Article 27(2) were irrelevant and to rebut the contention that these International Treaties prevent India from refusing a patent. The Report demonstrates the dangers of nicotine delivery products, which is a worldwide concern and not limited to India. WHO has in fact issued guidelines recommending a ban on production, manufacture, import, export, transport, sale, distribution etc., of such devices. The claimed invention is clearly injurious to public health and contrary to public order and hence, non-patentable under Section 3(b) and there is thus no legal infirmity in the impugned order, warranting interference in the present appeal.

30. Heard learned counsels for the parties and examined their rival submissions.

31. This appeal is filed by the Appellant challenging order dated 24.01.2025 passed by the Respondent refusing to grant patent in respect of

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invention titled "*Aerosol-Forming Substrate with Nitrogen-Containing Nucleophilic Compound*" in Patent Application No. 202217021141 on ground of lack of inventive step under Section 2(1)(ja) and non-patentability under Section 3(b) and (e) of 1970 Act.

32. The first ground raised by the Appellant that needs consideration is that three crucial documents *viz.* (a) Report of the Standing Committee of Parliament 'Review of Intellectual Property Rights Regime in India' in Rajya Sabha on 23.07.2021 (Annexure-I); (b) Report on 'Economic Burden of Tobacco Related Diseases in India' (Annexure-II); and (c) WHO Report on 'Global Tobacco Epidemic, 2021' (Annexure-III), were not notified to the Appellant either in the FER or in the hearing notice and were mentioned for the first time in the impugned order and hence, Appellant was deprived of an opportunity to rebut them or address arguments on these documents, which violates principles of natural justice. Respondent is unable to dispute the factual position but defends the action by asserting that these Reports were not used as prior arts but were only taken as reference points to make legal arguments or highlight policy guidelines.

33. Court finds merit in the submission of the Appellant. It is a settled law that no party can be condemned unheard and if the Respondent intended to rely on these documents, they should have been notified to the Appellant before taking the final decision, to enable the Appellant to deal with them. Impugned order reflects that these Reports have weighed heavily with the Respondent in upholding the objection under Section 3(b) and rejecting the submission of the Appellant on this aspect and thus ought to have been given to the Appellant prior to the decision or not relied upon and the defence that the documents were not prior arts cannot be accepted. In

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Otsuka Pharmaceutical Co. Ltd. v. Controller of Patents, 2022 SCC OnLine Del 4982, this Court has held that no person can be condemned unheard and all or any objection on which the Respondent wishes to place reliance, must be put to the applicant at the stage of issuance of FER/hearing notice. This position was affirmed in ***Perkinelmer Health Sciences Inc and Others v. Controller of Patents, 2023 SCC OnLine Del 8590***, wherein it was observed that no new grounds can be taken by the Controller/Examiner at the time of hearing and an applicant must be made aware of all objections before the hearing and afforded sufficient opportunity to contest. Similar view was taken by the Calcutta High Court in ***ITC Limited v. The Controller of Patents Designs and Trademark, MANU/WB/1167/2025***. Therefore, reliance on the three documents without giving opportunity to the Appellant to address arguments on them, violates principles of natural justice and is fatal.

34. On merits, I am of the view that Respondent has not taken into consideration several relevant and crucial submissions of the Appellant, which if considered may have led to a different conclusion. Claimed invention relates to an aerosol-forming substrate comprising one or both of cellulose and cellulose derivatives, where one or both are present in an amount of 15 weight percent to 85 weight percent on a dry weight basis; an aerosol-former; nitrogen-containing nucleophilic compound; and a disaccharide. Appellant asserts that cellulose or cellulose derivatives as an alternative to tobacco in an aerosol-generating substrate is known in the prior art, however, it was surprisingly found that aerosol-forming substrates not containing tobacco or those which are substantially-free of tobacco, may produce an aerosol having high concentration of aldehydes, particularly,

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formaldehyde and therefore, there was a need for reducing the formation of unwanted aldehydes by heating the substrate without burning. The other objective of the invention is to provide a mechanism for formation of stable and dense aerosol for a longer period of time. In other words, it is claimed that the solution in Claim 1 provides a composition where nitrogen-containing nucleophilic compound acts as aldehydes scavenger and use of disaccharide acts as medium to prolong release of aerosol-former for longer period of time even after 7 or 8 puffs. Respondent relied on three prior art documents D1-D3 and held that the claimed invention lacks inventive step under Section 2(1)(ja) of 1970 Act and relevant part of the order is as follows:-

> *"It has been observed that document D1 discloses that a large number of materials have been developed for use in making cigarettes, cigars and pipe tobacco, the materials being used to replace wholly or partly the nautral leaf tobacco usually employed. Many of these materials consist of a combustible material different from tobacco, e.g. cellulose, a cellulose ether or an oxidised cellulose. Further, Document D1 discloses an improved tobacco substitute for smoking, which substitute contains a quantity amounting up to 5% of its weight of a solid primary amino compound (equivalent to nitrogen-containing nucleophilic compound of the present invention) composed entirely of carbon, hydrogen, nitrogen and oxygen and decomposing under the action of heat at a temperature below its boiling point. Further, Document D1 discloses that the presence of the amino compound in the tobacco substitute has several advantageous effects. For example, where the substitute is one found to give smoke which is irritant or of an odour which is not generally acceptable the amino compound ameliorates or even completely eliminates these effects. An important effect of the amino compound is to increase nicotine impact so that a smaller quantity of nicotine can be used in a tobacco substitute than would otherwise be necessary to make the substitute acceptable. Document D1 also discloses some of the preferred amino compounds comprise no more than three amino groups in an aliphatic organic structure containing up to ten carbon atoms. Compounds of this type which have been found to be particularly satisfactory are urea, guanidine carbonate and lower amino acids.*
>
> *In order to this, in response to applicant submission that D1 does not disclose or teach use of a disaccharide. Further, compounds such as*

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glycerin are only use humectants in D1. D1 does not discuss or envisage any interactions between the humectants and disaccharides. While, Document D1 also discloses a "tobacco casing" as a flavouring ingredients including sugars, inverted sugars (equivalent to disaccharides as disclosed in the present invention i.e sucrose) and gums (Example 11). Further, Example 11 clearly discloses the impact of the humectant and disaccharides i.e sugar or inverted sugars which are equivalent to sucrose of the present invention. Document D1 also discloses butylene glycol, glycerol and propylene glycol containing a combustible substrate.

In view of the cited document D2, It has been observed that D2 discuss a successful tobacco substitute product which has a substantially lower amount of undesirable components than tobacco smoke, provide a flavor impact and combustion rate that is acceptably similar to that of tobacco.

Document D3 discloses an aerosol delivery device comprising: a reservoir including a liquid aerosol precursor composition; a heater in fluid communication with the reservoir and configured to vaporize the liquid aerosol precursor composition and subsequently form an aerosol; and a filter operatively arranged relative to the heater (e.g., an electrical heater) such that at least a portion of the formed aerosol passes therethrough, the filter being configured to bind selectively one or more target compounds. In some embodiments, the filter comprises cellulose-containing material and ion exchanged fibers. In some embodiments, the amount of cellulose-containing material in the filter ranges from about 1 to about 99% by weight based on the total weight of the filter. In some embodiments, the amount of ion exchanged fiber in the filter ranges from about 1 to about 99% by weight based on the total weight of the filter. In some embodiments, the cellulose-containing material comprises one or more of cellulose acetate, cellulose triacetate, cellulose propionate, cellulose acetate propionate, cellulose acetate butyrate, nitrocellulose, cellulose sulfate, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyethylmethyl cellulose, hydroxypropylmethyl cellulose, ethylhydroxyethyl cellulose, carboxymethyl cellulose, and regenerated cellulose fibers. In some embodiments, the cellulosecontaining material is cellulose acetate. In some embodiments, the ion exchanged fibers include nucleophilic functional groups selected from a primary amino group, a secondary amino group, a tertiary amino group, a hydrazine group, a benzenesulfonyl hydrazine group and combinations thereof. In some embodiments, the nucleophilic functional groups are a primary amine group or a secondary amine group. In some embodiments, the nucleophilic functional groups are present in the ion exchanged fibers in an amount ranging from about 0.5 mmol/g to about 5 mmol/g. In some embodiments, the nucleophilic functional groups are present in the ion exchanged fiber in an amount of at least 20% by weight based on the total weight of the ion exchanged fiber.

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In order to this, herein, it concluded that by teaching of the cited documents D1-D2, the composition disclosed in the present invention is obvious for person skill in the art. Hence, in view of the prior art documents D1, D2, and D3, adding a disaccharide such as sucrose, for the purpose of the aerosol generating system along with cellulosic materials (as a tobacco free or substantially free tobacco containing materials) is obvious for person skill in the art. Example 11 of the cited document D1 provided the impact of the disaccharides along with the humectants interaction. While the impact of the nucleaophilic compounds are clearly discloses the advantageous effect in the prior art document D1 as discloses in the present invention w.r.t. Figure 1-2. Hence, in view of the prior art documents, the subject matter of the amended claims 1-14 are still obvious for person skill in the art. So, the subject matter of the amended claims 1-14 lack inventive step u/s 2(1)j(a) of the patent act 1970 (as amended in 2005).”

35. From the aforesaid passages, it is evident that Respondent has not followed the procedure for determining inventive step in the claimed invention. In ***F. Hoffmann (Supra),*** Division Bench of this Court observed that the Controller must follow the five-step test, which includes identifying a person skilled in the art and then determining and analyzing the differences or similarities in the prior arts and features of claimed invention. Respondent has not identified the person skilled in the art and has in fact adopted a hindsight approach by cherry picking the components from the tobacco replacement material as taught in D1 and without any technical reasoning as to how and why a person skilled in the art would arrive at the claimed invention, come to a conclusion of obviousness. Thus, the impugned order is vitiated even on this ground, being contrary to the decisions in ***F. Hoffmann (Supra); Agriboard (Supra); Bristol-Myers (Supra)*** and ***Avery Dennison (Supra).***

36. Reliance on D1 by the Respondent as a prior art is questioned by the Appellant on multiple grounds. D1 relates to smoking materials, more particularly, with improvements therein, for use as substitute for tobacco

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prepared from natural leaf tobacco. D1 comprises a combustible substrate selected *inter alia* from alpha cellulose, oxidised cellulose etc. and naturally occurring plants gums and resins, nicotine as a salt and solid primary amine. Exemplary amino compounds are urea, glycine etc., however, D1 as per the Appellant does not disclose or teach use of a disaccharide and compounds such as glycerine are only used as humectants. It is also pointed out that D1 does not discuss or envisage any interaction between the humectants and disaccharides, which forms an essential technical component of the inventive step in the claimed invention. Appellant also points out that D1 is not an analogous art being directed towards conventional cigarettes as the composition is combustible, unlike the claimed invention, which is directed to be used in heat-not-burn device. Figure 4 in the claims specification depicts that adding a disaccharide such as sucrose results in delay of release of glycerine as an aerosol-former so that more glycerine is released at a later stage during use of the article. This relation between disaccharide and an aerosol-former is not suggested in D1. These submissions are not considered by the Respondent and had an important bearing on the decision. As rightly pointed by the Appellant, the reasoning appearing in the impugned order that D1 discloses a tobacco casing as a flavoring ingredient including sugars, inverted sugars and gums was not forthcoming either in the FER or the hearing notice inasmuch as in the FER, D1 was cited for teaching improvement in the flavor of the smoke of a tobacco substitute/reconstituted tobacco material and in the hearing notice, an assumption was raised that thermally degraded cellulose may also degrade to disaccharides and hence, comparable to Claim 1. Therefore, Appellant had no opportunity to rebut this ground.

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37. Appellant is also right that in order to come to a conclusion of obviousness, Respondent ought to have found that each and every element of Claim 1 was disclosed in the prior arts and person skilled in the art had the motivation to combine them without reasonable expectation of success. Contrary to this principle, Respondent has essentially relied on Example 11 of D1 and applied hindsight approach, using subject application as a guide through the maze of prior arts. Example 11 has been extracted in the earlier part of the judgment and evidences that it teaches a tobacco replacement material consisting of 8 ingredients, one of which is a tobacco casing. Urea is also used for preparing the replacement material and as brought forth by the Appellant, Example 11 also involves use of significant amounts of '*burley tobacco dust*' and '*bright tobacco dust*', which means that there is significant amount of tobacco component, despite the objective of D1 being to provide a tobacco replacement material and hence, Respondent ought to have considered whether D1 was the apposite prior art or taught away from the claimed invention. Contrary to D1, claimed invention prioritizes a formulation, where aerosol is generated without relying on tobacco, potentially incorporating only nicotine and non-tobacco volatile flavors compounds. Appellant rightly questions that if Example 11 of D1 employs over five times the maximum allowable tobacco content, would a person skilled in the art seeking to develop a tobacco-free or substantially tobacco-free aerosol substrate would consider Example 11 as a relevant prior art and this question is unanswered in the impugned order.

38. Appellant also highlights that Example 11 does not disclose the identity of the humectant employed and Respondent has inferred that the humectant is glycerine based on Example 15 and lines 26 and 27 of D1,

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which states '*plasticizers and humectants, such as butylene glycol, glycerol and propylene glycol*' and on this assumption, erroneously conflated the humectant used in Example 11 with aerosol-former of the claimed invention. This contention is *prima facie* correct. Another glaring error in the findings of the Respondent is with respect to the impact of humectants and disaccharides i.e., sugars or inverted sugars in Example 11 of D1. Appellant seeks to bring out that Respondent has misunderstood the concept of inverted sugars in Example 11 as being equivalent to use of disaccharides and to bring home this point, reliance is placed on two authoritative texts used in India and internationally for decades for teaching organic chemistry. The argument is that disclosure of inverted sugar is not disclosure of sucrose and to this extent, Court agrees with the Appellant. It is well known in the art that inverted sugar is an equimolecular mixture of glucose and fructose, both of which are monosaccharides and not disaccharides. In fact, inverted sugar is not equivalent to sucrose but is a product of sucrose hydrolysis. Chemically, sucrose is a disaccharide composed of one molecule each of glucose and fructose linked by a glycosidic bond. When sucrose is hydrolyzed, through acid or enzyme action, it breaks down into glucose and fructose resulting in invert sugar. Respondent's finding is thus contrary to knowledge in organic chemistry and the authoritative texts in the books, Organic Chemistry by Morrison and Boyd and Organic Chemistry by I L Finar. Impugned order also lacks any reasoning or rationale as to why a person skilled in the art, equipped with teachings of D1 (Example 11), would exclude 'burley tobacco dust' and 'bright tobacco dust' and include specifically claimed percentage of sucrose along with aerosol-former such as glycerine to arrive at the aerosol-forming substrate in the claimed

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invention.

39. Another important issue flagged by the Appellant is that D1 contains urea and unlike in the claimed invention, there is no disclosure of nitrogen-containing nucleophilic compound which acts as a formaldehyde scavenger this distinction is relevant both for objection under Section 2(1)(ja) as also Section 3(e) of 1970 Act. It is Appellant's case that Figure 1 of claimed specification depicts data showing that upto 4 times more formaldehyde is released from non-tobacco containing aerosol-forming substrates and thus demonstrates that nitrogen containing nucleophilic compounds urea and lysine present in the aerosol, forming substrate of the subject application, react with formaldehyde by eliminating formaldehyde from the aerosol. Figure 2 depicts a column chart of formaldehyde detected in aerosol-generated from various aerosol-generating articles having a heating element at a temperature of 350ºC and shows that amount of formaldehyde in the aerosol could be reduced by 39% when including 1 weight percent of urea as a formaldehyde scavenger and that no formaldehyde could be detected in the aerosol of the aerosol generating article comprising 5% urea. Figure 3 shows presence of disaccharide, sucrose which increases the amount of formaldehyde, and the release of formaldehyde can be reduced or suppressed by including nitrogen containing nucleophilic compounds in the aerosol, forming substrate, as claimed in the subject invention. Column denoted with 30 shows that no formal de hide could be detected in the aerosol of the aerosol generating article including 56 weight percent cellulose, 35 weight percent glycerine, 2 weight percent as a nitrogen containing nucleophilic compound, 4 weight percent carboxy methyl cellulose, and 3 weight percent cellulose fibers. The disaccharide facilitates

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conduction of heat from an outside heating element into the aerosol forming substrate, possibly assisting in reliable formation of the aerosol, once the aerosol forming substrate is heated in a heating chamber by an outside element. Figure 4 shows that addition of sucrose results in delayed release of glycerine so that more glycerine is released at the latest stage beginning with puff 7 or 8. Therefore, as rightly pointed out by Appellant, Respondent has failed to appreciate the disclosures in Figures 1-4 and hence, appreciate the synergistic effect encompassed by claims 1 to 14 of the claimed invention.

40. Appellant has brought forth that even D2 which discloses a tobacco substitute smoking material comprising a polysaccharide as a combustible organic ingredient, does not disclose the use of disaccharide and provides no teaching to modify the tobacco substitute taught therein to arrive at the claimed invention. D3 discloses aerosol delivery devices, methods of forming such devices and elements of such devices. Various embodiments of D3 such as the filter comprising cellulose containing material, the ion exchange fibers including nucleophilic functional groups, do not motivate, according to the Appellant, a person skilled in the art to modify the aerosol delivery device disclosed therein to include an aerosol-forming substrate claimed in the invention and again is silent on the use of disaccharide. It also does not disclose or anticipate that adding a disaccharide result in delay of release of aerosol-formers like glycerine. These issues brought forth by the Appellant have not received any consideration by the Respondent.

41. It is trite that to establish obviousness, the prior art references must suggest or teach all elements/limitations in the claimed invention and the teachings or motivations must be either in the references or in the knowledge generally available to one who is ordinarily skilled in the art so

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that the teachings could be modified or combined and merely citing references is not enough to establish obviousness and importantly, there must be a reasonable expectation of success. Impugned order fails to demonstrate how prior arts D1-D3 either alone or in combination, disclose the specific combination of components of aerosol-forming substrates in the Claims of the subject application and also do not envisage the advantageous technical effect in terms of providing an aerosol-forming substrate, which is substantially-free of tobacco and capable of delaying the release of aerosol-former such as glycerine and completely lacks in dealing with the argument of the nitrogen-containing nucleophilic compound acting as a formaldehyde scavenger. *Sans* consideration of all these issues, conclusions drawn by the Respondent under Section 2(1)(ja) as also Section 3(e) cannot sustain.

42. There is another aspect in the context of prior arts D1 and D2. D1 was published on 05.01.1974 and D2 on 01.04.1980 and the argument of the Appellant is that even otherwise being very old prior art documents, D1 and D2 were wrongly relied upon by the Respondent. In ***Societe Des (Supra),*** as also the earlier decision in ***Avery Dennison (Supra),*** this Court has held that age of the prior art cited is a relevant consideration for determining if the subject matter of the patent application would be obvious to the person skilled in the art or not. The fact that a piece of prior art has been available for a long time may indicate, contrary to the first impression, that it was not obvious to make the patented development from it. Relevant passages from the judgment in ***Societe Des (Supra)*** are as follows:-

> *"**64.** In terms of the decision of a Coordinate Bench of this Court in Avery Dennison Corporation v. Controller of Patents and Designs, 202/DHC/004697, the age of the prior art cited is a relevant consideration for determining if the subject matter of the Patent Application would be obvious to a person skilled in the art or not. The*

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relevant portion of the said judgment is as follows:

> *36. One of the sure tests in analysing the existence of inventive step would also be the time gap between the prior art document and the invention under consideration. If a long time has passed since the prior art was published and a simple change resulted in unpredictable advantages which no one had thought of for a long time, the Court would tilt in favour of holding that the invention is not obvious.*
>
> *37. Terrel on Law of Patents (16th Edition) opines that the age of the prior art and why it was not done before is one of the factors to be considered while deciding on obviousness. The observations made in the judgment Brugger v. Medic-Aid Ltd., [1996] R.P.C. 635 delivered by the UK Patents Court has been cited to substantiate the consideration of this factor. The relevant portion reads:*
>
> > *"The fact that a piece of prior art has been available for a long time may indicate, contrary to first impressions, that it was not obvious to make the patented development from it. It is useful to bear in mind in this regard the concept of long felt want. This is a particularly efficient expression. An apparently minor development which meets a long felt want may be shown to be non-obvious because, although the prior art has long been available, the development was not hit upon by others notwithstanding that there was a need for improvement (the 'want') and an appreciation of that need (the 'felt'). In other words the age of prior art may be an indication that a development from it is not obvious if it can be shown that the circumstances in the relevant trade were such that a failure of the development to appear earlier is surprising."*

65. *In the present case, the prior arts cited are having priority dates in the year 1995 whereas the present patent application has been filed with a priority date of 1st June, 2016. Thus, the prior arts cited are more than 20 years older than the subject Patent Application. Therefore, in my view, when the subject matter of the patent application is showing technical advancement over the cited prior arts, and when the cited prior arts are considerably old, it is a clear indicator of non-obviousness.*

66. *It is pertinent to note that the prior arts cited by the Indian Patent Office are the same as that were cited by the European Patent Office (EPO) when the corresponding European (EU) patent application was being prosecuted. The said EP patent application was granted vide publication EP3463332B1, dated 21st April, 2021. This, in my view, would also be a persuasive argument in support of the grant of the Indian Patent Application, especially when the same prior art has been cited.*

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> ***67.*** *Accordingly, the subject Patent Application satisfies the criteria of inventive step as the inventive concept of the subject patent application is a technical advancement over the prior art and is not obvious to a person skilled in the art."*

43. This crucial aspect has also been completely overlooked by the Respondent and dents the impugned order. Insofar as D3 is concerned, in the ultimate analysis and decision, Respondent has not relied on prior art D3 and therefore, this need not detain the Court.

44. Coming to the objection under Section 3(b) of 1970 Act, as noted above, Respondent has relied on three reports, which were neither a part of the FER nor the hearing notice and this is a glaring fallacy in the order. Appellant's grievance is that Respondent has completely misinterpreted Section 3(b) of 1970 Act and applicability of ENDS Act and was merely influenced by the fact that invention relates to aerosol-generating device or use of tobacco or nicotine. Legislative intent behind Section 3(b) was to increase the threshold for an invention to be refused as being non-patentable under Section 3(b), the primary or intended use of which may cause prejudice or injury to human health. Expression 'serious prejudice' is not defined in 1970 Act and dictionary meaning connotes something which will cause grave and serious prejudice. The argument is that to refuse an application, Respondent will have to examine whether serious prejudice is caused to human, animal or plant life or to the environment in the backdrop of scientific analysis and not on preconceived notion related to use of tobacco or nicotine.

45. Court finds merit in the argument that the Legislative intent behind Section 3(b) is to increase the threshold for granting patent on a claimed invention, which may be intended to cause prejudice or injury to human

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health. But, as rightly flagged by counsel for the Appellant, this analysis must be real with scientific basis and must come forth from the impugned order. Merely because the claimed invention relates to an aerosol-generating substance or device or use of tobacco or nicotine cannot *per se* be a ground to deny grant of patent. Appellant had urged before the Respondent that 1970 Act, nowhere mentions that the examination of patentability of an invention will be decided based on government policies and guidelines or any other Statute, save and except, in Section 4 which relates to the invention in the field of atomic energy and that there is no provision in the Indian Patents Act which bars patentability of an e-cigarettes or aerosol generating devices or invention directed to reducing the harmful effect of cigarette and thus, the refusal of the inventions on any other ground is unjustified. Appellant also argued that "electronic cigarette" is defined in ENDS Act to mean an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and the like devices, by whatever name called and whatever shape, size or form it may have, but does not include any product licensed under the Drugs and Cosmetics Act, 1940 ('1940 Act') and that there is no blanket ban even on electronic cigarettes and hence, even before the Appellant applies for a license under 1940 Act, refusing the grant of the Patent Applications in the garb of blanket ban on e-cigarettes in India is misplaced. Also that refusing grant of the invention on threshold under Section 3(b) is antithesis to technological research and progression in the field of Tobacco industry. The prime-most object of the patent system is to give a fillip and impetus for the betterment of industrial techniques in

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consideration of monopoly for limited years. Appellant illustrates technological progression in the field of tobacco industry and submits that because of the research in the field of tobacco industry various innovations have come to the public for better good. For example, invent of filter in conventional cigarette has substantially reduced the amount of smoke inhaled by a user or invent of heat not burn devices have reduced levels of harmful chemicals compared to smoke. Heat-not-Burn devices represent a major technological leap by incorporating complex electronic components and the invention may be around power source, heating system, sensors and controls etc. Therefore, Appellant is right that refusing the grant of patent, without appreciating the contribution of that invention and how it causes serious prejudice will definitely put an embargo on further development in the tobacco industry and the consumer, as a whole, will not be benefited with the research on the invention which reduces harmful effect of conventional cigarette. It was also rightly flagged that aerosol forming devices may or may not use tobacco or tobacco products, still they are beneficial to human health compared to conventional smoking cigarettes or e-cigarettes. Cigarette smoking increases the risk of chronic diseases, but heating instead of burning tobacco can lower these risks, contributing to tobacco harm reduction and therefore to deny grant of patent merely because the invention involves tobacco or nicotine, may not be a correct path to follow.

46. There is also merit in the contention that Respondent should not be oblivious of the fact that the some of these inventions have been approved for grant of patent in other jurisdictions *albeit* it is correct that decisions in other jurisdictions may not bind the Respondent. This is particularly

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important when the objection to the grant of patent relates to harmful effects of claimed inventions on human health or life. Appellant rightly urges that if an invention has been patented in one jurisdiction, it has crossed the threshold of being an invention which can primarily intend to cause harm to human health. No doubt, it is open to the Respondent to make an independent analysis and if there is substantial cogent material to hold otherwise, Respondent can refuse the application but only after the material is brought on record with an opportunity to the applicant to contest the same and then a reasoned order is passed, indicating how the invention is intended to cause harm. Unfortunately, this exercise is completely lacking in the impugned order and Respondent has rejected the application under the influence of a singular fact that invention pertains to aerosol-generating substrate/device and/or use of tobacco or nicotine by classifying the invention as covered under the ENDS Act and the bar imposed by the Government of India therein on e-cigarettes. In this context, I may refer to the following observations of the Calcutta High Court in ***ITC Limited (Supra)***:-

> *"6. Section 3(b) of the Act is set out below:*
>
> > *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;*
>
> *7. One of the objects of the Act is to promote the progress of scientific research and technology in public interest. This object is achieved by granting exclusive rights to inventors over their invention for a specific period of time. With the lapse of this period, the invention enters the public domain. The role of the Patent Office as an administrative authority is vital in the grant or rejection of patents. The responsibility and the work which has to be performed by the Office cannot be undermined in*

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achieving the purpose and object of the Act.

8. Section 3(b) focuses on the "primary or intended use or commercial exploitation" of an invention. On a plain reading of the section, it is essential to identify the utility of the invention. An invention, the primary or intended use or commercial exploitation of which, would be contrary to public order or causes serious prejudice to human, animal, plant life or health or the environment is not patentable. In the impugned order, the Controller has fundamentally erred in his understanding of the invention. Though the invention works on substrates (either solid or in liquid form) which may or may not contain tobacco compounds, it is not predicated or limited to the substrate at all. The impugned order erroneously proceeds on the basis that the invention shall exclusively be only used with substrates comprising of active tobacco compounds and thus cause prejudice to human life and health.

9. Once the primary or intended use of the proposed invention is determined, the second question which arises is whether the primary or intended use is contrary to public order or to morality or causes serious prejudice to human, animal, plant life to health or to the environment. Despite the minor difference in scope and language, the expression order public in the Trade Related Aspects of Intellectual Protection of Industrial Property (TRIPs) can always be looked as guidance in interpreting the words "public order" in section 3(b). The origins of this can be traced to Article 53A of the European Patent Convention (EPC). In this context, the provisions of section 1(3) and section1(4) of the 1977 Act which is based upon Article 53(a) of the European Patent Convention (EPC) which in turn is based on 4quater of the Paris Convention can also be considered in interpreting section 3(b) of the Act. The Guidelines indicate the purpose of the provision is to deny protection to inventions likely to induce riot or public disorder or to lead to criminal or other generally offensive behaviour (Terrell on the Law of Patents, 19th Edition, at 2-130).

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11. In concluding that the invention causes serious prejudice to human life and health and is barred under section 3(b) of the Act, the Controller has not provided any reasons nor furnish any justification at all. Admittedly, tobacco products are not per se unpatentable in India. There must be a nexus between how the mind has been applied to the matters in issue and the conclusion based thereon. This is conspicuously absent in the impugned order. [Uniworth Resorts Ltd. vs. Ashok Mittal & Ors. MANU/WB/0254/2007 : (2008) 1 Cal LT 1]. In passing the impugned order, there has also been a complete disregard to the intent principle i.e. intent behind the appellant's invention and misplaced reliance on the affect or harm principle in arriving at such conclusion. [HARVARD/ Oncomouse (T19/90) [1990] O.J. EPO 476, PLANT GENETIC SYSTEMS/

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Glutamine Synthetase inhibitors (T356/93) [O.J. EPO 545], Howard Florey/Relaxin (1995) OJ EPO 388 and Harvard/Transgenic Animals, T 315/03 (2006) OJ EPO].

12. The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage, and Advertisement) Act, 2019, as a possible ground in rejecting the application for patent has not been considered in the impugned order. This Act deals with the sale, manufacture, import export and not with the grant or non-grant of patent for an invention (Unreported decision in IPDPTA No.121 of 2023 ITC Ltd. vs. The Controller of Patents, Designs & Trademark dated 30 April, 2025 High Court at Calcutta). Despite the above, the respondent had advanced submissions on this aspect of the matter notwithstanding the fact that this ground has neither been taken in the pleadings nor mentioned in the impugned order. In such circumstances, any submissions in respect of the above ground stands rejected. It is impermissible to support the impugned order on additional grounds which are not reflected in the impugned order.

13. There is also an inherent fallacy in the impugned order inasmuch as it proceeds on the basis that grant of a patent confers a consequential affirmative right to sell or commercialize the product. This is not the rationale behind seeking a patent. The grant of patents do not control whether or how an invention is exploited. The grant of a patent also does not confer upon the patentee the right to use, sell or otherwise manufacture the subject invention. Historically, patent rights have been treated as exclusionary rights or negative rights inasmuch as they only gives the patentee the right to prevent third parties from manufacturing the subject invention. In an unreported decision in R J Reynolds Tobacco Company vs. The Controller Of Patents, Designs And Trademark, IPDPTA 31 of 2023, dated 16 April 2025, this Court inter alia, held as follows:

> *"It has been a longstanding principle of patent law that patents should not be granted for immoral inventions. On a plain reading, section 3(b) focuses on the primary or intended use or commercial exploitation of an invention. The underlying interest being ethical considerations. In similar context, Article 53(a) of the EPC 2000 provides that European patents 'shall not be granted in respect of inventions, the commercial exploitation of which would be "contrary to public order or morality".*
>
> *In the 161st Report of the Parliamentary Standing Committee on Commerce, in section 12.1(i), it has been observed that;*
>
> *"It was informed that section 3(b) of the Patents Act, 1970 prohibits patenting of technology, use or application at the sole discretion of the Controller if found by him to be 'contrary to public order or morality*

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or which causes serious prejudice to human, animal or plant life or health or to the environment'. Hence, the widely worded provision of Section 3 (b) is without any sufficient guidance or safeguards against arbitrary exercise of power by the Controller. It, therefore, may lead to refusal of socially useful inventions under patent protection. For example, nicotine chewing gums, which are used for dead diction to smoking, are denied patent on the ground of section 3(b). Furthermore, smoking devices which make smoking less hazardous are denied patents in India. It was suggested that that the provision should be amended wherein patents are not granted to inventions that are considered as against the law being in force. The Committee recommends the Department that the Section 3(b) of Indian Patent Act, 1970 should be amended so that a provision of a safeguard mechanism is included against the arbitrary exercise of power by the Controller in declining patents. A check and balance mechanism should be inserted under the Act which would ensure granting of patents to socially useful inventions or innovations. It, however, recommends that the provision be amended to limit the exclusion to only those inventions which are barred under any law for the time being in force."

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15. The preconceived and subjective notion that all tobacco products causes serious prejudice to human life and health without any reliance on scientific or technical evidence or any other supporting facts is unsustainable.

16. The finding that the subject invention is contrary to public order and morality is unreasoned, cryptic and without any basis. The fact that the Controller was of the view without consideration of any independent scientific or technical evidence that the usage of the invention affects public order and morality cannot be the basis for rejecting the invention. The interaction of patent laws and ethics is an uncomfortable relationship and has always produced difficulties. In such circumstance, section 3(b) ought not to be interpreted to deal with all subjective concerns of morality, public order or health regardless of any scientific or technical evidence or any cogent reasoning.

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18. In view of the above, the impugned order is unsustainable and set aside. The matter is remanded back to the Controller to decide the same afresh in accordance with law after giving a right of hearing of all the parties within a period of three months from the date of communication of this order. It is made clear that there has been no expression on the merits of the case and all questions are left open to be adjudicated upon by the Controller.""

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47. The same view has been taken by another Bench of the Calcutta High Court in ***ITC Limited v. The Controller of Patents, Designs & Trademark, MANU/WB/0990/2025***. This judgment is also relevant as it deals with the other contention of the Appellant based on Article 4quarter of Paris Convention and TRIPS Agreement. After noticing the two documents, Calcutta High Court has held that grant of patent should not be refused on the ground that sale of patented product or of a product obtained by means of a patented process is subject to restrictions and limitations resulting from the domestic law. Relevant passages are as follows:-

> *"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:*



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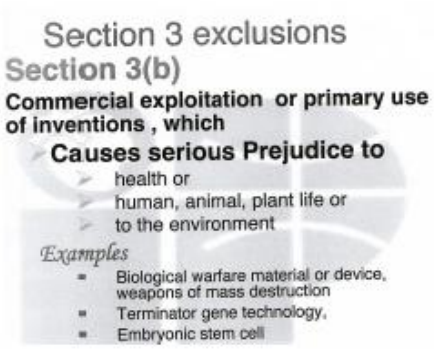

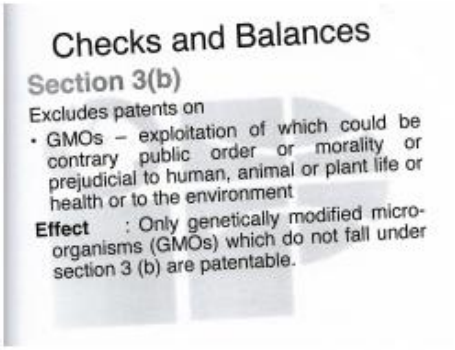

In none of the examples provided above discussing Section 3(b) exclusions mention tobacco, smoking or nicotine or inventions relating thereto. In the "Patents Manual" does not include tobacco/smoking/ nicotine related inventions at the time of giving examples of inventions that fall within the ambit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

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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.""*

48. In the judgment in ***R J Reynolds Tobacco Company v. The Controller General of Patents Designs and Trademarks and Anr, IPDPTA/31/2023***, decided on 16.04.2025, Calcutta High Court while dealing with rejection of a patent application on ground of Section 3(b) observed as follows:-

> *"A perusal of the impugned order demonstrates that there are no reasons in rejecting the subject application. The order proceeds on a preconceived notion that tobacco products are seriously harmful to human health. There is no other reason at all. The respondent Controller has not even dealt with either any of the evidence produced by the petitioner before the authorities or even discussed the subject invention. Despite the appellant having furnished a list of patents granted by the Indian Patent Office in respect of similar products, the respondent has neither dealt nor*

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considered the same. The fact that the subject invention causes serious prejudice to human health is a conclusion without any evidence at all.

It has been a longstanding principle of patent law that patents should not be granted for immoral inventions. On a plain reading, section 3(b) focuses on the primary or intended use or commercial exploitation of an invention. The underlying interest being ethical considerations. In similar context, Article 53(a) of the EPC 2000 provides that European patents 'shall not be granted in respect of inventions, the commercial exploitation of which would be "contrary to public order or morality".

In the 161st Report of the Parliamentary Standing Committee on Commerce, in section 12.1(i), it has been observed that;

> *"It was informed that section 3(b) of the Patents Act, 1970 prohibits patenting of technology, use or application at the sole discretion of the Controller if found by him to 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 widely worded provision of Section 3 (b) is without any sufficient guidance or safeguards against arbitrary exercise of power by the Controller. It, therefore, may lead to refusal of socially useful inventions under patent protection. For example, nicotine chewing gums, which are used for deaddiction to smoking, are denied patent on the ground of section 3(b). Furthermore, smoking devices which make smoking less hazardous are denied patents in India.*
>
> *It was suggested that that the provision should be amended wherein patents are not granted to inventions that are considered as against the law being in force. The Committee recommends the Department that the Section 3(b) of Indian Patent Act, 1970 should be amended so that a provision of a safeguard mechanism is included against the arbitrary exercise of power by the Controller in declining patents. A check and balance mechanism should be inserted under the Act which would ensure granting of patents to socially useful inventions or innovations. <u>It, however, recommends that the provision be amended to limit the exclusion to only those inventions which are barred under any law for the time being in force.</u>"*

The finding of the Controller that in his opinion, "it is obvious that tobacco products cause serious prejudice to human health" is unsubstantiated and bereft of any reasons. [Kabushiki Kaisha Toshiba vs. Asstt. Controller of Patents and Designs C.A. (Comm.IPD-PAT) 210/2022, Agriboard International LLC vs. Deputy Controller of Patents and Designs C.A. (Comm.IPD-PAT) 4/2022 and Alfred Von Schukmann vs. the Controller General of Patents, Designs and Trademarks and Ors.].

The finding that the process claimed by the present invention is seriously prejudicial to the human health is also unreasoned. There has been no

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independent application of mind insofar as the evidence or materials relied on by the appellant. The subjectivity of the Assistant Controller is written large in the impugned order without any reasoning or consideration of the scientific evidence or data relied on by the appellant.

In view of the above, the impugned order is unsustainable and is set aside. The matter is remanded to the Controller to have the subject application decided afresh within a period of four months from the date of communication of this order. It is made clear that there has been no adjudication on the merits of the case and all questions are left open to be decided in accordance with law.""

49. Thus, there is also merit in the contention that India being member of the Treaties, Respondent was obliged to consider the Paris Convention and TRIPS Agreement instead of being solely influenced by the ENDS Act. Respondent has also overlooked the two important issues raised by the Appellant, which needed consideration i.e., policies and provisions of law are constantly changing and evolving and there is every chance that the prohibition under ENDS Act may be completely or partly lifted in future and that patent is a negative right which does not automatically permit the patentee to use/sell the patented product or process and only entitles to prevent a third-party from using the invention without permission.

50. Appellant is also right that Respondent has refused the application because invention uses nicotine or tobacco, overlooking that there are many NRTs approved for quitting smoking in which nicotine is an active ingredient. Appellant also flags that nicotine patches, gums, lozenges are most common quit-smoking medicines. Ministry of Health and Family Welfare has included NRT in the national list of essential medicines for disorders due to psychoactive substance abuse. Nicotine powder is a pharmaceutically acceptable nicotine salt or nicotine salt hydrate and it is disclosed by way of an example that nicotine salicylate can be

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administered for fever relief and as an anti-inflammatory or pain killer or nicotine fumarate for treating multiple sclerosis, nicotine mono-pyruvate for treating chronic obstructive pulmonary disease (COPD) or for weight loss.

51. From a holistic perspective, this Court is of the view that the impugned order dated 24.01.2025 deserves to be set aside, owing to violation of principles of natural justice as also non-consideration of several crucial issues and documents referred to by the Appellant, as aforementioned, including consideration of D1 and D2, overlooking their dates of publication.

52. Accordingly, the appeal is partially allowed and impugned order dated 24.01.2025 is set aside. The matter is remanded back to the Respondent for consideration of Patent Application No. 202217021141 afresh. Decision shall be taken within five months from today, after granting an opportunity of hearing to the Appellant and considering all relevant issues raised and uninfluenced by the observations in this order or the impugned order.

53. It is made clear that this Court has not expressed any opinion on the merits of the case.

54. Appeal is disposed of in the aforesaid terms.

JYOTI SINGH, J

SEPTEMBER 9, 2026/AK

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