$~7

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

% *Date of Decision: 29th April, 2026*

\+ C.A.(COMM.IPD-PAT) 30/2025

VIB VZW & ANR. .....Appellants

Through: Mr. Sanuj Das and Ms. Aditi Subramaniam, Advocates.

versus

THE CONTROLLER OF PATENTS AND DESIGNS .....Respondent

Through: Ms. Arunima Dwivedi, CGSC with Ms. Himanshi Singh and Ms. Monalisha Pradhan, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J. (ORAL)

I.A. 17423/2025 *(Exemption)*

1. Allowed, subject to all just exceptions.

2. Application stands disposed of.

C.A.(COMM.IPD-PAT) 30/2025

3. This appeal is filed by the Appellants under Section 117A of The Patents Act, 1970 ('1970 Act') challenging impugned order dated 28.03.2025, whereby Respondent has refused to grant patent on Indian Application No. 201917035558 in favour of the Appellants.

4. To the extent necessary, the facts are that present invention relates to 'MEANS AND METHODS FOR ORAL PROTEIN DELIVERY'. European Priority Application No. 17158471.1 was filed on 28.02.2017 and PCT International Application No. PCT/EP2018/054966 (later published as

WO 2018/158335 A1) was filed on 28.02.2018 with a set of 17 claims. Indian Patent Application No. 201917035558 was filed as a National Phase Application out of PCT International Application on 04.09.2019. Request for Examination was filed by the Appellants on 16.11.2020 and First Examination Report ('FER') was issued on 18.10.2023, wherein Respondent raised objections of lack of novelty, lack of inventive step and non-patentability under Section 3(c), (d), (e) and (i) of the 1970 Act to which response was filed by the Appellants on 16.04.2024 with amended set of 10 claims. After hearing on 12.09.2024, Appellants filed post-hearing written submissions on 25.09.2024 along with amended set of 9 claims. By impugned order dated 28.03.2025, the Indian Patent Application was refused under Sections 2(1)(ja), 10(4)(a) and (c) and 10(5).

5. It is stated in the appeal that the present invention relates to Dried Formulations Comprising Culture Medium of Recombinant Yeast Host Secreting IgA Fc-Fused Recombinant Polypeptides and provides clear solutions for shortcomings of current oral delivery of therapeutic proteins. The invention concerns field of recombinant protein production in a host cell, more particularly, field of oral protein delivery. More specifically, invention provides oral pharmaceutical formulations comprising the culture medium of the recombinant host secreting a recombinant protein. The resulting oral pharmaceutical formulations are useful for treatment of gastro-intestinal and/or buccal disorders. Additionally, the oral pharmaceutical formulations are useful for prophylactic and vaccine purposes.

6. It is stated that peptides or proteins, including hormones, enzymes, ligands or inhibitors, including antibodies, regulate various cellular functions. Therefore, they are useful in the clinic to treat or prevent human

disorders by modulating physiological or pathological processes. In contrast to small-molecule drugs, the high selectivity of peptides or proteins to their targets may reduce side effects and toxicity to host cell. It is expected that the use of proteins or peptides for therapeutic purposes will continue to increase in the treatment of cancer, metabolic disorders, gastrointestinal diseases, buccal diseases, neurodegenerative and infectious diseases. Currently, protein drugs are largely manufactured using mammalian, plant, yeast or bacterial cell culture systems. These expressed proteins must be extracted and purified, which requires expensive and complex processes and cold storage and transportation. Biologies are generally delivered by intravenous or subcutaneous injection, which is effective but not desirable for patients, particularly, for chronic conditions. Injectable forms of protein drugs often require health care personnel for administration, resulting in frequent hospital visits and decreased patient compliance. Other routes of delivery such as transdermal, intranasal, inhalation and oral administration are under investigation, but oral delivery is generally considered as the most desired route.

7. It is further stated that despite decades of effort, oral delivery of peptides, proteins and antibody drugs remains a major pharmaceutical challenge with only a handful of such proteins in the market. The gastrointestinal (GI) tract is a hostile environment for polypeptides because it is evolutionarily optimized to break down nutrients and deactivate pathogens. While convenient for patients, there exist a number of technical barriers which make this route of administration challenging for large-molecule drugs. Certainly, the most important challenge is the enzymatic and pH-dependent degradation of drugs in the stomach and intestines. In

addition, there is the low permeability of epithelial cells that line the gastrointestinal (GI) tract and the intrinsic instability of these compounds. The highly acidic pH in the stomach results in protonation of proteins and their unfolding, which exposes more motifs that are recognized by protein-degrading enzymes. The enzymes in the stomach (pepsin), small intestines (e.g., chymotrypsin, amino- and carboxypeptidases) and the enzymes produced by the pancreas and bile, cleave the proteins into smaller fragments and single units. Because therapeutically active polypeptides (e.g., prophylactic, therapeutic of vaccine components) are also affected by these processes, the fraction surviving these degradation processes is generally low and variable, especially in the presence of food.

8. It is further stated that in addition, polypeptide drugs need to overcome multiple barriers designed to prevent the entry of dietary and bacterial antigens in order to reach the systemic compartment. To access the epithelial cell layer, the polypeptide first needs to diffuse through the mucus layer covering the intestinal epithelium. This epithelium is another important barrier as the tight junctions which seal the epithelial cells restrict the para-cellular transport (i.e., the passage between cells) to small molecules and ions smaller than 600 Da. In addition, the passage across the cell is mediated by luminally expressed endocytic receptors (e.g., vitamin B12 receptor, transferring receptor) and therefore necessitates conjugation to the respective ligands in order to be exploited in drug delivery. Yet another access point to the systemic compartment is the phagocytotic M-cells of Peyer's patches which sample luminal antigens and can take up particular substrates in the low micrometer range. However, the proportion of M-cells in the gut epithelium is small and varies greatly between species, which

complicates predictions of absorption in humans based on animal data.

9. Appellants submit that the invention seeks to overcome the technical problem that arises because plant production systems though capable of producing high amounts of recombinant proteins, owing to the lengthy and expensive regulatory procedures, would not be the best choice for producing edible vaccines. Lower eukaryotic organisms are more desirable as they are capable of producing higher amounts of recombinant proteins. It would be an advantage to use lower eukaryotic hosts such as yeasts for production of therapeutic proteins which can be orally delivered. It would also be desirable to be able to use only the culture medium comprising the secreted polypeptide instead of the recombinant yeast itself. Even more desirable it would be not to purify the therapeutic polypeptide from the culture medium and to use the culture medium as such.

10. Appellants claim that the invention provides clear solutions for shortcomings of the current oral delivery of therapeutic proteins. Invention involves a dried formulation obtained by drying the culture medium comprising a plurality of macromolecules larger than 5kDa of recombinant yeasts which secrete a therapeutic protein in the culture medium and which can be used for oral delivery of the dried formulation. Significantly, the formulation is not only protected by proteolysis and degradation in the gastrointestinal tract but the therapeutic proteins present in the dried formulation are also surprisingly biologically active. Further, at least one mechanism of the present invention is that yeast extracellular medium acts as a protected film around the therapeutic protein which prevents (or slows down) the proteolysis of the therapeutic protein in the gut. This is different from the situation wherein therapeutic proteins are expressed in plant seeds

wherein the dried seed matrix protects the therapeutic protein from degradation D8 - WO2014033313.

11. As stated, yet another possible mechanism is that the glycosylated therapeutic protein consists of (high) mannose sugar structures only. These bulky high-mannose structures might also protect the therapeutic peptide from proteolytic degradation in the gut. Figure 5 in the 'Summary' of invention depicts the bulky high-mannose glycosylation present on the V2A-IgAFc fusion produced in *Pichia pastoris* which recombinant protein is used in the present examples. Major advantage of the present invention is that there is no need for a purification of the therapeutic protein, meaning that a formulation comprising the medium as such or a dried formulation comprising multiple macromolecules larger than 5kDa present in the culture medium (including yeast produced own proteins) and the therapeutic protein present in the culture medium can be used as an oral pharmaceutical product. As brought forth, the pending claims were as follows:-

> *"1. A dried formulation obtained by i) subjecting the culture medium of a recombinant yeast host cell to a membrane separation process or a depth filtration process followed by ii) drying the culture medium obtained in step i) wherein the culture medium comprises a recombinant polypeptide fused to an IgA F c domain secreted into the culture medium by the recombinant yeast host cell and wherein the polypeptide is exogenous to the recombinant yeast host cell.*
>
> *2. The dried formulation as claimed in claim 1, wherein an oral admissible matrix is added to the separated or filtered medium prior to the drying.*
>
> *3. The dried formulation as claimed in claim 1 or 2, wherein the recombinant polypeptide is an immunoglobulin single variable domain.*
>
> *4. The dried formulation as claimed in any one of claims 1 to 3, wherein said exogenous peptide is a prophylactic or therapeutic peptide or wherein said exogenous peptide is a vaccine or forms part of a vaccine.*

5. The dried formulation as claimed in any one of claims 1 to 4, wherein the drying is carried out by spray-drying or by lyophilisation.

6. An oral pharmaceutical composition comprising a dried formulation as claimed in any one of claims 1 to 5 and a pharmaceutical excipient.

7. A food or feed product comprising a dried formulation as claimed in any one of claims 1 to 5.

8. The food or feed product as claimed in claim 7 which is a functional or medicinal food product.

9. The dried formulation as claimed in any one of claims 1 to 5 or a pharmaceutical composition as claimed in claim 6, wherein the polypeptide is an IL22 IgA Fc- fusion."

12. It is stated in the appeal that corresponding foreign applications of the present application have been granted patent in United States, Japan and Korea, where far more stringent examination and searches using state-of-art tools were conducted. However, Respondent has refused the application on the ground that the claimed invention lacks inventive step owing to cited prior art documents D1-D8 under Section 2(1)(ja) as also on the ground that amended claims 1-9 do not meet the requirements of Sections 10(4)(a) and (c) and 10(5) as the product-by-process claims 1-9 do not sufficiently define the invention and are not defining the scope of the product fully and particularly for which protection is sought. It is also held there is lack of clear characterization in the product and claimed formulation is devoid of technical features i.e., components of the composition. Respondent has further held that in the absence of SEQ ID numbers of the recombinant polypeptide used in the composition, claims seem vague and too broad. Judgments cited by the Appellants have been distinguished by observing that the way in which the product-by-process claims were framed in the said cases is totally different from the instant application.

13. Learned counsel for the Appellants submits that the impugned order is non-speaking and unreasoned and devoid of application of mind and is a verbatim reproduction of the hearing notice such that the objections listed therein have been cut-copy-pasted in the impugned order, without dealing with and analyzing Appellants' submissions. In response to the FER, Appellants reduced the claims to 10 and addressed each objection on merit, followed by detailed post-hearing written submissions, however, none of these submissions have been dealt with and thus, in light of the judgment of this Court in ***Boehringer Ingelheim Vetmedica GMBH v. Controller of Patents, 2024 SCC OnLine Del 8578,*** on ground of non-consideration of written submissions, the order deserves to be set aside.

14. Another glaring illegality in the impugned order is that the application has been refused on the ground that the source and geographical origin of biological material has not been disclosed under Section 10(4)(ii)(D). This finding is perverse on the face of the record inasmuch as in reply to FER dated 16.04.2024, Appellants expressly stated that the origin (source) of the biological material is 'van Belgium' and confirmed that the material was not sourced from India. In post-hearing written submissions dated 25.09.2024, the origin was again confirmed. Despite two unequivocal disclosures, Respondent persisted with the objection and has failed to give any reason why the disclosure by the Appellants was considered as a non-disclosure or inadequate disclosure.

15. It is further urged that Respondent has erroneously refused the application on ground of lack of inventive step owing to cited prior arts D1-D8, holding that the claimed invention is obvious to the person skilled in the art due to lack of technical features. Respondent has failed to identify a

single document as closest prior art and has not detailed or explained the difference between the alleged closest prior art and the claims of the invention. ***[Ref.: Fresenius Kabi Oncology Limited, An Indian Company of B-310, Som Datt Chambers-1, Bhikaji Cama Place, New Delhi-110066, India v. Glaxo Group Limited, A Company incorporated in England of Glaxo Welcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, England and Another, 2013 SCC OnLine IPAB 122].*** In fact, Respondent has also failed to identify person skilled in the art, which is the first-step required to be followed as per the judgment of the Division Bench of this Court in ***F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2015 SCC OnLine Del 13619***, wherein a five-step test was laid down which the Controller is required to follow while determining whether a claimed invention lacks inventive step or not. This position of law was reiterated in ***Tapas Chatterjee v. Assistant Controller of Patents and Designs and Another, 2025 SCC OnLine Del 6369*** by another Division Bench of this Court.

16. It is urged that Respondent does not explain why a person skilled in the art would combine D1-D8 to arrive at: (a) membrane filtration of yeast culture medium, followed by (b) drying the unpurified medium, to yield (c) an orally deliverable dried formulation with protective matrix effect. Several cited documents related to purified proteins or plant-seed-based system, however, they are structurally and functionally distinct from the claimed formulation. The complete specification demonstrates that *Pichia*-derived dried culture medium formulation is superior to plant-derived compositions in clearing F4+ETEC infection and this constitutes objective evidence of non-obviousness, which the Respondent completely failed to address and

wrongly held that the instant application does not provide any technical advancement in comparison to the cited documents.

17. It is urged that product-by-process claims are recognized and permissible under Indian patent law being sub-species of product claims, employed where the product's distinguishing characteristics arises and cannot be described adequately without reference to the process of manufacture. Such a claim is necessarily directed to a novel and inventive product, which cannot be fully described by its structure and is an amalgam between product and process patents *per se*. Respondent's finding that *'the claimed dried formulation is not defined by its composition, rather defined in terms of obtaining the composition'* is fundamentally flawed and fails to appreciate this claim format since Appellants are prosecuting a product-by-process claim as it is not possible to define the formulation in terms of the composition. Respondent acknowledges novelty and therefore, an adverse finding of non-patentability solely on the basis that product is not defined by its composition is illegal.

18. It is argued that Respondent's findings on lack of clarity, definitiveness and sufficiency of disclosure are patently illegal. While rendering a finding that amended claims 1-9 do not meet the requirement of Sections 10(4)(a) and (c) and 10(5) as the product-by-process claims do not sufficiently define the invention and scope of the product fully and particularly for which protection is sought, Respondent has simply copy-pasted the objection from the hearing notice and has not considered a single submission of the Appellants on this aspect. Appellants had submitted that 'Fc domain' in claim 1 has been particularly identified as 'IgA Fc domain'; fungal cell in claim 1 is particularly identified as yeast cell; and claims of

the present application are sufficiently disclosed in and are technically supported by the specification and functionality and structural characteristics of dried formulation are sufficiently clear from the description and claims and would not pose any difficulty to a skilled person. The observation that SEQ IDs are absent and in absence of SEQ IDs numbers of the recombinant polypeptide used in the composition, the claims seem vague and broad, is misplaced. The inventive feature is not the identity of the specific polypeptide, but the dried yeast culture medium formulation and its unexpected protective matrix effect is. On the aspect of lack of clarity and insufficiency, Respondent has merely pasted the objections from the hearing notice without a single observation on Appellants' detailed submissions explaining: (i) the IgA Fc domain identification; (ii) the yeast host system; (iii) the working examples and in vivo data; and (iv) how a skilled person could practice the invention across the claimed scope without undue experimentation.

19. Ms. Arunima Dwivedi, learned CGSC appearing for the Respondent defends the impugned order and submits that the order is reasoned and speaking and the application has been refused after considering the reply of the Appellants to the FER and the written submissions as also provisions of 1970 Act. Hearing was granted to the Appellants to explain the objections raised and there are no violations of principles of natural justice. Respondent has rightly held that the claimed invention as seen from the amended claims lacks inventive step owing to prior arts D1-D8 and the invention is very much obvious to the person skilled in the art. D1-D5 disclose a dried formulation, for example spray-dried or lyophilized, comprising a plurality of macromolecules used for example as a medicament or as part of a food

product. D6 discloses a dried lyophilized pharmaceutical composition comprising IL-6 antibody produced and secreted by yeast (Pichia) as Fc-fusion, for oral administration. D7 discloses a lyophilized formulation containing IL22-Fc fusion molecules and therefore, all features of the claimed invention, inspite of lacking technical features are obvious from prior arts D1-D8. Respondent found that the Appellants have not provided any technical advancement over the cited documents but claimed that anti-ETEC (VHH)-IgA Fc fusions have a superior effect of clearing an F4+ETEC infection, which is refuted from the teachings of D8. Moreover, from the prior arts, it is known that Fc-fusion proteins are bioengineered polypeptides that join the crystallizable fragment domain of antibody with another biological active protein domain or peptide to generate a molecule with unique structure-properties and significant therapeutic potential.

20. It is argued that amended claims 1-9 do not meet the requirements of Sections 10(4)(a) and (c) and 10(5) as these are product-by-process claims and do not define the scope of the product fully and particularly for which protection is sought. In the absence of SEQ ID numbers of the recombinant polypeptide used in the composition, the claims seem vague and too broad. Hence, it is urged that there is no merit in the appeal and the same be dismissed.

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

22. Present patent application relates to an invention titled ‘MEANS AND METHODS FOR ORAL PROTEIN DELIVERY’ and was filed as national phase application. When FER was issued, objections were raised by the Patent Office on lack of novelty, lack of inventive step and non-

patentability under Section 3(c), (d), (e) and (i) of 1970 Act. Appellants filed response to the FER contesting the objections followed by detailed post-hearing written submissions. Respondent has refused the application under Section 15 of 1970 Act holding that substantive requirements of Sections 2(1)(ja) and 10(4)(a) and (c) and 10(5) have not been met. Appellants have also failed to disclose the source and geographical origin of the biological material used in the invention and if the biological material was used from India, then permission from the competent authority i.e., National Biodiversity Authority, India should have been submitted.

23. Appellants assert that present invention relates to the field of recombinant protein production in a host cell, more specifically, field of oral protein delivery and provides oral pharmaceutical formulations comprising the culture medium of a recombinant host secreting a recombinant protein and resulting oral formulations are useful for treating GI and/or buccal disorders as also for prophylactic and vaccine purposes. It is claimed that prior to the present invention plant-seed-produced antibodies survived the gastric canal and were biologically active in the intestine. Plant production systems though capable of producing high amounts of recombinant proteins would not be the best choice for producing edible vaccines, however, owing to lengthy and expensive regulatory procedures and lower eukaryotic organisms are more desirable as they produce higher amounts of recombinant proteins. Thus, the present invention provides clear solutions for the shortcomings of current oral delivery of therapeutic proteins. Inventors have found that a dried formulation obtained by drying the culture medium comprising plurality of macromolecules larger than 5kDa of recombinant yeasts which secretes a therapeutic protein in the culture

medium, can be used for oral delivery of dried formulation. It is also asserted that major advantage of the present invention is that there is no need for purification of therapeutic protein, which means that a formulation comprising the medium as such or a dried formulation comprising multiple macromolecules larger than 5kDa in the culture medium and the therapeutic protein present in the culture medium can be used as oral pharmaceutical products.

24. The first and foremost contention of the Appellants is that the impugned order is unreasoned and does not take into consideration the written submissions of the Appellants, wherein response was given to each of the objections raised in the FER. On perusal of the impugned order, this Court finds merit in this submission. In ***Boehringer (supra),*** Court remanded the matter to the Controller on the ground that despite detailed submissions filed by the applicant seeking to distinguish the prior arts from the subject invention, the impugned order was passed without going into the explanation/justification offered and in a blanket manner, Controller concluded that the arguments/submissions were 'not fully persuasive' but even this finding was without any justification. In the instant case, Appellants have elaborately addressed the objection of lack of inventive step and distinguished the prior arts D1-D8, however, the submissions have not even been considered by the Respondent. On this ground alone the impugned order deserves to be set aside.

25. Appellants have also rightly flagged that Respondent has erroneously refused the application under Section 10(4)(ii)(D) on the ground that Appellants have failed to disclose the source and geographical origin of the biological material used in the invention, overlooking that the origin was

unequivocally disclosed on two occasions i.e., in reply to the FER dated 16.04.2024 and written submissions dated 25.09.2024 stating therein that the origin (source) of the biological material is *'van Belgium'* and the material was not sourced from India. This, to my mind, is a glaring fallacy in the order inasmuch as there is a disclosure by the Appellants of the source and geographical origin of the biological material, both in reply to the FER and in the written submissions.

26. Learned counsel for the Appellants is also right in arguing that Respondent has failed to identify the person skilled in the art as also the closest prior art apart from failing to appreciate the differences between the cited prior arts D1-D8 and the claims in the invention. In ***F. Hoffmann (supra)*** and ***Tapas Chatterjee (supra),*** the Division Benches of this Court have emphasized on the importance of following five-step test to determine obviousness/lack of inventive step. The first test is to identify an ordinary person skilled in the art. Thereafter, the Controller is required to identify the differences, if any, between the cited matter and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical or practical applications and then to decide whether those differences, viewed in the knowledge of alleged invention, constitute steps which would be obvious to an ordinary person skilled in the art and rule out a hindsight approach. In ***Tapas Chatterjee (supra),*** the Division Bench held that the five steps elucidated in ***F. Hoffmann (supra)*** are to be followed sequentially. None of these steps have been followed by the Respondent in the instant case and in fact, even the person skilled in the art has not been identified.

27. The impugned order suffers from yet another illegality. Respondent

has nowhere explained why a skilled person would combine D1-D8 to arrive at: (a) membrane filtration of yeast culture medium, followed by (b) drying the unpurified medium to yield (c) an orally deliverable dried formulation with protective matrix effect. Respondent does not consider the differences brought forth in the prior arts and the claimed invention as: (a) prior art D1 discloses a dried oral formulation of a lipase from the high-lipase producing mutant yeast *Yarrowia lipolytica.* The difference in D1 and claim 1 is that D1 does not disclose a recombinant yeast host cell and the lipase is not exogenous to *Yarrowia lipolytica* and D1 does not cite or suggest an Fc fusion; (b) D2 discloses growth hormone fragments produced in yeast cells but no Fc fusions are disclosed or suggested; (c) D3 discloses single chain antibodies targeting F4 fimbriae. These are made in plants or yeasts and are purified and there is no reference to dried formulations of the culture medium of a recombinant yeast cell and no Fc fusions are disclosed or suggested. Hence, the claimed dried formulation is inventive over both D2 and D3 prior arts.

28. It is urged that D4 discloses H5 hemagglutinin made in yeast expression systems. There is no mention/suggestion of Fc fusions. D5 discloses dried RHVD VP60 capsid protein expression in *Pichia pastoris,* which is obtained after purification from the culture medium followed by drying with lyophilization. Thus, there is no drying of the culture medium comprising the exogenous recombinant protein in itself and there is no mention of Fc fusion in D5. D6 discloses production of anti-human IL-6 antibodies in yeast. No dried formulations of the extracellular medium are disclosed or suggested. Perusal of the impugned order shows that Respondent has not even looked into the differences pointed out between

prior arts D4-D6 and the claimed invention and the error of not considering the differences *qua* D1-D3 has replicated *qua* D4-D6.

29. Impugned order further reflects that the differences brought forth *qua* D7-D8 have also been glossed over. Appellants highlighted before the Respondent that D7 discloses IL22-Fc fusion proteins expressed in yeast, which are obtained by classical purification steps and there is no drying described of the extracellular medium of yeast wherein the fusion proteins are secreted. In other words, no dried formulation of the extracellular medium is disclosed or suggested in D7, which is a crucial difference. D8 can also not serve as a prior art since the anti-ETEC VHHs are produced in plants and not in yeast. Present invention involves the use of yeast host cell, while D8 uses plant seeds for antibody production. Membrane separation process or depth filtration, recited in the present claims reduce permeate compounds from the culture medium, which is not described in D8 and D8 in fact focuses on producing antibodies in plant seeds without such a filtration process, distinguishing the manner of obtaining the final product. D8 focuses on whole seeds containing the antibody, rather than a filtered culture medium, making the claimed product distinct and inventive. All these differences flagged by the Appellants may have made a considerable difference to the ultimate decision by the Respondent but are not even considered. Not according any consideration to the points raised by the Appellants is not only violation of principles of natural justice but also defeats the whole exercise of calling for response to FER and permitting filing of post-hearing written submissions.

30. Appellants are also right that there is yet another glaring illegality in the impugned order inasmuch as Respondent has overlooked the unexpected

technical effect of the invention, where the specification demonstrates that Pichia-derived dried culture medium formulation is superior to plant-derived compositions in clearing F4+ETEC infection. This point is sidelined by merely observing that D8 refutes this finding, which teaches that an antibody can protect against ETEC infection in a passive immunization set up, which as the Appellants point out focuses on whole seeds containing the antibody, rather than a filtered culture medium. The distinctions brought forth with prior art D8 do not even find mention in the impugned order.

31. Appellants have also endeavored to demonstrate that Respondent has fundamentally misapprehended the claim format, which was a product-by-process claim. It is urged that the entire purpose of prosecuting product-by-process claims is precisely because it is not possible to define the formulation by compositional features alone and therefore, the finding that claimed dried formulation is not defined by its composition and rather defined in terms of obtaining the composition, is erroneous. The observation in the order that in absence of SEQ ID numbers of the recombinant polypeptide used in the composition, the claims are vague and broad, according to the Appellants, is misplaced since the inventive feature is not the identity of the specific polypeptide but the dried yeast culture medium formulation and its unexpected protective matrix effect. This Court is unable to discern from the impugned order if this point even crossed the mind of the Respondent. In fact, the case laws relied upon by the Appellants have been cursorily dealt with by one line observation that the way in which the product-by-process claim was framed in the cited decisions was totally different from the instant application. Court, therefore, agrees with the Appellants that the instant application has not been examined in the manner

it ought to have been under the provisions of the 1970 Act and basis the judicial precedents on the subject and resultantly, an important right of the Appellants for a fair consideration of the patent application is lost.

32. For all the aforesaid reasons, I am of the view that the matter needs to be remanded back to the Respondent. Accordingly, this appeal is partially allowed, quashing the impugned order dated 28.03.2025 and directing the Respondent to reconsider Indian Patent Application No. 201917035558 after granting opportunity of hearing to the Appellants and taking into consideration response to the FER and post-hearing written submissions. Needless to state that Respondent shall pass a reasoned and speaking order after dealing with all the issues flagged by the Appellants. Decision will be taken within four months from today, uninfluenced by the observations in this order or the impugned order.

33. Appeal is disposed of in the aforesaid terms.

JYOTI SINGH, J

APRIL 29, 2026/VP