$~1

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

\+ C.A.(COMM.IPD-PAT) 35/2024

PIONEER HI-BRED INTERNATIONAL INC. .....Appellant

Through: Mr. Debashish Banerjee and Ms. Vaishali Joshi, Advocates.

versus

THE CONTROLLER OF PATENTS .....Respondent

Through: Mr. Jagdish Chandra, CGSC with Ms. Maanya Saxena, Mr. Lakshay Kumar, Ms. Sanskriti Sharma, Mr. Vikram Singh Dalal and Mr. Abhishek Sharma, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

O R D E R

% 22.07.2026

1. This appeal is filed on behalf of the Appellant under Section 117A of Patents Act, 1970 ('1970 Act') challenging impugned order dated 19.02.2024 passed by the Respondent, whereby Indian Patent Application No. 201617008869 has been rejected on ground of non-patentability under Section 3(c) of 1970 Act.

2. The subject Indian Patent Application No. 201617008869 was filed by the Appellant on 14.03.2016 and Request for Examination was filed on 10.08.2017. First Examination Report (FER) was issued by the Patent Office on 07.08.2020 and response was filed by the Appellant on 03.05.2021. Hearings was held on 13.12.2023 and on 23.01.2024, Appellant filed post-hearing written submissions along with amended claims 1-8. By order dated

19.02.2024, Respondent refused the application on ground of non-patentability of the claimed invention under Section 3(c) of 1970 Act.

3. It is stated that in the FER, objection of lack of novelty was raised *qua* claim 36 owing to prior art D2 and *qua* claims 1-52 in view of prior arts D1-D5. Claims 10-52 were considered non-patentable under Section 3(c), (d), (j) and (h) of 1970 Act and out of the 52 claims, claims 10-19 pertained to 'isolated polypeptide' and 'recombinant polypeptide' and were objected to under Section 3(c). Claims 1-52 were also objected to as not sufficiently disclosed. Appellant filed a response to FER with amended claims 1-52 renumbered as claims 1-11. Hearing notice was issued by the Patent Office, objecting to claims 3, 4, 8 and 9 as lacking clarity and conciseness under Section 10(4)(c) and 10(5) of 1970 Act as also to claim 1 as lacking definitiveness under Section 10(5). Objection of non-patentability under Section 3(c) was raised *qua* claims 3, 4, 6 and 7 relating to 'isolated polypeptide' and 'recombinant polypeptide'. During the hearing, claims 1-11 were amended and renumbered as claims 1-8 and finally, by the impugned order, all claims were refused despite objection being raised only with respect to claims 3 and 4.

4. Learned counsel for the Appellant submits that the impugned order suffers from an error apparent on the face of the record, besides illegalities on merits. Impugned order rests solely on objections to claims 3 and 4, yet subject application has been rejected in entirety. There is no reason whatsoever in the order to reject claims 1 and 2 and 5 to 8 and on this ground alone, the impugned order deserves to be quashed. Without entering into the merits of rejection of claims 3 and 4, Respondent has erred in refusing the subject application, overlooking the request of the Appellant

made vide email dated 07.02.2024 to delete claims 3 and 4 and accept three sets of auxiliary claims for consideration.

5. It is further argued that even on merit the objection of Section 3(c) *qua* claims 3 and 4 is unsustainable in law. Section 3(c) precludes patentability of a mere discovery of a scientific principle or formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature. Impugned order does not reflect which limb of Section 3(c) was invoked by the Respondent to refuse the application. Even otherwise the reason for rejection is flawed. The field of invention relates to the field of molecular biology and is titled "*INSECTICIDAL PROTEINS AND METHODS FOR THEIR USE*". The claimed invention is directed to novel genes that encode pesticidal proteins. The pesticidal proteins and nucleic acid sequences that encode them are useful in preparing pesticidal formulations and in the production of transgenic pest-resistant plants. The claimed invention does not qualify as a mere discovery of living things or a non-living substance in nature and was wrongly rejected under Section 3(c). Respondent has misdirected himself by stating that *"Here, a percentage identity of more than 80% includes in its ambit, a polypeptide with 100% identity to SEQ ID NO. 2, i.e. naturally occurring polypeptide. Furthermore, as per the present description, for example refer Tables 5, 6, and 7, several naturally occurring homologues of PIP-72 Aa polypeptide of SEQ ID NO. 2, for example PIP-72 polypeptides of SEQ ID NO. 927 and 928 which are naturally occurring polypeptides isolated from Pseudomonas chlororaphis and Pseudomonas brassicacearum respectively, are also included in the ambit of the said claims. Even if they are synthesized in the lab, but the final outcome will be the same as or identical several naturally occurring PIP*

polypeptides which are encompassed in the broad ambit of claims 3 and 4.", and has completely failed to technically comprehend the claimed invention, the objective of which is to provide isolated or recombinant nucleic acid molecules capable of encoding a PIP-72. Claimed invention relates to a nucleic acid molecule or a polypeptide, produced in synthetic conditions with significant human intervention, that can mimic the activity/action of PIP-72. Respondent has completely ignored the portions of dependent claims 2 and 4, wherein it is clearly stated that the encoded PIP-72 comprises of 1-17 amino acid substitutions at various positions when compared to SEQ ID NO: 2 i.e., the naturally occurring sequence. Thus, irrespective of the nature of the polypeptide, the claimed invention is directed as well as restricted to a synthetic and man-made polypeptide, sharing property resemblance with the natural peptide. Reliance is placed on the judgment of the Madras High Court in ***Immunas Pharma v. Assistant Controller of Patents and Designs, Government of India, 2024 SCC OnLine Mad 480,*** where the Court held that in Indian law, Section 3(c) uses the expression 'occurring in nature' to qualify 'discovery of a non-living substance' and while it could be argued that this qualifier is only intended to underscore that the exclusion will not apply to a non-living substance that is man-made, the explanation does not withstand close scrutiny because such non-living substance, if man-made and novel, would not be discovered, it would be created or invented. It would also not surmount Section 2(1)(j) hurdle and Section 3(c) exclusion is clearly not intended for such non-living substances. It was also observed that statutory prescription is "discovery of any … non-living substance occurring in nature". Both the use of the noun "discovery", which implies finding something which already exists and not

producing, engineering or making something and the use of the present continuous form "occurring in nature", indicate that the exclusion will only apply to the process of finding a hitherto undiscovered non-living substance by identifying and isolating it from nature. It is urged that in light of these observations of the Court, the claimed invention cannot be considered as non-patentable under Section 3(c), as Appellant does not claim the discovery of a naturally occurring substance and the invention is restricted to a synthetic and man-made polypeptide, sharing property resembling with the natural peptide, produced after significant human intervention.

6. Mr. Jagdish Chandra, learned CGSC appearing for the Respondent submits that the impugned order suffers from no legal infirmity. Section 15 of 1970 Act empowers the Controller to refuse an application seeking grant of patent, if it does not qualify or meet the requirements of the provisions of the 1970 Act. Section 3(c) specifically excludes from patentability, the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature and therefore, bars patenting of naturally occurring nucleic acid sequences or polypeptides, even if isolated or produced recombinantly, if they are identical to their natural counterparts. Claim 3 of the instant application relates to a recombinant PIP-72 polypeptide having at least 80% identity to SEQ ID NO: 2 and Claim 4 depends on it. However, the specification itself shows that SEQ ID NO: 2 is a naturally occurring polypeptide isolated from Pseudomonas chlororaphis. A claim for "at least 80% identity" also covers the 100% identical natural sequence. Merely calling it "recombinant" does not change the fact that the substance remains the same as what exists in nature. Under Section 3(c), the discovery of a naturally occurring substance

cannot be patented. Therefore, claims 3 and 4 directly include the natural sequence and are clearly barred under Section 3(c).

7. It is urged that in the decision in ***Regents of the University of California v. The Controller of Patents*** in C.A.(COMM.IPD-PAT) 481/2022, concerning a patent application for a recombinant Salmonella microorganism filed by the Regents of the University of California, Court upheld the Patent Office's refusal on the ground, *inter alia*, that the claims were so broad that they covered Salmonella with naturally occurring, endogenous loss-of-function mutations and thus fell within Section 3(c).

8. As for rejecting the entire application, it is explained that Patents Act does not empower the Controller to allow claims 'in part' by excluding claims which cannot be granted. While examining an application under Section 15, when the Controller finds that an application does not comply with the provision of 1970 Act, such that it contains claims falling under Section 3(c), applicant is required to amend the application as directed, failing which the Controller is entitled to refuse the application. In the present case, Appellant was granted an opportunity to delete Claims 3 and 4 but it chose not to do so and there was no option but to refuse the entire application under Section 15 as there was no power to segregate valid claims from invalid claims. The refusal is therefore lawful and procedurally correct.

9. Heard learned counsels for the parties and examined their submissions.

10. The instant Indian Patent Application No. 201617008869 was filed in respect of invention titled "*INSECTICIDAL PROTEINS AND METHODS FOR THEIR USE*". The claimed invention relates to novel genes that encode pesticidal proteins and the pesticidal proteins and nucleic acid sequences

that encode them are useful in preparing pesticidal formulations as also for production of transgenic pest-resistant plants. Background and summary of the invention are as follows:-

> *"**BACKGROUND OF THE INVENTION***
>
> *Biological control of insect pests of agricultural significance using a microbial agent, such as fungi, bacteria or another species of insect affords an environmentally friendly and commercially attractive alternative to synthetic chemical pesticides. Generally speaking, the use of biopesticides presents a lower risk of pollution and environmental hazards and biopesticides provide greater target specificity than is characteristic of traditional broad-spectrum chemical insecticides. In addition, biopesticides often cost less to produce and thus improve economic yield for a wide variety of crops.*
>
> *Certain species of microorganisms of the genus Bacillus are known to possess pesticidal activity against a range of insect pests including Lepidoptera, Diptera, Coleoptera, Hemiptera and others. Bacillus thuringiensis (Bt) and Bacillus popilliae are among the most successful biocontrol agents discovered to date. Insect pathogenicity has also been attributed to strains of B. larvae, B. lentimorbus, B. sphaericus and B. cereus. Microbial insecticides, particularly those obtained from Bacillus strains, have played an important role in agriculture as alternatives to chemical pest control.*
>
> *Crop plants have been developed with enhanced insect resistance by genetically engineering crop plants to produce pesticidal proteins from Bacillus. For example, corn and cotton plants have been genetically engineered to produce pesticidal proteins isolated from strains of Bt. These genetically engineered crops are now widely used in agriculture and have provided the farmer with an environmentally friendly alternative to traditional insect-control methods. While they have proven to be very successful commercially, these genetically engineered, insect-resistant crop plants provide resistance to only a narrow range of the economically important insect pests. In some cases, insects can develop resistance to different insecticidal compounds, which raises the need to identify alternative biological control agents for pest control.*
>
> *Accordingly, there remains a need for new pesticidal proteins with different ranges of insecticidal activity against insect pests, e.g., insecticidal proteins which are active against a variety of insects in the order Lepidoptera and the order Coleoptera including but not limited to insect pests that have developed resistance to existing insecticides.*
>
> ***SUMMARY OF THE INVENTION***

Compositions and methods for conferring pesticidal activity to bacteria, plants, plant cells, tissues and seeds are provided. Compositions include nucleic acid molecules encoding sequences for pesticidal and insecticidal polypeptides, vectors comprising those nucleic acid molecules, and host cells comprising the vectors. Compositions also include the pesticidal polypeptide sequences and antibodies to those polypeptides. The nucleic acid sequences can be used in DNA constructs or expression cassettes for transformation and expression in organisms, including microorganisms and plants. The nucleotide or amino acid sequences may be synthetic sequences that have been designed for expression in an organism including, but not limited to, a microorganism or a plant. Compositions also comprise transformed bacteria, plants, plant cells, tissues and seeds.

In particular, isolated or recombinant nucleic acid molecules are provided encoding Pseudomonas Insecticidal Protein-72 (PIP-72) polypeptides including amino acid substitutions, deletions, insertions, and fragments thereof, and combinations thereof. Additionally, amino acid sequences corresponding to the PIP-72 polypeptides are encompassed. Provided are isolated or recombinant nucleic acid molecules capable of encoding a PIP-72 polypeptide of SEQ ID NO: 849 as well as amino acid substitutions, deletions, insertions, fragments thereof and combinations thereof. Nucleic acid sequences that are complementary to a nucleic acid sequence of the embodiments or that hybridize to a sequence of the embodiments are also encompassed. Also provided are isolated or recombinant PIP-72 polypeptides of SEQ ID NO: 849 as well as amino acid substitutions, deletions, insertions, fragments thereof and combinations thereof.

Methods are provided for producing the polypeptides and for using those polypeptides for controlling or killing a Lepidopteran, Coleopteran, nematode, fungi, and/or Dipteran pests. The transgenic plants of the embodiments express one or more of the pesticidal sequences disclosed herein. In various embodiments, the transgenic plant further comprises one or more additional genes for insect resistance, for example, one or more additional genes for controlling Coleopteran, Lepidopteran, Hemipteran or nematode pests. It will be understood by one of skill in the art that the transgenic plant may comprise any gene imparting an agronomic trait of interest.

Methods for detecting the nucleic acids and polypeptides of the embodiments in a sample are also included. A kit for detecting the presence of a PIP-72 polypeptide or detecting the presence of a nucleotide sequence encoding a PIP-72 polypeptide in a sample is provided. The kit may be provided along with all reagents and control samples necessary for carrying out a method for detecting the intended agent, as well as instructions for use.

The compositions and methods of the embodiments are useful for the production of organisms with enhanced pest resistance or tolerance. These organisms and compositions comprising the organisms are desirable for agricultural purposes. The compositions of the embodiments are also useful for generating altered or improved proteins that have pesticidal activity or for detecting the presence of PIP-72 polypeptides or nucleic acids in products or organisms."

11. As brought forth by the Appellant, after amendments in the initial claims filed, the final claims under consideration were claims 1-8. Details of amended claims filed after response to FER owing to objection under Section 3(c) in the hearing notice as also those filed after hearing i.e., auxiliary request and finally, amended claims rejected in the impugned order under Section 3(c) are as follows:-

Particulars	**Claims rejected under Section 3(c)**
Amended claims filed after response to FER, which were objected under Section 3(c) in the hearing notice.	3. An isolated polypeptide comprising a nucleic acid molecule encoding a PIP-72 polypeptide having insecticidal activity against Western corn rootworm (*Diabrotica virgifera virgifera*), wherein the encoded PIP-72 polypeptide comprises an amino acid sequence having at least 80% identity to SEQ ID NO: 2. 4. The isolated polynucleotide as claimed in claim 3, wherein; A. the encoded PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO: 2, or B. the encoded PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO 2; or C. the encoded PIP-72 polypeptide as claimed in claim 3 or 4A which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or D. the encoded PIP-72 polypeptide as claimed in claims 3 or 4B, which has insecticidal activity against Western

	corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or E. the encoded PIP-72 polypeptide as claimed in claims 3 or 4B, which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or F. the encoded PIP-72 polypeptide as claimed in claims 3 or 4B, which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or G. wherein the encoded PIP-72 polypeptide as claimed in claims 3 to 4F, comprises an amino acid motif as represented by positions 37-51 of SEQ ID NO: 846, SEQ ID NO: 847, SEQ ID NO: 848 or SEQ ID NO: 849.
Amended claims filed after hearing, which were objected under Section 3(c). (Auxiliary request)	3. A recombinant PIP-72 polypeptide having insecticidal activity against Western corn rootworm (*Diabrotica virgifera virgifera*), wherein the encoded PIP-72 polypeptide comprises an amino acid sequence having at least 80% identity to SEQ ID NO: 2. 4. The recombinant PIP-72 as claimed in claim 3, wherein; A. wherein the PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO: 2, or B. the PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO 2; or C. wherein the PIP-72 polypeptide as claimed in claim 3 which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or D. the encoded PIP-72 polypeptide as claimed in claims 1, which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: …

	Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or E. The PIP-72 polypeptide as claimed in claims 3 to 4A, comprises an amino acid motif as represented by positions 37-51 of SEQ ID NO: 846, SEQ ID NO: 847, SEQ ID NO: 848 or SEQ ID NO: 849.
Amended claims rejected under Section 3(c) in the impugned order.	3. A recombinant PIP-72 polypeptide having insecticidal activity against Western corn rootworm (*Diabrotica virgifera virgifera*), wherein the encoded PIP-72 polypeptide comprises an amino acid sequence having at least 80% identity to SEQ ID NO: 2. 4. The recombinant PIP-72 as claimed in claim 3, wherein; A. wherein the PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO: 2, or B. the PIP-72 polypeptide comprises 1 to 17 amino acid substitutions at position …, compared to the corresponding amino acid of SEQ ID NO 2; or C. wherein the PIP-72 polypeptide as claimed in claim 3 which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or D. the encoded PIP-72 polypeptide as claimed in claims 1, which has insecticidal activity against Western corn rootworm, comprises an amino acid sequence of the formula: … Wherein said amino acid sequence has at least 80% identity to SEQ ID NO: 2; or E. The PIP-72 polypeptide as claimed in claims 3 to 4A, comprises an amino acid motif as represented by positions 37-51 of SEQ ID NO: 846, SEQ ID NO: 847, SEQ ID NO: 848 or SEQ ID NO: 849.

12. Respondent refused the application under Section 3(c) and relevant part of the order is as follows:-

> *"With regard to the objection u/s 3(c) of the Act under the head Non-Patentability u/s 3, the Applicant has submitted that- "claims 3 and 4 are directed to a recombinant are directed to "recombinant" insecticidal polypeptides comprising said insecticidal polypeptides which are produced using molecular biology techniques and involve human intervention and significant ingenuity. Therefore, the subject matter of these claims do not relate to any naturally occurring substance within the scope of Section 3(c) of the Act". It is further submitted by the applicant*

that- "claimed polypeptide is not merely the product of nature but is modified as a result of substantial human intervention. The 'recombinant polypeptide' is not a naturally molecule but is prepared in vitro. Being recombinant, the claimed polypeptide of claims 3 and 4 cannot be objected under section 3(c) as they do not occur in nature." To support this argument, the applicant has relied on Examples- 1-9 of the specification.

However, applicant's arguments are not found to be convincing and satisfactory for the reason that even if a naturally occurring sequence is prepared in the lab using molecular biology techniques and by human effort and intervention (as described in examples- 1-9 of the present specification), but if the lab synthesised protein/polypeptide is identical, in terms of structure, i.e. its amino acid sequence, to the naturally occurring sequences, then it cannot be distinguished from the naturally occurring sequence. Or in other words, a naturally occurring PIP-72 polypetide will be identical in structure and hence indistinguishable from the lab synthesised version of the same PIP-72 polypetide irrespective of the fact that it is synthesised by artificial means using molecular biology techniques and involving human intervention.

In the present case, claim 3 recites-"A recombinant PIP-72 polypeptide having insecticidal activity against Western com rootworm (Diabrotica virgifera virgifera), wherein the PIP- 72 polypeptide comprises an amino acid sequence having at least 80% identity to SEQ ID NO: 2. "Here, a percentage identity of more than 80 percent includes in its ambit, a poypeptide with 100% identity to SEQ ID No. 2, i.e naturally occuring polypeptide. Furthermore, as per the present description, for example refer Tables 5, 6 and 7, several naturally occurring homologues of PIP-72 Aa polypeptide of SEQ ID NO.2 , for example PIP72 polypeptides of SEQ ID No. 927 and 928 which are naturally occuring polypeptides isolated from Pseudomonas chlororaphis and Pseudomonas brassicacearum respectively, are also included in the ambit of the said claims. Even if they are synthesised in the lab, but the final outcome will be the same as or identical to several naturally occurring PIP polypeptides which are encompassed in the broad ambit of claims 3 and 4. Further, the applicant has not excluded such natural polypeptides from the ambit of the claim or has not defined or restricted the claim to particular polypeptides which are non-natural. Hence, the subject matter of claims 3 and 4 is still considered as including in its ambit, naturally occurring polypeptide sequences which is statutorily non patentable u/s 3(c) of the Act.

In this regard, it is also considered relevant to point out that for the same reasons as discussed above, polynucleotide claims (i.e. claims 3 and 4 of the claim set filed on 03.05.2021 in response to the FER) were also objected as not being allowable u/s 3(c) of the Act and were subsequently cancelled by the applicant.

The applicant, in the submissions, has also made reference to granted claims of similar nature in an Indian patent, however, the applicant should note that decision in any patent application is taken by a Controller after following the due process of law and based on the facts and circumstances of the case and documents on record. As explained in detail in the forgoing paragraphs, the CS in the present case has clear proof that at least some of the polypetides claimed in claim 3 and 4 are identical to naturally occurring ones. Hence, considering the facts and circumstances of the present case, it is held that the subject matter of claims 3 and 4 is statutorily non-patentable u/s 3(c) of the Act which proscribes discovery of any living thing or non-living substances occurring in nature from being patented.

5. Thus, after having considered the applicant's submissions (oral as well as written) and all the documents on record and in view of the aforementioned analysis and findings, it is concluded that the requirement of objection raised in the hearing notice dated 12.10.2023 and subsequently maintained through correspondence dated 01.02.2024 with respect to non-allowability of claims directed towards recombinant PIP-72 polypeptide (i.e. claims 3 and 4 of latest filed claims) under section 3(c) of the Patents Act, 1970 (as amended), has not been complied with. Therefore, I hereby order that the grant of a patent is refused for patent application No. 201617008869 under section 15 of the Act."

13. The first and foremost contention raised by the Appellant is that *sans* any objection against claims 1 and 2 and 5 to 8, the same could not have been rejected. The specific objection under Section 3(c) was *qua* claims 3 and 4 and there was no justification to reject the application in entirety. Perusal of the claims shows that Claim 1 is also an independent claim and no objection was raised *qua* its patentability. The argument on behalf of the Respondent that Controller has no power to reject an application after segregating the valid claims, is neither here nor there and to my mind, this is a case of incomplete examination of the entire set of claims and therefore, the matter deserves to be remanded.

14. Without prejudice to this submission, learned counsel for the Appellant brought forth that Section 3(c) precludes patentability of inventions which are: (a) mere discovery of a scientific principle; (b)

formulation of an abstract theory; or (c) discovery of any living thing or non-living substance occurring in nature and the present invention is aimed at providing isolated or recombinant nucleic acid molecules capable of encoding a PIP-72 i.e., what is claimed is a nucleic acid molecule or a polypeptide, produced in synthetic conditions with significant human intervention that can mimic the activity/action of PIP-72. It is also urged by the Appellant that Respondent has completely ignored the portions of dependent claims 2 and 4, wherein it is clearly stated that the encoded PIP-72 comprises of 1-17 amino acid substitutions at various positions when compared to SEQ ID NO: 2 i.e., naturally occurring sequence and therefore, irrespective of the nature of the polypeptide, the claimed invention is directed as well as restricted to a synthetic, man-made polypeptide, sharing property resembling the natural peptide. In a nutshell, the case of the Appellant is that the invention does not qualify as a mere discovery of living thing or a non-living substance in nature and the claimed polypeptide only arises as a result of substantial human intervention and does not occur naturally. Respondent, on the other hand, as can be gleaned from the order, was of the view that even if a naturally occurring sequence is prepared in the lab using molecular biology techniques and by human effort and intervention but if the lab synthesized protein/polypeptide is identical, in terms of its structure i.e., its amino acid sequence, to the naturally occurring sequences, then it cannot be distinguished from the naturally occurring sequence and in this background, rejected the application observing that in the instant case, claim 3 shows that a percentage identity of more than 80% include in its ambit a polypeptide with 100% identity to SEQ ID NO: 2 i.e., a naturally occurring polypeptide and therefore, even if synthesized in

the lab, the outcome will be that it will be same as several naturally occurring PIP polypeptides, which are encompassed in the broad ambit of claims 3 and 4.

15. The essence of the impugned order essentially is that even if a naturally occurring sequence is prepared in a lab using molecular biology techniques and by human effort and intervention but if the resultant protein/ polypeptide is identical in its structure to the naturally occurring sequences, then the claimed invention cannot be patented owing to proscription under Section 3(c) of 1970 Act. The Madras High Court in ***Immunas Pharma (supra)*** examined the ambit and scope of Section 3(c) in the Indian statutory context while also examining the judgments of the US Supreme Court in this regard and the observations will be instructive. It is observed by the Madras High Court as follows:-

> *"17. Reverting to Indian law, as noticed earlier, Section 3(c) uses the expression "occurring in nature" to qualify "discovery of a non-living substance." While it could be argued that this qualifier is only intended to underscore that the exclusion would not apply to a non-living substance that is man-made, in my view, said explanation does not withstand close scrutiny because such non-living substance, if man-made and novel, would not be discovered; it would be created or invented. If man-made but not novel, it would be produced and not discovered. It would also not surmount the Section 2(1)(j) hurdle and the Section 3(c) exclusion is clearly not intended for such non-living substances. What is the sequitur of the use of the expression "occurring in nature" : would a synthetic version of a substance that rarely occurs in nature but is required to be produced in large quantities for the treatment of serious illnesses qualify for or be excluded from patent protection? Should a patent applicant establish that such non-living substance never occurs in nature? The text of clause (c) of Section 3 contains guidance.*
>
> *18. The statutory prescription is "discovery of any ... non-living substance occurring in nature". Both the use of the noun "discovery"- which implies finding something which already exists and not producing, engineering or making something - and the use of the present continuous form "occurring in nature" indicate that the exclusion will only apply to the process of finding a hitherto undiscovered non-living substance by identifying and*

isolating it from nature. While reaching this conclusion, I take on board the presumption in statutory construction that redundancy should not be imputed to Parliament, and that the expression "occurring in nature" should not be robbed off all meaning and purpose. Ultimately, it should not be lost sight of that Section 3(c) is confined to patent exclusions or ineligibility and passing through such filter does not guarantee the grant of patent.

19. The real challenge with regard to a patent application in respect of a synthesized non-living substance, especially a monoclonal antibody, is establishing novelty, technical advance and not patent eligibility. For such purpose, the sequence of the antibody, especially the CDRs, may need to be compared with known antibody sequences. The patent applicant may also be required to establish that it does not fall within other exclusions in Section 3, such as sub-section (d) thereof, and further satisfy the requirements of Section 2(1)(j) of the Patents Act. The judgments of the IPAB, such as Biogaia, The University of British Columbia and Health Protection Agency record substantially similar conclusions. Although not a concern in this case because of the nature of claims, the other legitimate concern from the Indian Patent Office perspective, in the context of monoclonal antibodies, could be to closely examine the width of claims so as to ensure that very broad claims focused entirely or largely on functionality are not allowed because that could impede instead of fostering inventiveness in future.

20. The conclusion of the respondent that the antibodies claimed in the appellant's invention occur in nature was strongly refuted by learned counsel for the appellant on the basis that the antibody was engineered by an elaborate process. In order to substantiate such contention, the appellant relied on internal page 16 of the complete specification, which, in relevant part, is set out below:

> *"The monoclonal antibodies of the present invention can be produced as follows:*
>
> *Synthetic A-beta 1-42 (Peptide Institute Inc., Osaka) is dissolved in distilled deionized water or a 10 mM phosphatic buffer solution, and this is incubated at 37%b C for 18 hours. Then the peptides are separated by 4-12% SDS-PAGE, and visualized by CBB staining, and the portion of the A-beta 1-42 tetramer alone which is not contaiminated with the A-beta 1-42 monomer is cut out and used as an antigen. On the other hand, a prepararation containing a large amount of the A-beta 1-40 oligomer is prepared by mixing (i) a modified A-beta 1-40 prepared by chemically linking 6-carboxytetramethylrhodamine (6-Tamra) (SIGMA) to the N terminus of a synthetic A-beta 1-40 peptide using a conventional method with (ii) synthetic A-beta 1-40 (Peptide Institute, Inc., Osaka) at a ratio of*

5 : 100, 10 : 100, 20 : 100, 30 : 100,40 : 100, 50 : 100, 60 : 100, 70 : 100, or 80 : 100, preferably 90 : 100, or more preferably 100 : 100, and carrying out polymerization reaction for three hours, preferably six hours, or more preferably 20 hours. Next, Balb-c mice are immunized with 2.5 ug of either the A-beta 1-42 oligomer emulsified using complete Freund's adjuvant by injecting the antigen into their foot pad. Subsequently, booster immunizations are carried out six times. Hybridomas are produced from the inguinal lymph node by fusion with Sp2/O-Ag14 cells using polethylene Glycol 1500"

16. The conclusion that one draws from the judgment is that the statutory prescription in Section 3(c) is 'discovery of any … non-living substance occurring in nature' and the word 'discovery' implies finding something which already exists and not produced, engineered or made and therefore, the exclusion will only apply to the process of finding a hitherto undiscovered non-living substance by identifying and isolating it from the nature. The Court posed to itself a question whether a patent applicant is required to establish that such non-living substance never occurs in nature and observed that the guidance was in Section 3(c) itself and the answer is in the negative. The decision of this Court in ***Diamond Star Global Sdn. Bhd. v. Joint Controller of Patents and Designs, 2023 SCC OnLine Del 1879,*** is also helpful in understanding the proposition and relevant passages are as follows:-

"30. The patent regime, the world over, spans two overarching, and equally important, commercial considerations. On the one hand, the very raison d' etre of patent is fostering of scientific temper, and protection of the inventive faculties of persons who, expending their scientific and technical knowledge, inventing new products and processes, thereby incrementing the state of existing scientific knowledge. On the other, the grant of a patent results in a monopoly, in the patent holder, of the right to use the invention during the life of the patent, thereby excluding its availability to all others who may desire to create something similar. The grant of a patent, therefore, carries with it the acceptance that, on the expiry of the life of the patent, the invention would be thrown open to the public. Effecting of minute or non-incremental changes in a patented invention, with a view to claim a new invention and a new patent,

therefore, constitutes evergreening of the patent, which is completely proscribed in law. Where, however, the new product, or process, involves a genuine "inventive step" over the existing state of knowledge as represented by prior art, the invention becomes patentable.

31. The task of the authority who is approached with an application seeking grant of a patent - and of the Court seized with a challenge to the decision of the said authority - is, therefore, often to balance these two considerations, and ascertain whether the claimed invention genuinely represents an "inventive step" over existing knowledge in the form of prior art. In arriving at this decision, the authority, and the Court, is required to bear in mind the existing statutory patent regime in force - in India, in the form of the Patents Act, 1970.

xxx xxx xxx

36. Mr. Vaidyanathan, as already noted, places considerable emphasis on Section 3(c). The provision has, in my considered opinion, to be interpreted as it stands. The word "mere", as used in the opening part of the said Clause would apply, in my opinion, both to the first part, i.e. "discovery of a scientific principle or the formulation of an abstract theory" as well as to the second part, i.e. "discovery of any living thing or non-living substances occurring in nature". It is only mere discovery of a living thing, or non-living substance occurring in nature which, therefore, according to me, would fall within the second part of Section 3(c).

37. To analogize the issue to the facts of the present case, for example, if someone were to seek a patent for guaiacol, it would be possible to reject the application on the ground that guaiacol is a substance occurring in nature and, therefore, even if it had not been earlier discovered, the mere discovery of guaiacol was not patentable as an invention, in view of the proscription contained in Section 3(c). This, in fact, appears to me to be one of the major grounds on which the Controller has erred in the impugned order. A running thread, through the impugned order as well as in the FER which preceded it, is the observation of the Controller that the applicant was merely seeking to take advantage of the property of a naturally occurring substance, i.e. wood vinegar from the Rhizophora apiculata tree, being the absence of guaiacol. To the extent that the appellant was, in fact, stressing on the absence of guaiacol in the wood vinegar obtained from the Rhizophora apiculata tree, the observations of the Controller do not brook any cavil. Where, however, the Controller has erred is in failing to observe that the appellant was not seeking to merely patent wood vinegar obtained from the Rhizophora apiculata tree. The claim of the appellant was that, as an antimicrobial additive to skin care preparations, which would be free of any pungent constituents as well as capable of eradicating harmful bacteria even while preserving beneficial lactic acid bacteria, the wood vinegar obtained from the Rhizophora

apiculata tree, added to the skin care preparations at a strength of 18 to 22%, would provide optimum results. It is in this background that the appellant sought to patent the process by which the wood vinegar obtained from the Rhizophora apiculata tree was added to the skin care preparations at a concentration of 18 to 22%, and the product which was so added, in Claims 1 to 14 and Claim 15, respectively, in the appellant's application.

38. Within the ambit of the expression "new product or process" in Section 2(1)(j), as per the law declared by the Supreme Court in Novartis AG would be included not merely "something altogether new or completely unfamiliar or strange or not existing before" but also "something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind"". The Supreme Court, therefore, advocates according, to the expression "new product or process" in Section 2(1)(j), an expansive, rather than a restrictive, interpretation, and Article 141 of the Constitution of India makes that interpretation binding on every authority lower in the judicial hierarchy, including this Court. I do not see how the claims of the appellant, of which it sought a patent, which identified the Rhizophora apiculata tree as the appropriate source of the wood vinegar to be used, the process to which the wood vinegar would have to be subject, and the appropriate strength in which the wood vinegar, so processed, would have to be added, with other additives, while preparing the skin care formulation, can be regarded as lacking in any inventive step. The claims of the appellant are interdependent, not independent, and have to be seen as such.

39. I do not find, in the application submitted by the appellant, any categorical admission that there were other earlier preparations of wood vinegars, which were added to skin care preparations, so as to confer antimicrobial properties. The submission of Mr. Vaidyanathan that the appellant's application was deficient as it did not compare the invention which the appellant sought to patent with other wood vinegars which were added to skin care preparations, so as to demonstrate the greater efficacy or preferable properties of the wood vinegar obtained from the Rhizophora apiculata tree and added at a concentration of 18 to 22%, is not, therefore, in my view, acceptable.

40. Even if, arguendo, the submissions, were to be accepted, that, in my considered opinion, cannot really constitute a legitimate basis to reject the appellant's application as wanting in any inventive step. There is no denial, in the impugned order, of the fact that no earlier person had recognized the Rhizophora apiculata tree as the source of the wood vinegar which was free of guaiacol and, therefore, of the pungency which guaiacol imparted to the wood vinegar, or of the fact that, when added to the skin care preparations at a concentration of 18 to 22%, it would confer

optimum antimicrobial properties, which would enable it to selectively target harmful bacteria and retain beneficial lactic acid bacteria. The complete specifications filed by the appellant before the Controller contained detailed workings of how, when the appellant's product was added, these properties were found to result. As such, it cannot, in my considered view, be held that the appellant's application was lacking even in respect of sufficiency of disclosure.

xxx xxx xxx

43. What the FER as well as the impugned order of the Controller fails to notice, is that none of the cited prior art documents D-1 to D-3 either identified Rhizophora apiculata as the appropriate plant or tree, the wood vinegar of which was free from guaiacol or identified the said wood vinegar as, being most appropriate as an additive to skin care preparations at a concentration of 18 to 22%, to distinguish between the beneficial and harmful bacteria. These two properties, which, in a manner of speaking, constitute USP of the invention which the appellant sought to patent, are not taught by any of the prior art documents D-1 to D-3.

44. The impugned order of the Controller does not contradict any of the grounds on which the appellant had, in its response to the FER, contested D-1 to D-3 as being appropriate prior art. Further, the impugned order of the Controller fails to recognise the inherent inventive step involved in (i) identifying the wood vinegar obtained from the Rhizophora apiculata as being free of guaiacol and, therefore, suitable for addition of skin care cosmetics, (ii) working out the composition of 18 to 22% as the appropriate strength in which, on addition of the said wood vinegar to the skin care preparations, optimum antimicrobial properties, which would do away with harmful bacteria even while preserving beneficial lactic acid bacteria. The disclosures in the application submitted by the appellant were, ex facie, sufficient to support the claims, the scope of which the impugned order misconstrues."

17. Therefore, in light of the aforesaid judgments, there is merit in the contention of the Appellant that Respondent ought to have considered the detailed submissions bringing forth that the objective of the claimed invention is to provide isolated or recombinant nucleic acid molecules capable of encoding a PIP-72 and what was being claimed was a nucleic acid molecule or a polypeptide, produced in synthetic conditions with significant human intervention that can mimic the activity/action of PIP-72 and also that the Respondent ought not to have ignored portions of

dependent claims 2 and 4, where it is clearly stated that encoded PIP-72 comprises of 1 - 17 amino acid substitutions at various positions when compared to SEQ ID NO: 2 i.e. naturally occurring sequence and therefore, irrespective of the nature of polypeptide, the claimed invention is directed as well as restricted to a synthetic, man-made polypeptide, sharing property resemblance with the natural peptide.

18. In view of the aforesaid reasons, the patent application requires complete examination and hence, fresh consideration. Accordingly, the impugned order dated 19.02.2024 passed by the Respondent is set aside. Respondent shall carry out complete examination of the entire set of claims and thereafter issue a fresh notice of hearing to the Appellant and proceed further in accordance with law. The entire exercise will be completed in not later than 5 months from today. It is made clear that this Court has not expressed any opinion on the merits of the case.

19. Appeal is allowed and disposed of.

JYOTI SINGH, J

JULY 22, 2026
S.Sharma