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

% ***Judgment Reserved on: 10th February, 2025***
Judgment pronounced on: 21st February, 2025

\+ C.A.(COMM.IPD-PAT) 481/2022

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA .....Appellant

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

versus

THE CONTROLLER OF PATENTS .....Respondent

Through: Mr. Rohan Jaitley, CGSC with Mr. Kunwar Varun Pratap Singh, Mr. Dev Pratap Shahi, Mr. Yogya Bhatia and Ms. Ranjana Jetley, Advocates.
Dr. R Bhanumathi, Deputy Controller of Patents & Designs (through VC)

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

1. The present appeal has been filed under Section 117A of the Patents Act, 1970 (hereinafter 'Act') and is directed against the order dated 14th July, 2022 (hereinafter 'impugned order') passed by the Assistant Controller of Patents and Designs (hereinafter 'Controller'), whereby the Indian Patent Application No. 201717005699 titled *'VACCINE FOR LIVESTOCK PRODUCTION SYSTEMS'* (hereinafter 'subject patent application'), which

relates to a recombinant Salmonella microorganism based live vaccine for preventing enteric bacterial infection, has been refused.

BRIEF FACTS

2. Brief facts necessary for deciding the present appeal are set out below:

2.1. The appellant, The Regents of the University of California, is an entity based out of the United States of America.

2.2. The subject patent application was filed as a national-phase application under the Patent Cooperation Treaty ('PCT'), claiming priority from a US Patent Application with a priority date of 29th August, 2014. The appellant had filed the subject patent application on 17th February, 2017 with the Indian Patent Office, Delhi. The bibliographic details of the application are given below:

Indian Application No.	201717005699
Applicant	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
Priority Application No. & Date	U.S.A.62/043459; Dated 29th August, 2014
International Application No. & Filing Date	PCT/US2015/047549 dated 28th August, 2015
International Publication No. & Date	WO 2016/033532 Al July 30, 2020
PROSECUTION	
India Filing Date	17th February, 2017
Date of publication u/s 11A	2nd June, 2017
Request for Examination	31st May, 2018
First Examination	24th March, 2021

Report Issue Date	
First Examination Report Response Filed on	16th July, 2021
Hearing Notice Issued Date	20th October, 2021
Date of Hearing	22nd November, 2021
Written Submissions under Section 14 filed by Applicant on	7th December, 2021
Controller Decision	14th July, 2022

2.3. A request for examination of the said application was filed by the appellant on 31st May, 2018, and the First Examination Report (hereinafter 'FER') was issued on 24th March, 2021. The following objections were communicated to the appellant *via* the said FER:

a. Lack of inventive step under Section 2(1)(ja) of the Act;
b. Non patentable under Section 3(c), 3(d), 3(e), 3(i) of the Act;
c. Lack of unity of invention under Section 10(5) of the Act;
d. Insufficient disclosure under Section 10(4) of the Act.

2.4. In reply to the objections raised in the FER, the appellant's agent submitted a detailed response *via* letter dated 16th July, 2021.

2.5. Thereafter, a hearing was scheduled for 22nd November, 2021, and the following objections were communicated to the appellant *via* the hearing notice:

a. Lacks inventive step under Section 2(1)(j) of the Act;
b. Non patentable under Section 3(c), 3(d) and 3(e) of the Act;
c. Broader scope under Section 59(1) of the Act;
d. Lack of sufficiency of disclosure and unity of invention under Section 10(4) and 10(5) of the Act.

2.6. Post hearing, written submissions along with amended claims were filed by the appellant before the Patent Office on 7th December, 2021.

3. The impugned order was passed by the Patent Office on 14th July, 2022, refusing the subject patent application on the ground that the claims of the subject patent application do not fulfil the mandatory requirements under Section 10(4) and 10(5) of the Act and that the subject matter claimed is not eligible for patent protection on account of Section 3(c) of the Act.

4. The impugned order holds that the complete specification of the subject patent application has not sufficiently disclosed the recombinant Salmonella microorganism-based live vaccine as required under Section 10(4) and 10(5) of the Act. Moreover, it also holds that, in light of insufficiency in the disclosure, the claims of the subject patent application are too broad and could also cover naturally mutated Salmonella microorganisms. Hence, the subject patent application falls into the excluded subject matter under Section 3(c) of the Act.

5. The relevant extracts from the impugned order are set out below:

5.1. Regarding objection under Section 3(c) of the Act, the Controller has held as under:

> ***"The amended claims are very broad and wide and cover any Salmonella with a loss of function mutation in the dam gene and at least one further loss of function mutation in a gene selected from the group consisting of: sifA, spvB and mgtC. Thereby the scope of claim does not cover specific microbes exemplified as the applicant agent states, it is more a concept claim covering the genus salmonella with mutations in dam gene + one or more of (sifA, spvB and mgtC). Thereby applicant agent argument is not persuasive. The claims on record attract section 3(c) of Act."***
>
> [Emphasis Supplied]

5.2. Regarding Section 10(4) and 10(5) of the Act, the Controller has held as under:

> ***"Claim 1 relates to "A recombinant Salmonella microorganism, wherein said microorganism comprises a loss of function mutation in the dam gene and at least one further loss of function mutation in a gene selected from the group consisting of: sifA, spvB and mgtC wherein the microorganism is a Salmonella enterica subsp. Enterica serovar selected from the group consisting of S. Typhimurium, S. Enteritidis, S. Dublin, S. Newport, S. Choleraesuis, and S. Bovismorbificans..." The said claims provide innumerable permutation combinations and lack adequate support in complete specification and does not encompass the range and scope of subject matter covered in the claims.***
> ***The genetically modified microorganisms and a vaccine encompassing it claimed in the instant application lacks support, clarity, disclosure and definiteness over the entire scope of claimed subject matter. The claimed subject matter ie, A recombinant Salmonella microorganism, wherein said microorganism comprises a loss of function mutation in the dam gene and at least one further loss of function mutation in a gene selected from the group consisting of: sifA, spvB and mgtC wherein the microorganism is a Salmonella enterica subsp. Enterica serovar selected from the group consisting of S. Typhimurium, S. Enteritidis, S. Dublin, S. Newport, S. Choleraesuis, and S. Bovismorbificans and wherein the loss of function mutation is selected from the group consisting of an insertion, a deletion and/or substitution of one or more nucleotides in said genes.***
> ***The claims thereby covers wide range of organisms which are unique in themselves due to the attributed genetic modification, however claims define it in terms of numerous permutation and combinations of genetic modifications it could encompass and lack adequate disclosure to identify what is covered by the claims or what exactly is claimed. The claims disclose no organism/ the specific gene sequences / their mutations basically what they disclose are permutation combinations.***
> ***The GMO ie, recombinant Salmonella so created is capable of inducing an immune response in a subject against a Salmonella microorganism. The GMO's thus claimed here has several unique facets which are not adequately disclosed nor is it available to the public.***
> ***A statement that the organism has been modified to have specific activity/ immune response in a host without disclosing the organism or mutants and how it could be worked out to achieve desired results puts the skilled person under the burden of undue experimentation to achieve the same results, ie, in this case the GMO ie, recombinant Salmonella so created and capable of inducing an immune response in a subject against a Salmonella microorganism ….. In the absence of adequate***

disclosure under section 10(4)(a) and 10(4)(b) or deposition of the organism as required u/s 10(4)(d), a person skilled in art may be subjected to undue experimentation to arrive to the exact same GMO having ability to inducing an immune response in a subject against a Salmonella microorganism …. Thereby complete specification and claims lack sufficient technical disclosure and do not qualify u/s 10(4)(c) and 10(4)(d)of Act.

Same objection holds good for claim 5 wherein they disclose "A vaccine composition for inducing an immune response in a subject to a Salmonella microorganism, said composition comprising the recombinant microorganism as claimed in claim 1 or 2, in an amount sufficient to elicit an immune response in the subject and an adjuvant, diluent, carrier or excipient.". There is no disclosure of the vaccine comprising the vaccine. ***In view of the above the instant application thereby does not satisfy the requirement under section 10(4) and 10(5) of Patent Act."***

[Emphasis Supplied]

SUBMISSIONS BY THE PARTIES

6. Mr. Debashish Banerjee and Ms. Vaishali Joshi, counsel appearing on behalf of the appellant, has made the following submissions:

6.1. The respondent has erred in refusing the subject patent application under Section 3(c) of the Act. Claim 1 of the subject patent application specifically covers a novel recombinant Salmonella microorganism from serovars under the sub-species of Salmonella referred to in claim 1. Moreover, the mutation exemplified in the subject patent application does not arise naturally, as recombinant microorganisms are artificially produced. It also results in complete loss of function mutations that will not occur naturally.

6.2. Regarding the objection under Section 10(5) of the Act, the impugned order lacks adequate reasoning for refusing the grant of the subject patent application under Section 10(5) of the Act. Thus, this objection violates the principles of natural justice.

6.3. Regarding the objection under Section 10(4) of the Act, the respondent has erred in holding that the claims provide innumerable permutations and

combinations. It is evident from the reading of claim 1 that the combinations of the loss of function mutations would be 7 for each organism. Thus, for six organisms, as claimed in claim 1, the total combinations would be 42 or (7 x 6). Therefore, the basis of refusal under Section 10(4) is erroneous.

6.4. The requirement of deposit of biological material under Section 10(4)(d) of the Act only arises when the description in the specification does not satisfy clauses (a) and (b) of Section 10(4) of the Act and if such material is not available to the public. Based on the disclosure made in the complete specification of the subject patent application, any skilled person could reproduce the invention without needing to access a deposit. Moreover, the Salmonella microorganism used in the subject patent application is available to the public.

6.5. The respondent has failed to appreciate the disclosure on page 14, line 21 onwards in the specification, which discloses the formulation of the vaccine. Thus, the claimed vaccine composition can be prepared without undue experimentation.

6.6. The subject patent application has also been granted in multiple other jurisdictions including by the European Patent Office and the United States Patent and Trademark Office.

7. *Per Contra*, Mr. Rohan Jaitley, learned CGSC assisted by Mr. Varun Pratap Singh, counsel appearing on behalf of the respondent, has made the following submissions:

7.1. Regarding Section 3(c) of the Act, the amended claims 1 to 4 of the subject patent application are very broad and cover any Salmonella with a loss of function mutation in the *dam* gene and at least one further loss of function

mutation in a gene selected from the group consisting of: *sifA*, *spvB* and *mgtC*. Thereby, the scope of the claims does not cover specific microbes exemplified, and it is more of a concept claim covering the genus Salmonella with mutations in *dam* gene + one or more of (*sifA*, *spvB* and *mgtC*), which also occurs naturally. Hence, the claims on record attract Section 3(c) of the Act.

7.2. Regarding Section 10(4) and 10(5) of the Act, the amended claims 1 to 4 provide innumerable permutation and combination, lack adequate support in the complete specification and do not encompass the range and scope of the subject matter covered in the claims. Moreover, the calculation of the appellant showing 42 outcomes is also erroneous since it does not consider the insertion, deletion and/ or substitution mutations that could be made in the selected genes of referred serovars of the Salmonella subspecies.

7.3. The claims of subject patent application could result in innumerable unique recombinant Salmonella variants. Hence, the subject patent application fails to fulfil the requirements under Section 10(4)(a) and 10(4)(b). Moreover, deposition of the organism to an International Depository Authority under the Budapest Treaty as required under Section 10(4)(d)(ii) was also not made. A person skilled in art may be subjected to undue experimentation to arrive at the same Genetically Modified Organism (GMO), having the ability to induce an immune response in a subject against a Salmonella microorganism. Therefore, complete specification and claims lack sufficient technical disclosure and do not qualify under Section 10(4)(c) and 10(4)(d) of the Act. The same objection is also maintained regarding claim 5, where the composition has been made using the same recombinant

Salmonella microorganism.

7.4. As the claims of the subject patent application fail to fulfil Section 10(4)(a) and 10(4)(b) of the Act and the recombinant microorganism is not available to the public, the said microorganism is required to be deposited. In the absence of such a deposit and for falling under Section 3(c) of the Act, the present appeal has no merit and is liable to be dismissed.

ANALYSIS AND FINDINGS

8. I have heard the learned counsel for the parties and examined the records of the case.

9. It is evident from a perusal of the impugned order that the learned Controller has refused the subject patent application under Section 3(c) of the Act as claims 1 and 2 of the subject patent application are too broad and also cover naturally existing variants/ serovars of Salmonella microorganism. Further, claims 1 to 5 have not been sufficiently disclosed as required under Section 10(4) and 10(5) of the Act. The strict requirement of sufficient disclosure when the subject matter is based on a naturally available biological material is evident from the proviso (ii) to Section 10(4) of the Act, which will be dealt in detail in coming paragraphs.

10. In the present case, the objection under Section 3(c) has to be seen in conjunction with the objections under Section 10(4) and 10(5) of the Act.

OBJECTION UNDER SECTIONS 10(4) AND 10(5) OF THE ACT

11. I will first deal with the objection of lack of sufficient disclosure under Section 10(4) of the Act and of broad claims under Section 10(5) of the Act. For ease of convenience, relevant parts of Section 10(4) and 10(5) of the Act are set out below:

> *"10. Contents of specifications. —*

xxx xxx xxx

(4) Every complete specification ***shall****—*

(a) ***fully and particularly describe the invention and its operation or use and the method by which it is to be performed;***

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection*;*

(c) end with a claim or claims defining the scope of the invention for which protection is claimed."

xxx xxx xxx

(5) The claim or claims of a complete specification ***shall*** *relate to a single invention, or to a group of inventions linked so as to form a single inventive concept,* ***shall be clear and succinct*** *and* ***shall be fairly based on the matter disclosed in the specification.****"*

[Emphasis Supplied]

12. Section 10(4) and 10(5) of the Act specifically defines the manner in which the disclosure and the claims are to be made in the complete specification. Section 10(4) and 10(5) of the Act uses the word '**shall**', which makes it clear that every requirement under Sections 10(4) and 10(5) is mandatory for the complete specification of a patent application to be valid in India.

13. According to Section 10(4)(a) of the Act, every complete specification should describe the invention in full and provide full particulars thereof. Section 10(4)(b) of the Act requires the applicant to disclose the best method for working the same, which is known to the applicant and for which he claims protection.

14. From a perusal of the complete specification of the subject patent application, it is clear that the broader inventive concept covered in the subject patent application is a vaccine composition for inducing an immune response in a subject to a Salmonella microorganism, where it claims both genetically modified Salmonella microorganisms used in the vaccine composition and the vaccine itself. The genetically modified Salmonella strains are obtained

through specific loss-of-function mutations in the *dam* gene and at least one additional gene selected from *sifA*, *spvB*, and *mgtC* through insertion, deletion and/or substitution mutations. While the Salmonella serovars mentioned in claim 1, *i.e.*, *S. Typhimurium*, *S. Enteritidis*, *S. Dublin*, *S. Newport*, *S. Choleraesuis*, and *S. Bovismorbificans*, the genes referred above[1], and loss-of-function mutations can occur naturally, the inventive contribution of the subject patent application lies in the deliberate introduction of mutations at specific sites of multiple genes that disrupt gene function to attenuate virulence, making these modified strains suitable for use in vaccine compositions. For clarity of the invention, the final amended claims are reproduced here below:

> *"We Claim:*
> *1.* ***A recombinant Salmonella microorganism****, wherein said microorganism comprises a* ***loss of function mutation in the dam gene*** *and at least* ***one further loss of function mutation in a gene selected from the group consisting of: sifA, spvB and mgtC*** *wherein the microorganism is a* ***Salmonella enterica subsp. Enterica serovar*** *selected from the group consisting of* ***S. Typhimurium, S. Enteritidis, S. Dublin, S. Newport, S. Choleraesuis, and S. Bovismorbificans.***
> *2. The recombinant Salmonella microorganism as claimed in claim 1, wherein the loss of function mutation is* ***selected from the group consisting of an insertion, a deletion and/or substitution of one or more nucleotides in said genes.***
> *3. The recombinant Salmonella microorganism as claimed in claim 1 or 2, wherein the microorganism is S. Typhimurium.*
> *4. The recombinant Salmonella microorganism as claimed in claim 1 or 2, wherein the at least one further loss of function mutation is in the sifA gene.*
> *5.* ***A vaccine composition for inducing an immune response in a subject to a Salmonella microorganism****, said composition comprising the recombinant microorganism as claimed in claim 1 or 2, in an amount sufficient to elicit an immune response in the subject and an adjuvant, diluent, carrier or excipient."*

[1]The genetic information of the genes used in the subject patent application is given in the complete specification along with NCBI accession number and Locus tag.

15. At this juncture, a reference may be made to the relevant extracts (complete specification, page 12, line 26 onwards) from the detailed description, which is reproduced here below:

> *"The attenuated* ***Salmonella microorganisms of the present invention can be prepared by known techniques, e.g, by deletion mutagenesis, insertional inactivation or substitution of one or more nucleotides in the target genes. <u>The skilled person will appreciate that the target genes do not necessarily need to be mutated, provided that the expression of the native gene product is in some way disrupted</u>****. For example, the mutation may be made upstream of the target gene, for example in a promoter or regulatory region."*

16. From a combined reading of the afore-mentioned claims and the relevant extracts from the complete specification, it is established that the claims of the subject patent application cover and encompass various types of loss of function mutations in selected genes of Salmonella microorganisms. The detailed description further specifies the relevance of these genetic mutations. However, the detailed description clarifies that the target genes do not necessarily need to be deliberately mutated as long as the expression of the native gene product is functionally disrupted in some way. In my considered view, this broadens the scope of the subject patent application to include any method of gene disruption, not limited to deliberate genetic modifications. Hence, it is crucial to have sufficient disclosure to define the scope of subject patent application and to make sure that the subject patent application does not cover naturally mutated Salmonella microorganism, which is excluded under Section 3(c) of the Act.

17. In my considered view, a detailed examination of the complete specification, clearly reveals that the detailed description refers only to disclosure and example of deletion mutation of *S. Typhimurium dam* vaccine candidates. The relevant portion from the example (complete specification,

page 18) is reproduced here below:

> *"7.2. Construction of S. Typhimurium dam vaccine candidates comprising an additional attenuating mutation*
> ***S. Typhimurium UK-1 Adam was constructed by introducing an in-frame 300 bp deletion of defined dam sequence**, termed damA232 [19], using standard genetic protocols [20]. The resultant S. Typhimurium UK-1 damA232 strain (MT31 34) was shown to be sensitive to the purine analog, 2-aminopurine (2-AP), which is toxic to strains lacking a non-functional DNA adenine methylase [21 , 22], and was used as the parental Salmonella dam vaccine strain for all studies. **Secondary virulence-attenuating deletion mutations were introduced into the parental S. Typhimurium UK-1 damA232 strain utilising suicide vector pCVD442 as described [20], resulting in the construction of in-frame deletions of defined coding sequence in the following targeted genes: dam aroA (MT31 38; 1056 bp deletion); dam htrA (MT3142; 1341 bp deletion); dam mgtC (MT31 46; 606 bp deletion); dam sifA (MT31 50; 807 bp deletion); dam spiC (MT31 54; 306 bp deletion); dam spvB (MT31 58; 1563 bp deletion); and dam ssa\/ (MT31 62; 1959 bp deletion). The resultant genetic constructs were confirmed by PCR using primers that flank the deleted sequences**."*
>
> [Emphasis Supplied]

18. Hence, the above-extracted working example and detailed description, which are limited to deletion mutations, do not disclose the inventive contribution fully that also covers insertion and substitution. Accordingly, in my considered view, the lack of specific disclosures in respect of insertion and substitution mutations results in an insufficiency of disclosure, which renders the subject patent application non-compliant with the mandatory requirements under Section 10(4)(a) of the Act.

19. Moreover, in my assessment, such partial disclosure as made in the subject patent application will also not be sufficient to enable a person skilled in the field of microbiology to perform the invention as mandated under Section 10(4)(b) of the Act, without additional guidance. Given that the disclosure itself is incomplete, it cannot be said to be compliant with the requirement to disclose the best method for performing the said invention in

terms of Section 10(4)(b) of the Act.

20. Hence, I conclude that the subject patent application fails to sufficiently disclose the invention as mandatorily required under Section 10(4)(a) and 10(4)(b) of the Act.

21. According to Section 10(4)(c) of the Act, the claims of the patent applications are mandatorily required to define the scope of the protection. Moreover, under Section 10(5) of the Act, the claims '*shall be clear and succinct and shall be fairly based on the matter disclosed in the specification*'.

22. In ***AGFA NV & Anr.* v. *The Assistant Controller of Patents and Designs & Anr.***[2], I had an occasion to consider the objection of lack of clarity in claims. In the said judgment, I have held that lack of clarity arises when the language of the claim is ambiguous, imprecise, or fails to clearly define the scope of the invention, rendering the claims indefinite and consequently making it difficult for a person skilled in the art to ascertain its precise boundaries.

23. It has been submitted by the appellant that claim 1 only covers seven combinations of the loss of function mutations for each organism. Thus, for six organisms, as claimed in claim 1, the total combinations would be limited to 42 combinations (7 x 6, where 7 is the number of combination and 6 is the number of Salmonella subspecies referred in claim 1). According to the appellant, these combinations clearly define the scope of protection sought in the subject patent application. In support of the said assertion, the appellant has submitted a table showing the same. The same is reproduced below for ease of reference:

[2]2023:DHC:4030

Loss of function mutation in gene (1)	At least one further loss of function mutation in a gene selected from the group consisting of: *sifA*, *spvB*, and *mgtC*	Combination
Dam	*sifA*	1
Dam	*spvB*	1
Dam	*mgtC*	1
Dam	*sifA+spvb*	1
Dam	*sifA+mgtC*	1
Dam	*spvB+mgtC*	1
Dam	*sifA+spvB+mgtC*	1
TOTAL COMBINATIONS		7

24. In response to the aforesaid table, the respondent has argued that the calculation presented by the appellant misses out the aspect of different mutations, *i.e.*, insertion, substitution and/ or deletion, which is the core of the subject patent application as per claim 2. In my considered view, the three mutations, if performed on one or more nucleotides in the said genes of serovar selected from the six Salmonella microorganisms referred to in claim 1 for obtaining loss of function mutation, would cover a large number of mutant Salmonella organisms, which has not been clearly defined in the amended claims of the subject patent application. The Controller has correctly held that the recombinant Salmonella microorganism claimed in the subject patent application with a loss of function mutation consisting of an insertion,

deletion and/ or substitution of one or more nucleotides in said genes/ gene sequence results in numerous permutation and combination of genetic modifications in the genes which are harboured in the organisms.

25. At this stage, it is apposite to refer to the findings of the Supreme Court in ***Novartis AG v. Union of India and Ors.***[3], wherein it was underscored that the scope of the claims must be commensurate with the actual disclosure in the complete specification and, under no circumstances, can it exceed the extent of that disclosure. The said observation is particularly relevant in the present case, where the claims, as drafted, appear to extend beyond the actual disclosure by covering insertion and substitution mutation, which are not defined in the complete specification, while also encompassing naturally occurring mutations, and thereby creating ambiguity regarding the true inventive contribution. In my assessment, in respect of the subject patent application, this creates ambiguity regarding the true inventive contribution. As observed by the Supreme Court in ***Novartis AG*** (supra), the risk of such broad and ambiguous claims is that they do not serve the purpose of promoting innovation. The relevant extract of the judgment of the Supreme Court in ***Novartis AG*** **(supra)** are set out below:

> *"138. The submissions of Mr. Andhyarujina and Mr. Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the Appellant can be summed up by saying that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.*
>
> *139.* ***The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent.*** *Under the scheme of patent, a monopoly is granted to a*

[3] 2013 INSC 198

private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. ***To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.***

xxx xxx xxx

156. However, before leaving Hogan and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. ***We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers****, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."*

[Emphasis Supplied]

26. In light of my above assessment, I find that the claims of the subject patent application fail to provide a clear and precise definition of the full scope of recombinant Salmonella organisms covered in the subject patent application, even after a conjoint reading of the claims and the complete specification. Moreover, the claiming of insertion and substitution mutation will not be considered to be fairly based on the subject matter disclosed in the specification, on account of the absence of detailed support or working embodiments demonstrating these mutations.

27. Hence, the claims of the subject patent application fail to fulfil the requirements under Sections 10(4)(c) and 10(5) of the Act.

28. According to proviso (ii) of Section 10(4) of the Act, the patent applicant is required to deposit the biological material with an International Depository Authority (IDA) under the Budapest Treaty if the biological material mentioned in the specification is not able to meet the requirements

under Section 10(4)(a) and 10(4)(b) of the Act, and if the said biological material is not available to the public. The relevant proviso to Section 10(4) of the Act is reproduced hereunder:

> *"Provided that—*
>
> *xxx xxx xxx*
>
> *(ii)* ***if the applicant mentions a biological material in the specification which may not be described in such a way as the satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty*** *and by fulfilling the following conditions, namely:—*
>
> *(A)* ***the deposit of the material shall be made not later than the date of filing the patent application in India*** *and a reference thereof shall be made in the specification within the prescribed period;*
>
> *(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;*
>
> *(C) access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of the priority;*
>
> *(D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.*
>
> [Emphasis Supplied]

29. I have already held that the subject patent application does not meet the requirements under Section 10(4)(a) and (b) of the Act. However, regarding the public availability of the recombinant Salmonella microorganism, it is the argument of the appellant that the Salmonella microorganism is commonly available and, hence not to be deposited. However, it is clear from the above reproduced proviso that, in the subject patent application, it is the deposition of recombinant Salmonella that is required; not the source bacteria. Hence, the recombinant Salmonella claimed in the subject patent application, being a modified bacteria which will not be accessible to the public, is liable to be deposited in the recognised depository according to the Budapest Treaty

referred to in Section 10(4)(d)(ii) of the patents act, 1970. A reference may be made to paragraph no.11.2 of *The Patent Office Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals* of October 2014, regarding the sufficiency of disclosure concerning bacterium-based inventions:

> ***"11.2 Sufficiency of disclosure with respect to biological material and deposits:*** *If the* ***invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty.*** *The deposit of the material shall be made not later than the date of filing of the application in India, and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification, including the name, address of the depository institute and the date and number of the deposit."*
>
> [Emphasis Supplied]

OBJECTION UNDER SECTION 3(C) OF THE ACT

30. Now, I will deal with the second objection under Section 3(c) of the Act. Section 3(c) of the Act excludes any living thing or non-living substance occurring in nature from patenting. The relevant Section is reproduced hereunder:

> *"3. What are not inventions.— The following are not inventions within the meaning of this Act,—*
>
> *xxx xxx xxx*
>
> *(c) 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****"*
>
> [Emphasis Supplied]

31. It is the submission of the respondent that the subject patent application covers serovars of Salmonella microorganism sub-species referred to in claim 1 where the loss of function mutations *via* insertion, deletion and/ or

substitution of one or more nucleotides in *dam* gene fused with *sifA* and/ or *spvB* and/ or *mgtC* or in combinations is made. On behalf of the respondent, it is further submitted that several loss-of-function mutants of Salmonella microorganisms referred to in claim 1 are present naturally. Moreover, the genes referred to in claim 1 are endogenously present. Hence, the broad claim on such endogenous mutations also covers naturally occurring variants of Salmonella bacteria with loss of function mutation.

32. In response, the appellant has submitted that since there is no pending objection of novelty in the subject patent application, the Salmonella microorganism covered in the subject patent application cannot be said to be occurring in nature.

33. From the relevant extract of the detailed description set out in paragraph no.15 hereinabove, it is clear that the subject patent application is so broad that it covers naturally occurring mutations as well. The complete specification explicitly states that the target genes do not necessarily need to be mutated, but that their expression can be disrupted through upstream regulatory changes. In my assessment, the broad scope of the claims raises concerns that naturally occurring loss-of-function variants of Salmonella, whether due to spontaneous mutations or regulatory disruptions, may fall within the claimed invention. Hence, I am of the view that unless the subject patent application has been sufficiently disclosed with enabling disclosure and with clear claims, there shall be a serious prejudice that the endogenous mutations claimed in the subject patent application could cover those present naturally and would consequently be non-patentable under Section 3(c) of the Act.

34. In the overall facts and circumstances of this case, all the grounds cited by the Controller for refusing the subject patent application under Section 15 of the Act are upheld. The subject patent application is hit by non-patentability under Section 3(c) of the Act, lacks sufficient disclosure in terms of Section 10(4) of the Act and the claims of the subject patent application are indefinite and not fairly based on the disclosure made in the specification in terms of section 10(5) of the Act.

35. Consequently, I do not find any merit in the present appeal and the same is dismissed.

36. The Registry is directed to supply a copy of the present order to the Office of the Controller General of Patents, Designs and Trade Marks on e-mail ID - llc-ipo@gov.in, for compliance.

AMIT BANSAL
(JUDGE)

FEBRUARY 21, 2025
Vivek/-