(2021) 02 IPAB CK 0016

Intellectual Property Appellate Board, Mumbai

Case No: Original Application No. 68 Of 2015/PT/MUM

Biogaia Ab		APPELLANT
	Vs	
Controller Of Patents And Designs		RESPONDENT

Date of Decision: Feb. 13, 2021

Acts Referred:

- Indian Patents Act, 1970 - Section 2(1)(j), 3(c), 3(j), 10(4)(ii), 15, 117A

Hon'ble Judges: Dr. B.P. Singh, Technical Member; Manmohan Singh, J

Bench: Division Bench

Advocate: Hari Subramaniam

Final Decision: Allowed

Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 13/05/2015, passed by the Respondent,

being the Assistant Controller of Patents & Designs, (then) under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellantsâ€™

Indian patent application no. 2569/MUMNP/2008.

2. The Summary of Invention as explained by the learned counsel of the appellant is as under:

Â The present invention relates to novel strains of lactic acid bacteria created by the applicant and use thereof for their ability to increase cytokine IL-

IO levels, for prophylaxis and/or treatment of colic. In particular, the present relates to Lactic acid bacteria for reducing infantile colic; Colic is

frequent, prolonged and intense crying or fussiness in a healthy new born babies and infants. Possible contributing factors that have been explored,

inter alia, include imbalance of healthy bacteria in the digestive tract or food allergies or intolerances; At present there is no cure for colic. The current

treatment paradigm for colic consists of either pharmacological and/or non-pharmacological methods, providing at best marginal reduction of

symptoms. Studies have shown that up to 5% of treated infants may develop side effects, including breathing difficulties, apnea, seizures, syncope,

asphyxia, coma and muscular hypotonia upon pharmacological intervention. In addition, non-prescription medication utilizing sedative or sleep- inducing

drugs have a potential for serious side effects associated with respiratory diseases, thus limiting their widespread use in treating colic;

Â A safer non-prescription medication for treatment of colic has largely included the administration of simethicone or dimethylpolysiloxane, a non-

absorbable, over-the-counter drug, which reduces the size of intestinal gas bubbles. Simethicone has a very safe profile and is frequently

recommended, despite several studies demonstrating that effectiveness of Simethicone on infantile colic is no better than placebo. As a result, the

most common treatment for colic today is to simply wait for the baby to grow out of the condition;

Â Therefore, before the priority date of the present application there was a need for safe and effective compounds and compositions and techniques

that prove useful for treating colic in infants and young children.

Â The present invention overcomes the disadvantages of the prior art by providing a novel and isolated probiotic strain Lactobacillus reuteri DSM

17938 for use in the treatment of infantile colic which produces IL-10. (IL 10 is interleukin 10 which produces immune responses in a human body).

Thus, the applicant has for the first time, created a new strain of Lactobacillus from an existing strain and discovered it use in treatment for infantile

colic;

Â It has been well known for many years that elevated IL-10 or Interleukin-10 levels suppress over-activated immune systems. It has also previously

been demonstrated that gut motility is controlled by neurological signals, that are connected to the intestinal immune system and that colic is a

consequence of increased gut motility, for example, due to bacterial overgrowth;

Â In industrialized countries, hygienic measures begin as early as the birthing process, which disrupts the neonateâ€™s capacity to uptake the

motherâ€™s gut microflora. As a consequence, different microflora is established in the infant. Instead of harboring for example Escherichia coli and

Lactobacilli, the newborns are more often colonized with Staphylococcus aureus and other skin bacteria;

Â The inventors of the present invention have made the unexpected finding that while over-growth of skin bacteria over- activates the babyâ€™s

immune system, leading to over-activated gut motility and colic as a consequence, the invented strain of bacteria, L. reuteri DSM 17938, has capacity

of promoting IL-10 production, which leads to maturation of the TR (T cell receptors) system i.e., proliferation of CD4+CD25+TR cells. Up-regulation

of CD4+CD25+ cells leads to calmed gut motility and consequently to beneficial effects on babies with colic;

Â The present invention comprises of the following claims:

â€œClaim1: A biologically pure culture of Lactobacillus reuteri DSM 17938

Claim 2: The product for reducing infantile colic, comprising a biologically pure culture of Lactobacillus reuteri strain DSM 17938 as claimed in claim

1.â€

Â The learned counsel of the appellant has submitted that biologically pure strain of Lactobacillus reuteri DSM 17938 was never known in the art.

Â Biologically pure strain of Lactobacillus reuteri DSM 17938 has been created and isolated by human intervention.

Â Because biologically pure strain of Lactobacillus reuteri DSM 17938 was never known, it had to be deposited in the International Depository under

Budapest Treaty.

Â Only new strains of bacteria, developed by human intervention are patentable in USA, Europe, Australia and most other countries. Mere discovery

of an existing substance is not patentable anywhere in the world.

The corresponding applications for the present invention have been granted patents in several experienced jurisdictions such as U.S.A, Europe,

Australia, Taiwan, China, Russia, Canada, South Korea, Ukraine, Japan, Mexico, New Zealand, South Africa, Singapore, Vietnam and Georgia.

Further, the International Search Authority (ISA) published a search report on 03 October 2007 (and subsequently an International Preliminary Report

on Patentability (IPRP)) on the corresponding PCT International Application No. PCT/SE2007/050371, wherein, it found claims 1 to 9 (equivalent to

as-filed claims 1 to 9 of the present application) as held novel and inventive.

Â It is pertinent to mention that the IPRP did not find the claims of the corresponding PCT International Application non- patentable.

Â In particular, the corresponding EP Application No. 07748543.1 proceeded to grant as EP 2040723 on 28 November 2012 with claim 1 thereof

being identical to claim 1 pending on the present application.

3. It is the case of the appellant that

Â The impugned Order is liable to be set aside since the same been passed without application of mind and does not provide any reasoning as to how

Section 3(c) is applicable in the present case and in fact, is misconceived in refusing the present application on the basis thereof;

Â The only ground on which the present application was rejected was under Section 3(c), i.e., the claimed subject matter is naturally occurring.

The Respondent has failed to appreciate that the isolated strain of the microorganism covered by the present invention is a novel strain. The

Respondent has merely accused but failed to show that the claimed strain exists in nature. The Respondent has quoted mere statements from the

description given in context of general species of Lactobacillus reuteri;

Â The Respondent has failed to understand the difference between mere discovery as envisaged in Section 3 (c) and invention which involves a

human intervention. The Respondent has also failed to appreciate the difference between naturally occurring species of bacteria and isolated strains of

bacteria or bacteria strains which has been modified by human intervention. The Respondent has failed to appreciate that during isolation, a known

starting may get modified. The Respondent has ignored the description and experimental data provided by the Appellant to show effectiveness of the

invented selection method and use of the isolated strain Lactobacillus reuteri DSM 17938 for the treatment of colic;

Â The Respondent has completely ignored the prosecution history of the Appellantsâ€™ application in rather stringent jurisdictions such as U.S.A.

and Europe which have provisions similar to section 3(c) of Indian Patents Act, 1970 wherein the discoveries and naturally occurring organisms are

not patentable. Further the Respondent has failed to appreciate the fact that the objection of naturally occurring of Lactobacillus reuteri DSM 17938

was not even raised in any of the jurisdictions. It is noteworthy that the Appellants have filed the present application in nearly 26 jurisdictions and have

been granted patents in nearly 17 jurisdictions and no refusal in any other jurisdictions;

Â The Respondent has failed to understand the meaning of the invention to select strains for certain characteristics under specific culture conditions,

when done, with an objective of obtaining a specific strain that would be effective for a specific pathological condition like colic. The Respondent did

not appreciate that just any simple selection may not be sufficient for obtaining a bacterial strain that is effective for a specific pathological condition;

Â The Respondent has overlooked the in vivo results provided by the Appellants showing advantageous effects of the new strain Lactobacillus reuteri

DSM 17938 for colic and has simply passed a decision reading selective portions of the specification;

Â The Respondent has overlooked the depository requirements under the Budapest Treaty and given in the Section 10(4)(ii) of The Patents Act, 1970;

Â Therefore, it is very clear that the Respondent has approached this application with a pre-judged view and has not applied his mind in passing the

impugned order.

Â Since the Lactobacillus strain of Annexure D has been deposited in the International Depository under Budapest Treaty and referred to in the

present application, it is deemed to be part and parcel of the present application.

4. Letâ€™s have a look on the operating part of the order of the Respondent:

Â The subject-matter claimed in claim 1 falls within the scope of statutorily non-patentable invention under Section 3 (c) of the

Act, as being directed to a biologically pure culture of Lactobacillus reuteri DSM 17938, which is one of the naturally occurring inhabitants of

gastrointestinal tract of animals and is routinely found in intestine of healthy animals, including humans. Thus, the inventors of present application have

isolated such naturally occurring strain of Lactobacillus reuteri from the gastrointestinal tract of human. This naturally occurring strain was further

tested for its capacity to promote production of IL-10 and maintained as a pure culture. Consequently, the claimed subject-matter relates to an isolated

bacterial pure culture (L. reuteri DSM 17938) capable of producing IL-10, which constitutes a discovery of living thing occurring in nature, and hence

not allowed under Section 3 (c) of the Act.

Â Similarly, the subject-matter claimed in claim 2, which is directed to a product comprising a biologically pure culture of L. reuteri DSM 17938 as

claimed in claim 1 for reducing infantile colic, falls within the scope of statutorily nonpatentable invention under Section 3 (c) of the Act. Although

claim 2 is drafted as a product claim, but there is nothing like a product in said claim. In fact, an isolated pure culture of L. reuteri DSM 17938 would

be treated as a final product because there is no other (active) ingredient present in the product and the scope of protection is sought only for the

isolated bacterial pure culture under the guise of product claim. Just by drafting the product claim only comprising an isolated pure culture of L. reuteri

DSM 17938 does not exclude it from the scope of Section 3 (c) of the Act. By utilizing the drafting skill, the Applicantâ€™s agent has tried to claim

an isolated pure culture of L. reuteri DSM 17938 under the guise of product claim, which is not allowed for the reasons given above under the

exclusions of Section 3 (c) of the Act.

Â Applicantâ€™s submissions and arguments, inter alia, also refer to Section 3 (j) of the Act, which excludes the microorganisms such as bacteria

from the list of statutorily non-patentable inventions. However, the Applicant has failed to read said provision of the Act together with the provision of

Section 3 (c), which includes the discovery of living thing occurring in nature under the list of non-patentable invention. It means that although Section

3 (j) provides to allow the claims for a microorganism, but the claimed microorganism shall not be the discovery of living microorganism occurring in

nature according to Section 3 (c). As a result, the claimed pure culture of Lactobacillus reuteri DSM 17938, which is isolated from the gastrointestinal

tract of human being, does constitute the discovery of living thing occurring in nature. The inventors of present application as such have done nothing

with the claimed bacterial strain and, as acclaimed, if any human intervention was involved that was involved in isolating and maintaining the pure

culture; however these are very routine techniques in the field of microbiology as to the isolation and preservation of pure cultures. Thus, the

Applicantâ€™s submissions and arguments are not found to be persuasive.

Â In view of above said conclusions, the claimed subject-matter of claims 1 to 2 is statutorily non-patentable subject-matter and thus, I refuse to

proceed further with this application for patent No. 2569/MUMNP/2008 under Section 15 of the Act.

5. Letâ€™s refer the statutory provision of section 3(c) Available at https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html of the Patents

Act, 1970:

â€œSection 3

What are not inventions

â€¦

(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;â€¦â€ The MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE Available at

http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_ further emphasizes the relevant

provisions as to what will constitute the excluded subject matter under this section.

â€œThe 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 is not an invention.

a) A claim for discovery of scientific principle is not considered to be an invention, but a process of manufacture, based on the use of such principle,

resulting in a substance or an article may be considered to be an invention.

b) A scientific theory is a statement about the natural world.

These theories themselves are not considered to be inventions, no matter how radical or revolutionary an insight they may provide, since they do not

result in a product or process. However, any practical application of such theory in the process of manufacture of an article or substance, may well be

patentable.

c) The fact that a known material or article is found to have a hitherto unknown property is a discovery and not an invention. But if such discovery

leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be

considered to be an invention. For example, the property of a particular known material to be able to withstand mechanical shock is a discovery and

therefore not patentable, but a claim to a railway sleeper made of such material would not fall foul of this exclusion, and would be allowable if it

passed the tests for novelty and inventive step.

d) Similarly, finding of a new substance or micro-organism occurring freely in nature is a discovery and not an invention.

The GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT Available at

http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf also clarifies the issue as follows:

SECTION 3(c): SCIENTIFIC PRINCIPLES OR ABSTRACT THEORY OR DISCOVERY OF LIVING THINGS OR NON-LIVING

SUBSTANCES

According to Section 3 (c) of the Act, 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 is not a patentable invention. Products such as microorganisms, nucleic acid sequences, proteins,

enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter. However, processes of isolation of these

products can be considered subject to requirements of Section 2 (1) (j) of the Act.

..

It further states that Although, microorganisms are excluded from non-patentability list, a conjoined reading with Section 3

(c) of the Act implies that only modified microorganisms, which do not constitute discovery of living thing occurring in nature, are patentable subject

matter under the Act.

1. The above quoted provisions of law and the practices of the patent office show that any living thing or non-living substance occurring in nature or

products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature or finding of a

new substance or micro-organism occurring freely in nature are not held to patentable subject matter. Hence, while mere isolation of naturally

occurring new substance or microorganism is not held patentable but any genetically modified microorganisms or nucleic acid sequences are not

excluded from patentability, if other criterion for patentability such as novelty, inventive step and industrial applicability is fulfilled.

2. We have noted that the applicant has filed two International applications relating to similar subject matter. The instant application is based on the

first International application no. PCT/SE2007/050371. The second International application no. PCT/SE2007/050382 though designated India; but the

applicant chose not to enter the national phase at Indian Patent office.

3. The written opinion of International Searching Authority in respect of PCT/SE2007/050371 found that :

4. The International Preliminary Report on Patentability holds as under:

5. It is evident that the first examination report issued from Indian Patent Offcie did not take any objection on the groundd of Novelty. The main

objections are as follows:

Â Claim 1, which is directed to a biologically pure culture of Lactobacillus reuteri DSM 17938, is not allowable u/s 3 (c) of the Patents Act, 1970 (as

amended), as it attempts to claim a microorganism (i.e. L. reuteri) occurring in nature.

Â Claim 2 is directed to a composition, however it is defined by a single active ingredient (i.e. a biologically pure culture of L. reuteri DSM 17938).

Thus, it is considered that applicant attempts to claim a biologically pure culture of L. reuteri DSM 17938 only just by presenting it in the form of

composition claim. Accordingly, the subject-matter of claims 2-3 also falls within the ambit of Section 3 (c) of the Act. Further, a dependent claim 3

does not define any technical features as such for which scope of protection could be allowed, rather it defines functional feature for which no scope

of protection could be allowed.

Â Claim 4, which is directed to a product comprising the composition of claim 2 or 3, is nothing but a composition claim, which is characterized by a

single active ingredient (i.e. a biologically pure culture of L. reuteri DSM 17938), since a second feature, i.e. ingestible carrier defined therein is not

supported by description and original claims. Thus, it is considered that applicant again attempts to claim a biologically pure culture of L. reuteri DSM

17938 only just by presenting it in the form of product claim. Hence, the subject-matter of claim 3 also falls within the ambit of Section 3 (c) of the

Act.

Â Without prejudice, the subject-matter of claims 2 and 4 is redundant in view of scope of protection or definition of subject- matters is concerned.

Â Claim 6 is directed to a method of treatment, which is statutorily barred from the patentability u/s 3 (i) of the Act and hence, what is claimed therein

is not a patentable subject- matter as per said Section of the Act.

Claims 1-7 lack an inventive step, as required u/s 2 (1) (j) of the Act, in view of teaching of D1: Savino et al., ""Lactobacillus reuteri ATCC 55730

versus simethicone in the treatment colic: A perspective randomised study: 328"", PEDIATRIC RESEARCH, WILLIAMS AND WILKINS,

BALTIMORE, MD, vol. 58, no. 2, 1 August 2005, page 411 and D2: Kastner et al., ""Antibiotic susceptibility patterns and resistance genes of starter

cultures and probiotic bacteria used in food"", SYSTEMATIC AND APPLIED MICROBIOLOGY, URBAN UNO FISCHER VERLAG, vol. 29, no.

2, 1 March 2006, pages 145-155.D1 is considered to represent the most relevant state of the art and discloses (see abstract) Lactobacillus reuteri

ATCC 55730 in the treatment of infantile colic. The subject-matter of the present application differs from D1 in that a further L. reuteri strain is

provided for use in the treatment of infantile colic, namely L. reuteri DSM 17938. The problem to be solved may therefore be regarded as providing an

alternative L. reuteri strain for use in the treatment of infantile colic. The proposed solution is L. reuteri DSM 17938. However, this solution does not

involve an inventive step, because it is obvious in the light of the prior art for the following reasons:It is well known (See D2) that L. reuteri ATCC

55730 comprises antibiotic resistance gene carrying plasmids and that such plasmids are not wanted in probiotic cultures and should be eliminated.

Hence, the teaching of D2 would have prompted the skilled person to modify or adapt the closest prior art D1, while taking account of that teaching,

thereby arriving at something falling within the terms of the claims, and thus achieving what the present application achieves.

6. Therefore, it is evident that while no objection was taken on ground of lack of â€˜noveltyâ€™; the objection on â€˜inventive stepâ€™ was treated

as having been met by the respondent which is evident from his order quoted below:

Â In view of Applicantâ€™s submissions and amendments in claims, requirements of FER objections 2-6, 8-10 and 12 are treated as met.

7. We have further noted that in para 6 of the FER the respondent held as â€œâ€¦.L. reuteri ATCC 55730 comprises antibiotic resistance gene

carrying plasmids and that such plasmids are not wanted in probiotic cultures and should be eliminated. Hence, the teaching of D2 would have

prompted the skilled person to modify or adapt the closest prior art D1, while taking account of that teaching, thereby arriving at something falling

within the terms of the claims, and thus achieving what the present application achieves.[Emphasis added]

8. Hence once the respondent agreed with the submission of the applicant and waived the objection on the ground of inventive step; he also accepted

that the claimed strains of L. reuteri DSM 17938 are plasmid cured strains obtained from L. reuteri ATCC 55730. It is evident that such cured product

cannot be naturally occurring and hence considering the submission of the appellant and the provisions of the law on the subject, we are not inclined to

accept the argument of respondent with regard to applicability of section 3(c) of the Patents Act, 1970.

9. We have also noted that the complete specification explicitly does not mention about the plasmid cure but there is no objection on to grounds of

either â€œlack of sufficiency of disclosureâ€ or on the ground of claim basis on the description. Therefore, we are inclined to give benefit of doubt to

the applicant on this aspect.

10. Secondly, we find that claim 2 cannot be sustained as it was never claimed in claims 1-9 of this application.

11. We, therefore, direct the appellant to file a single claim as follows:

â€œA biologically pure culture of Lactobacillus reuteri DSM 17938 for reducing infantile colic.â€ within 4 weeks from issuance of this order.

12. We, therefore, set aside the order of respondent dated 13/05/2015 and direct him to grant the patent on the amended single claim within 4 weeks

from the issuance of this order.

13. Keeping in view the above conditions, the instant appeal is allowed. No cost.