(2021) 02 IPAB CK 0005

In the Intellectual Property Appellate Board

Case No : Original Application No. 12 Of 2020/PT/MUM

Adrenomed Ag — APPELLANT

Vs

Deputy Controller Of — RESPONDENT

Date of Decision : 01-02-2021

Acts Referred:
Indian Patents Act, 1970 — Section 2(1)(j), 3(d), 3(e), 3(i), 15, 57, 117A

Citation : (2021) 02 IPAB CK 0005

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

Bench : Division Bench

Advocate : R. Parthasarathy, Vindhya S. Mani, Ayushman Khetarpal, Sudarshan Singh Shekhawat, Sutapa Jana

Final Decision : Allowed

Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 17/12/2019, passed by the Respondent,

being the Deputy Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellantâ??s Indian

patent application no. 1189/MUMNP/2014.

2. It is the case of the appellant that :

The impugned order is bad in law since Claims 1-11 of the present application have neither been objected nor rejected on any ground whatsoever in

the impugned order. Hence, at least these Claims should have been granted. Further, it is respectfully submitted that the non-application of mind in the

impugned order is apparent from its bare reading. The first page of the impugned order is merely reiteration of record. Thereafter, the second page of

the impugned order begins by providing reasoning as to how the claimed invention of the instant application is novel and inventive to conclude that

â??â?¦ None of cited art defines claimed Anti-ADM antibody. â?¦â?. Thereafter, the impugned order reproduces amended Claims 1 and 12 in a

verbatim manner. Thereafter, the impugned order has cited extracts from the complete specification which are irrelevant to the applicability of Section

3(i) of the Act and finally, the impugned order provides erroneous reasoning as to how Claims 12-14 of the instant application are non- patentable in

accordance with Section 3 (i) of the Act, before rejecting the instant application in its entirety on the sole ground of non-patentability of subject matter

of Claims 12-14 under Section 3(i) of the Act.

Â It is further submitted that the impugned order is bad in law owing to the improper interpretation of Section 3(i) of the Act to reject the present

application by holding that the subject matter of Claims 12-14 is non-patentable.

Â The impugned order had rejected the present application without providing proper reasoning under Section 15 of the Act wherein the only ground

for rejection is that the subject matter of Claims 12-14 is non-patentable under Section 3(i) of the Act.

It is submitted that the Respondent in the impugned order has expressly acknowledged novelty and inventive step of the amended Claim 1 and, thus,

also of all the claims dependent on Claim 1 by stating that â??â?¦ Claim 10 has been merged in claim 1 and technical feature of Anti-ADM antibody,

such as CDR has been defined in claim 1. None of cited art defines claimed Anti-ADM antibody. â?¦â??.

The impugned order is devoid of proper reasoning. The impugned order has cited extracts from the complete specification which are irrelevant to the

applicability of Section 3(i) of the Act and finally, provides erroneous reasoning as to how Claims 12-14 of the instant application are non-patentable in

accordance with Section 3 (i) of the Act, before rejecting the instant application, in its entirety, on the sole ground of non-patentability of subject matter

of Claims 12-14 under Section 3(i) of the Act.

Â The impugned order has neither rejected nor raised any objection on any ground whatsoever in the impugned order in respect of Claims 1-11 of the

instant application and, thereby, has upheld the patentability of such Claims.

Â It is also submitted that the impugned order is erroneous in rejecting of Claims 12-14 as non-patentable under Section 3(i) of the Act.

Â It is submitted that a pre-requisite for the applicability of Section 3(i) of the

Act with respect to a Claim is that it should be directed to a process or a

method of treatment. The subject matter of the claimed invention is ADM antibody or an anti- ADM antibody fragment binding to adrenomedullin or

an anti-ADM non-Ig scaffold binding to adrenomedullin. The Appellant, thus, submits that the subject matter of the claimed invention, including the

objected Claims 12 to 14, is NOT a process or method of treatment but a product/ composition.

It is submitted that if the reasoning of the impugned order is accepted, all the product claims of pharmaceutical formulations, compositions, etc. which

are usually used in combination with other medicines would become non-patentable which is clearly against the well-settled principles of law and

practice. It is also pertinent herein to mention that the Respondent has already waived off the objections of clauses (d) and (e) of Section 3 of the Act

during the prosecution of the present application and has expressly admitted the novelty and inventiveness in respect of entire amended set of Claims.

Â Without prejudice, it is submitted that India is a signatory of Trade Related Aspects of Intellectual Property (TRIPS) and a member of world Trade

Organization (WTO), hence under Article 27(1) of the TRIPs Agreement, it was obligatory to provide protection to inventions whether products or

processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Further, it is

submitted that Article 27(3)(a) of the TRIPS Agreement allows member nations to exclude from patentability diagnostic, therapeutic, and surgical

methods for the treatment of humans and animals. It is submitted that India adopted the exemption of Article 27(3) (a) of the TRIPS under section 3(i)

of the Act and, thus, the legislative intention as apparent is that Section 3(i) of the Act only excludes methods of treatment that render humans or

animals free of disease or increase their economic value or that of their products. As stated above Claims 12 to 14 are not methods of treatment.

Thus, it is clear that the claimed subject matter of the present invention is not directed to â??any process for treatmentâ? and does not fall under

Section 3(i) of the Act.

Â It is to be noted that the impugned order has stated that Claims 12 to 14, when read with figure 7 and example 5 of the instant application, are

related to use of claimed Anti- adrenomedullin (ADM) antibody or anti-ADM

antibody fragment in combination of vasopressors such as

catecholamine. The impugned order has thereafter termed this as â?? combination therapyâ? to conclude that Claims 12 to 14 are not patentable. It is

submitted that there is nothing in clause (i) of Section 3 of the Act which prohibits patenting of pharmaceutical products which are used in combination

with other pharmaceutical products. Rather, cited portion of figure

7 and example 5 of the instant application shows novelty, inventiveness, therapeutic efficacy and synergistic effect of the product claimed in Claims 12

to 14.

Â Without prejudice, it is also submitted that the pharmaceutical products as claimed in Claims 12 to 14 used in combination with other pharmaceutical

products i.e. vasopressors are for ameliorating the acute condition in the patient who is in need for stabilizing the circulation and not to â??render (the

patient) free of diseaseâ?? as required in Section 3(i) of the Act.

Â Without prejudice to the above, it is submitted that the issuance of new objection pertaining to Section 3(i) of the Act only in the hearing notice was

beyond the scope of the objections issued in the First Examination Report (FER) and is prima facie contrary to the provisions of the Act.

Â Therefore, for all the above reasons, it is most humbly prayed that this Honâ?? ble Board may be pleased to set aside the impugned order. It is

most humbly prayed that this Honâ??ble Board may be pleased to direct the Controller to grant the patent with claims 1-14 of the instant Patent

Application No. 1189/MUMNP/2014. It is most humbly prayed that this Honâ??ble Board, in any case, may be pleased to hold that claims 1-11 of

the instant Patent Application No. 1189/MUMNP/2014 are patentable and direct that a patent be granted for these claims.

3. We have noted that the instant application was filed at IPO as PCT National phase application based on PCT International Application No.

PCT/EP2012/072930, with originally filed 26 claims.

4. The First Examination Report (FER) was issued on 10/01/2019 with the following main objections:

Claim(s) (1, 3, 4, 7, 8, 12, 17, 19, 20, 23-26) lack(s) novelty, being anticipated in view of disclosure in the document cited above under reference for the

following reasons:

The treatment of sepsis, an acute disease, with an anti- adrenomedullin antibody as in document D1, implies the prevention of organ dysfunction or

organ failure, e.g. prevention of heart and kidney dysfunction (Figures 3 and 4). The antibody was administered intravenously in combination with a

isotonic sodium chloride solution (page 1299, right-hand column, first paragraph). It is, moreover, noted that in general the binding affinity of an

antibody for its antigen is at least 0.0000001 M. Hence, claims 1, 3-4, 7-8, 12, 17,19-20 and 23-26 are not novel over D1.

Although, diabetes and cancer are not considered to be acute diseases, they are considered to be encompassed by claim 12, because they are listed as

particular embodiments. The treatment of tumours as in D2, also implies prevention of organ dysfunction or organ failure. Diabetes is linked to

dysfunction of the pancreas.

Hence, the treatment of diabetes by means of an anti-ADM antibody as in D3, falls within the scope of claim 12.

Therefore, claim 12 is not novel over D2 and D3.

As the subject-matter of claims 1, 3-4, 7-8, 12, 17, 19-20 and 23-26 is not new, the claims are not novel.

Claim(s) (1-26) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference for the following reasons:

In the present application shows that an antibody raised against the N-terminal region of mature mouse adrenomedullin (NT-M; amino acids 1-19;

SEQ ID NO: 18), is effective at treating sepsis and kidney injury due to sepsis, Gentamicin or ischemia/reperfusion. The claims, however, refer to a

broad range of diseases, ""acute disease or acute condition"", and any organ. Though, different diseases and disorders have different causes and

different proteins involved. The present application does not provide evidence that the present antiadrenomedullin antibody would be effective at

treating or preventing all acute diseases and acute conditions, and any kind of organ dysfunction or failure. Moreover, there is no evidence that

adrenomedullin (ADM) plays a role in all said medical conditions. Hence, the application does not teach for which therapeutic indications, besides

sepsis and kidney dysfunction, the present anti- adrenomedullin antibody would be effective.

The subject matter of the claims do not constitute an invention as per section

2(1) (j) of the Patents Act, 1970 as amended by the Patents

(Amendment) Act 2005 as the above-mentioned claims lack inventive step for instance cited documents.

Document D1 discloses the treatment of sepsis in an animal model based on cecal ligation and puncture (CLP) by means of a neutralizing polyclonal

antiadrenomedullin (ADM) antibody. Said antibody, moreover, prevented/ reversed alterations in cardiac output, stroke volume, microvascular blood

flow (e.g. in the kidney) and thereby prevented the hyperdynamic response during sepsis. The pharmaceutical composition was administered by

means of infusion. In claims 2, 5-6, 9-11 and 14-16 the antibody differs functionally or structurally from the antibody of D1. There is no common

effect associated to said various differences. The problem to be solved may, therefore, be regarded as to provide a further anti-adrenomedullin

antibody for use in the treatment of sepsis or an acute disorder or condition in general.

Document D2 discloses the treatment of glioblastoma in a tumor xenograft model by means of a polyclonal antibody raised against adrenomedullin.

The Examples show that an antibody raised against the N-terminal (NT) region of mature adrenomedullin results in a higher survival rate in the

treatment of sepsis than an antibody raised against the middle region (MR) or the C-terminal (CT) region (Table 4). Moreover, the NT antibodies

show the lowest ADM neutralization activity (Table 3) and an increase of the half life of ADM (Example 3). Hence, the particular high survival rate

of the NT antibody is considered to be linked to particular functional properties which are due to binding of the NT region.

Therefore, an anti-ADM antibody binding to the N-terminal amino acids 1-21 of mature adrenomedullin or comprising the six CDR sequences

represented by SEQ ID NOs 1-6 for use in therapy of sepsis or kidney injury may be considered to involve an inventive step over D1, wherein the

antibody is a polyclonal anti-ADM antibody. However, present claims 5 and 14-15 include therapeutic uses which have not been disclosed in the

application.

Document D3 discloses the treatment of diabetic obese rats with the monoclonal anti-adrenomedullin antibody MoAb-G6.

It is noted that the additional embodiments of claims 6, 18 and 21-22 are mere

arbitrary selections or routine alternatives that do not contribute an

inventive step.

SEQ ID 115 of US 2009/0169547 A1 anticipates sequence id no 7 of the present application. The sequence id no 115 has 100% coverage and 92 %

similarity with seq.id. no.7 of the instant application US 2009/0169547 A1 is published on 02/07/2009.

SEQ ID 45 of US 2006/0140932 A1 anticipates sequence id no 8 of the present application. The sequence id no 45 has 100% coverage and 90.3 %

similarity with seq.id. no.8 of the instant application US 2009/0169547 A1 is published on 29/06/2006. It is observed that other sequences are also

human origin in nature and isolated from human sources.

From the teachings of the above documents, for any person skilled in the art it would be obvious to carry the above research, in view of this claims 1-

26 lacks inventive step.

Claim(s) (1-18, 19-26) are statutorily non-patentable under the provision of clause (d and e) of Section 3 for the following reasons: Claims 1-18 are

not allowable u/s 3 (d) of the Act because these claims attempt to claim a subject-matter (amino acid sequence or Anti-Adrenomedullin (ADM)

antibody or an anti-ADM antibody fragment), which seem to use of known antibody and not allowable u/s 3 (d) of the Act, in view of cited art in

report.

The subject-matter of claims 19-26, which is directed to a pharmaceutical composition is considered to be a mere admixture of a polypeptide or an

antibody or an anti-ADM antibody fragment in the absence of any specific disclosure to the contrary in the specification, what is claimed in said

claims held to be not patentable u/s 3 (e) of the Act.

5. The appellant submitted the response to the FER and submitted amended set of claims with 22 claims.

6. A hearing notice was issued on 05/11/2019 with the following objections:

Non-Patentability u/s 3

The documents US6440421 B1 and US2010/0239554 A1 disclose amino acid sequence same as that of the claimed amino acid sequence; which seem

to use of known sequence. Therefore, objection u/s 3(d) cannot be waived.

The subject-matter of claims 15-22, which is directed to a pharmaceutical

composition is considered to be a mere admixture of a polypeptide or an

antibody or an anti-ADM antibody fragment in the absence of any specific disclosure to the contrary in the specification, More ever it does not clearly

define the composition in terms of its % or proportion of components and should be defined clearly & incorporated in claim 15-22; what is claimed in

said claims held to be not patentable u/s 3 (e) of the Act.

Claim 1, 2, 6, 9, 12-22 as worded fall under scope of section 3(i) of The Patents Act, 1970. Mode of administration and condition of patient and type of

disease treated, combination therapy is not allowable.

Scope

1. Claims are not clearly worded in respect the words like â??at least "", ""preferably 50 %, more preferably > 50 %,most preferably, not more than 80

%"", it should be reworded suitably.

Definitiveness

Claim 3, 7, 12 are not definitive as there is reference of Example, Merge claim 10 in claim 1 to clearly define the invention.

7. Hence, it is noted that considering the response to the FER; the hearing notice waived off the objections on the ground of lack of novelty and

inventive steps and retained those on the grounds of non-patentability under section 3(d), 3(e) and added a fresh objection under section 3(i) of the

Patents Act, 1970 apart from other objections as narrated above.

8. We note that after the hearing at IPO , the appellant submitted written arguments under Rule 28(7) on 04/12/2019 and in response to the objections

under sections 3(e) and 3(i) ; they submitted as under:

OBJECTION 3 (e):

The Controller has objected to claims 15-22, as being statutorily non- patentable under the provision of clause (e) of Section 3. To overcome the

objection of the Learned Controller, we have deleted the claims 15-22. Accordingly, the objection stands moot. [Emphasis added]

OBJECTION 3 (i):

The Controller has objected to claims 1, 2, 6, 9, 12-22, as being statutorily non-patentable under the provision of clause (i) of Section

3. The Applicant respectfully submits that the claims 15 to 22 have been deleted and claims 1, 2, 6, 9 and 12-14 have been suitably amended to

overcome the objections of the Learned Controller.

9. It is worth noting that claims 15-22 which stand deleted, as admitted by the appellant were all relating to a â??pharmaceutical formulationsâ??.

10. The operating portion of the order of the respondent is as under:

Upon perusal of records, I found that below mentioned objections over claims falling under scope of section 3(d), 3(i), claims not definitive, claims not

clearly worded etc. were communicated in hearing notice. For sake of convenience objection communicated in hearing notice is produced as under:

â??Claim 1, 2, 6, 9, 12-22 as worded fall under scope of section 3(i) of The Patents Act, 1970. Mode of administration and condition of patient and

type of disease treated, combination therapy is not allowable.â??

Hearing was held on 19/11/2019 and hearing proceedings are produced as under:

â??Agent submitted that they will merge claim 10 in claim 1.

Objection communicated on claim 15-22 and objection 2, 3(a) communicated.

Agent submitted that they will merge claim 10 in claim 1 and CDR sequence are different of cited art.

Claimed antibody has increased binding affinity to N terminal of sequence of at least 4 aa with in SEQ of aa 1-42 of mature human ADM.

Above submission is taken on record.

Two week time has been given to file written submission and amended set of claims.â??

If, I see fig 7 in description, this figure shows the Noradrenalin requirements for early and late treatment with NT-M. Example 5 is related to

requirement of the catecholamine, which was measured after administration of either non specific mouse IgG to a total of 6 mice as control group,

NT-murine antibody to a group of 5 mice immediately after CLP (early treatment) or NT-murine antibody to a group of 3 mice 15.5h after CLP (late

treatment). The reduction of the catecholamine requirement is a measure for the stabilization of the circulation. Thus, the data show that the ADM

antibody, especially the NT-M antibody, leads to a considerable stabilization of the circulation and to a considerable reduction of the catecholamine

requirement. The circulation-stabilizing effect was given in early treatment (immediately after CLP) and treatment after full sepsis development (late

treatment) (see fig. 7).

Written submission with regard to objection raised in para 3 of hearing notice is duly considered as necessary amendment in claim has been carried

out. Amended set of claims filed on 04/12/2019 and 14 in no. are before me for consideration. Claim 15-22 has been deleted. Claim 10 has been

merged in claim 1 and technical feature of Anti-ADM antibody, such as CDR has been defined in claim 1.

None of cited art defines claimed Anti-ADM antibody. Claim 1 is related to Anti-Adrenomedullin (ADM) antibody or an anti-ADM antibody fragment

binding to adrenomedullin or an anti-ADM non-Ig scaffold binding to adrenomedullin for use in therapy of an acute disease or acute condition of a

patient that suffers from an chronic and/or acute disease or acute condition for prevention or reduction of organ dysfunction or prevention of organ

failure, wherein said antibodies or antibody fragment or nonIg scaffold binds to region of at least 4 amino acids within sequence of aa1-42 of mature

human ADM (SEQ ID NO. 23);and wherein said antibody or fragment is a human monoclonal antibody or fragment that binds to ADM or a fragment

thereof wherein the heavy chain comprises the sequence selected from the group comprising: SEQ ID NO: 1 GYTFSRYW, SEQ ID NO: 2

ILPGSGST20SEQ ID NO: 3 TEGYEYDGFDY and wherein the light chain comprises the sequences selected from the group comprising SEQ ID

NO:4 QSIVYSNGNTY SEQ ID NO: 5 RVS SEQ ID NO: 6 FQGSHIPYT.

For sake of convenience claim 12 is produced as under:

â??Anti-Adrenomedullin (ADM) antibody or an anti-ADM antibody fragment binding to adrenomedullin or an anti-ADM non-Ig scaffold binding to

adrenomedullin according to any of the claims 1 to 11 to be used in combination with vasopressors e.g. catecholamine and/ or fluids administered

intravenouslyâ??

Amended Claims 12 -14 still fall under section 3(i) of The Patents Act, 1970 as these claims are related to use of claimed Anti- adrenomedullin

(ADM) antibody or antiADM antibody fragment in combination of vasopressors such as catecholamine. If I read these claims along with fig 7 and

example 5 in description, these claims are related to combination therapy and use of ADM antibody with catecholamine at early and late treatment

and dosage form of claimed antibody and catecholamine and mode of administration, which is not allowable under section 3(i) of The Patents Act,

1970, while claim 8, 9, 1 are related to disease condition in patient to be treated by combination therapy as defined in claim 12-14, while claim 1 is

related to antibody for use in therapy of an acute disease or acute condition of a patient that suffers from an chronic and/or acute disease or acute

condition for prevention or reduction of organ dysfunction or prevention of organ failure.

In view of above facts and finding, hearing proceedings under section

14, written submission filed on 04/12/2019, I refuse to grant patent on the Patent application, 1189/MUMNP/2004 under Section 15 of the Patents Act,

1970 on the ground of

b) Not patentable subject matter of claim 12-14 under Section 3(i) of the Patents Act, 1970.

11. Letâ??s have a look on the statutory provisions with regard to section 3(i) of the Patents Act, 1970.

Section 3 Available at https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html

What are not inventions

The following are not inventions within the meaning of this Act,â?

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a

similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

12. The Guidelines for examination of patent applications in the field of Pharmaceuticals Available at

https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for- examination-of-patent-applications-

pharmaceutical.pdf has explained the applicability of section 3(i) as under:

â??6.1 According to Section 2 (1) (j) of the Act, an ""invention"" means a new product or process involving an inventive step and capable of industrial

application. An invention will be patentable only if it is new in the light of prior art, or is not anticipated by prior art. From the plain reading of section

2(1)(j), it is amply clear that only products and/or processes for making pharmaceutical compounds are considered to be inventions under the said

clause. Sometimes, it is observed that applicants file claims in the following

manner:

1) Use of compounds in the treatment of ----------

2) A product or a substance (which is known) for the treatment of new disease (which is nothing but use/application claim). The above two categories

of claims are not to be considered as inventions, since the claimed subject matter neither pertains to product nor to process. Further, an objection with

regard to Section 3(i) and Section 3(d) would be invoked.

10.20 In the field of pharmaceuticals, it is noticed that method of treatments are often claimed in the guise of composition claims. Sometimes, such

claims are converted to product claims during examination procedure. Such amendments shall be examined as per Section 57 read with section 59 of

the Act.â?? [Emphasis added]

13. The Guidelines for Examination of Biotechnology Applications for Patent Available at

https://www.ipindia.gov.in/writereaddata/Portal/ IPOGuidelinesManuals/1_38_1_4-biotech- guidelines.pdf explains about the provisions relating to

section 3(i) as follows:

Sometimes the claims are so drafted that a combination/composition of drugs in certain dosage forms is claimed, but the claimed subject- matter

relates to application or administration of individual drugs in simultaneous, sequential or concomitant manner. In such cases, although the claims are

directed to a combination/composition of drugs, but the claimed invention resides in the method of administration of individual drugs in the said manner

and thus, it falls within the scope of section 3 (i) of the Act. [Emphasis added]

14. Letâ??s have a look on the existing claims 12-14 quoted below:

12. Anti-Adrenomedullin (ADM) antibody or an anti-ADM antibody fragment binding to adrenomedullin or an anti-ADM non-Ig scaffold binding to

adrenomedullin according to any of the claims 1 to 11 to be used in combination with vasopressors e.g. catecholamine and/ or fluids administered

intravenously.

13. Anti-Adrenomedullin (ADM) antibody or an anti-ADM antibody fragment binding to adrenomedullin or anti-ADM non-Ig scaffold binding to

adrenomedullin according to any of the claims 1 to 12 to be used in combination

with ADM binding protein and/or further active ingredients.

14. Pharmaceutical formulation comprising an anti-ADM antibody or anti- ADM antibody fragment or anti-ADM non-Ig scaffold according to any of

claims 1 to 14 useful in a therapy of an acute disease or acute condition of a patient that suffers from a chronic and/or an acute disease or acute

condition; wherein said pharmaceutical formulation is in the dosage form of a solution, a ready-to-use solution and a freeze- dried state; wherein said

dosage form is for intra-muscular, intra- vascular or for infusion administration.

15. It is worth noting that claims 15-22, all oriented towards â??A pharmaceutical formulation...â? were deleted by the appellant to meet the official

requirements as held in para 8 ante; but surprisingly, it is not the Â fact. Claim 14 quoted above, is amended version of claim 15, with features of

original claims 20 to 23 added therein, which were deleted in response to FER itself. No reason is provided either, by the appellant, to retain a

pharmaceutical formulation claim. All they say is that since the claims 15-22 stand deleted, the objection becomes moot. Therefore, the re-instatement

of claim 14 oriented towards â??A pharmaceutical formulation..â? after having deleted all such claims (15-22) and without assigning any reason for

the same, is not acceptable and cannot be allowed.

16. The use/ application Claims:

Â It is the contention of the learned counsel of the appellant that a pre-requisite for the applicability of Section 3(i) of the Act with respect to a Claim

is that it should be directed to a process or a method of treatment. Since the claimed invention including the objected Claims 12 to 14, is NOT a

process or method of treatment but a product/composition the provisions of section 3(i) should not have been invoked by the respondent.

Â Letâ??s have a look on Guidelines for Examination at EPO Available at https:// www.epo.org/law-practice/legal-

texts/html/guidelines/e/f_iv_4_16.htm with regard to â??Use claimsâ??. A ""use"" claim in a form such as ""the use of substance X as an insecticide"" is

regarded as equivalent to a ""process"" claim of the form ""a process of killing insects using substance X"". Thus, a claim in the form indicated is not to be

interpreted as directed to the substance X recognisable (e.g. by further additives) as intended for use as an insecticide. Similarly, a claim for ""the use

of a transistor in an amplifying circuit"" is equivalent to a process claim for the

process of amplifying using a circuit containing the transistor and is not

to be interpreted as being directed to ""an amplifying circuit in which the transistor is used"", nor to ""the process of using the transistor in building such a

circuit"". However, a claim directed to the use of a process for a particular purpose is equivalent to a claim directed to that very same process.

The Guidelines of Examination at USPTO MPEP 2173.05(Q) ""USE"" CLAIMS explains that I. A ""USE"" CLAIM SHOULD BE REJECTED

UNDER ALTERNATIVE GROUNDS BASED ON 35 U.S.C 101 AND 112 In view of the split of authority as discussed above, the most

appropriate course of action would be to reject a ""use"" claim under alternative grounds based on 35 U.S.C. 101 and 112.

Â We have already mentioned that IPO under its own Pharmaceutical Guidelines Supra 2 and Bio-Technology Guidelines Supra 3 has explained that

3(i) could be invoked in â??useâ?? claims as specified therein.

Â We have reviewed the objections of respondent in respect of 3(i) in hearing notice vis- a- vis the response of the appellant.

The objection:

Claims 1, 2, 6, 9, 12-22 as worded fall under scope of section 3(i) of The Patents Act, 1970.

The Response:

The Controller has objected to claims 1, 2, 6, 9, 12-22, as being statutorily non-patentable under the provision of clause

(i) of Section 3. The Applicant respectfully submits that the claims 15 to 22 have been deleted and claims 1, 2, 6, 9 and 12-14 have been suitably

amended to overcome the objections of the Learned Controller.

Â Letâ??s have a look on the amendments of claims affected by the appellant to overcome the objection at that stage. In is interesting to note that all

the claims 2- 13 the marked clause is deleted and â??useâ?? was deleted from claim 14 also. The argument against non-applicability of section 3(i)

was never raised and the claims were amended as shown herein below:

It could be, therefore, observed that while the amendment of rest of the claims was sufficient to overcome the objection taken on the ground of

section 3(i), the amendment of claims 12-14 couldnâ??t, and the objections to these claims were retained.

Â A comparative study of the relevant provisions with regard to â??useâ?? claims and the applicability of section 3(i) of the Patents Act, 1970, must

have reassured the appellant that Indian Patent Regime takes due care of all its International obligations while completely safeguarding its National

Interests and the laws in India are fully TRIPS compliant.

17. The learned Controller while refusing the application held as under:

â??Amended Claims 12 -14 still fall under section 3(i) of The Patents Act, 1970 as these claims are related to use of claimed Anti- adrenomedullin

(ADM) antibody or antiADM antibody fragment in combination of vasopressors such as catecholamine.â??

18. Hence, Looking at the provisions of the law and explanations provided in the guidelines both Nationally and Internationally in respect of

â??useâ?? claims and applicability of section 3(i) as well as considering the appellantâ??s own admission, when they amended the claims to

overcome such objections initially without countering the objection itself, we have no hesitation to accept the findings of the respondent.

19. We, therefore, direct the appellant to file amended set of claims deleting claims 12-14 from the body of the claims and submit existing claim 1-11

within 3 weeks from the issuance of this order, as there is no objection on to these claims in the impugned order of the respondent.

20. Considering the above facts, we set aside the order of the Respondent dated 17/12/2019 and direct the respondent to grant the patent on the

amended set of claims 1-11, within 3 weeks from the date of filing the amended set of claims.

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

