Intellectual Property Appellate Board

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OA/48/2020/PT/DEL

TUESDAY, THIS THE 27TH DAY OF OCTOBER, 2020

HON'BLE SHRI JUSTICE MANMOHAN SINGH **CHAIRMAN**
HON'BLE DR. B.P. SINGH **TECHNICAL MEMBER (PATENTS)**

1. **TONY MON GEORGE**
   THE REGENTS OF THE UNIVERSITY OF MICHIGAN
   1600 HURON PARKWAY, 2ND FLOOR ANN ARBOR
   MICHIGAN 48109 USA

…APPLICANT/APPELLANT

(Represented by: Ms Archana Shankar and Devinder Singh Rawat)

Versus

1. **CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADEMARKS**
   TRADE MARK REGISTRY BRANCH MUMBAI,
   INTELLECTUAL PROPERTY BHAVAN, NEAR ANTOP HILL HEAD POST OFFICE, S.M.ROAD,
   ANTOP HILL, MUMBAI - 400 037.

2. **ASSISTANT CONTROLLER OF PATENTS AND DESIGNS**
   TRADE MARKS REGISTRY, DELHI
   PLOT NO. 32, SECTOR 14
   DWARKA, DELHI -110075

…RESPONDENT

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 13/03/2020, passed by Respondent No. 2, being the Assistant Controller of Patents &

Designs, under Section 15 of the Indian Patents Act, refusing to grant the Appellants' Indian patent application no. 6001/DELNP/2013.

2. A brief case history is given herein below:

Sl No.	Date	Particulars
1.	04/07/2013	6001/DELNP/2013 Filed as PCT National Phase Application on "Stem Cell Factor Inhibitor" (Title)
2.	10/01/2012	PCT/US2012/020782 (PCT Application)
3.	10/01/2011	U.S.A.61/431246 (Priority Application)
4.	19/07/2012	WO2012/096960A2 (International Publication)
5.	05/12/2014	Publication Date (U/S 11a)
6.	09/01/2015	Request For Examination Date
7.	05/12/2014	Publication Date (U/S 11A)
8.	20/06/2018	Date of First Examination Report
9.	13/12/2018	Date of Response to FER
10.	19/11/2019	Date of Hearing Notice
11.	17/12/2019	Date of hearing
12.	23/12/2019	Hearing Rescheduled
13.	13/03/2020	Date of Impugned Order of the Respondent No. 2
14.	22/05/2020	Date of Filing this Appeal to IPAB

3. The present patent application titled "STEM CELL FACTOR INHIBITOR" was filed with the Indian Patent Office on 04/07/2013 and allotted application no. 6001/DELNP/2013. The present patent application is derived from PCT Application No. PCT/US2012/020782 dated 10/01/2012 and claims priority from US61/431,246 dated January 10, 2011.

4. The application was published under the provisions of Section 11A of the Patents Act, 1970 on 05/12/2014. A request for examination for the said application was filed on 09/01/2015.

5. This application was examined and First Examination Report (FER) was issued on 20/06/2018. In response to the objections raised in the said FER, the Appellants' Agent submitted a response via their letter dated 13/12/2018.

6. Thereafter, a hearing was scheduled for 17/12/2019, in the matter and following objections were communicated vide a hearing notice dated 19/11/2019. On 12/12/2019 an extended Hearing Notice was issued, appointing hearing for 23/12/2019.

7. The respondent no.2 issued the impugned order on 13/03/2020.

8. Aggrieved by this impugned order the appellant has preferred this appeal.

9. **About the Invention:**

   9.1 The patent specification clearly provides that unlike some other therapies that produce undesirable side effects due to interfering with general intracellular signalling pathways, the embodiments provided herein eliminate or minimize such side effects by modulating the activity of SCF. Consequently, toxicity is minimized. Moreover, targeting an extracellular ligand removes the need to deliver a composition into a cell to interact with an intracellular target. In some embodiments, the compositions are delivered into the airway, thus providing an advantage over previous technologies that require oral administration and, as such, resulting in systemic bioavailability.

   9.2 The claimed embodiments also include method of preparing an antibody (e.g., a monoclonal antibody) targeting stem cell factor comprising the steps of providing a peptide comprising or consisting of an immunogenic portion of SCF,

immunizing a host with the peptide, isolating an immune cell from the host, preparing a hybridoma using the immune cell, and isolating the antibody or antigen-binding fragment thereof.

9.3 Further details of the invention including SCF are as follows:

i. The SCF protein is found in 2 isoforms, namely isoform a and isoform b, which have differential function. SCF isoform b is a disease causing agent in fibrosis and tissue remodeling diseases (e.g., chronic kidney disease, IPF, asthma, scleroderma).

ii. SCF isoform "a" has a normal and important biological role in haematopoiesis and in other biological functions (e.g., pigmentation and mast cell production).

9.4 In contrast to previous anti-SCF antibodies that target SCF without discrimination between the two isoforms (and that consequently bind and inhibit both isoforms), the claimed antibody binds only to SCF isoform b.

9.5 Thus, an antibody that binds to both SCF isoform b and isoform a has unwanted side effects due to disrupting the normal biological role of SCF isoform a in the human body. In particular, inhibiting both isoforms inhibits blood formation similarly to what is observed in a patient who has a SCF deficiency (e.g., in a SCF knock-out mouse). Further, the antibody targeting only isoform b does not inhibit blood production. Thus, by deduction, it is the inhibition of SCF isoform a that causes the unwanted blood production side effects.

9.6 Therefore, the present invention is endowed with a special technical effect, i.e. the composition comprising the antibody binds specifically to SCF isoform b and not to SCF isoform a.

9.7 The results as filed in corresponding EP case on show strong binding of the antibody of the invention (specific for SCF isoform b) to human SCF isoform b, thereby demonstrating strong binding specificity of the presently claimed antibody for SCF isoform b.

9.8 The results further show that inhibiting both SCF isoforms a and b decreases haematopoiesis while inhibition of only SCF isoform b does not affect haematopoiesis. These results show the advantage of the antibody of the invention, i.e. the antibody of the invention does not have negative side effects that are produced by another non-specific antibody that binds to both isoforms (negative side effects are due to inhibiting the biological role of isoform a in hematopoiesis).

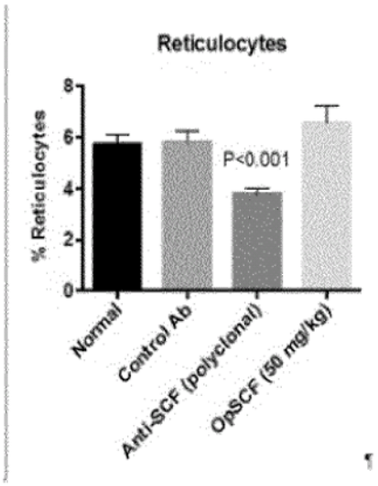

Fig. 2. Effects of SCF isoforms a and b on hematopoiesis.

10. The patent application no. 6001/DELNP/2013 filed as PCT National Phase Application with 30 claims, shown as below, just in

line with the PCT International application:

1. *A method of treating a fibrotic or tissue remodeling disease comprising administering a therapeutically effective amount of a stem cell factor inhibitor to a subject with or at risk for a fibrotic or tissue remodeling disease.*
2. *The method of claim 1, wherein the inhibitor is an isolated antibody or antigen-binding fragment thereof.*
3. *The method of claim 1, wherein the administering prevents or reduces the severity of at least one symptom of the disease.*
4. *The method of claim 2, wherein the antibody is a monoclonal antibody or antigen-binding fragment thereof.*
5. *The method of claim 2, wherein the antibody or antigen-binding fragment thereof specifically binds to stem cell factor.*
6. *The method of claim 2, wherein the antibody or antigen-binding fragment thereof specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8.*
7. *The method of claim 2, wherein the antibody is a polyclonal antibody.*
8. *The method of claim 1, wherein the inhibitor is a small interfering RNA.*
9. *The method of claim 1, wherein the subject has an abnormal activity of stem cell factor.*
10. *The method of claim 1, wherein the subject has abnormal collagen production.*
11. *The method of claim 1, wherein the disease is fibrosis.*

12. *The method of claim 1, wherein the disease is a remodeling disease.*

13. *The method of claim 1, wherein the disease is a pulmonary disease.*

14. *The method of claim 1, wherein the disease is idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, acute respiratory distress syndrome, cystic fibrosis, peribronchial fibrosis, hypersensitivity pneumonitis, or asthma.*

15. *The method of claim 1, wherein the disease is sclerodoma, inflammation, liver cirrhosis, renal fibrosis, parenchymal fibrosis, endomyocardial fibrosis, mediatinal fibrosis, nodular subepidermal fibrosis, fibrous histiocytoma, fibrothorax, hepatic fibrosis, fibromyalgia, gingival fibrosis, or radiation-induced fibrosis.*

16. *The method of claim 2, wherein the antibody or antigen-binding fragment thereof is delivered into an airway of the subject by intranasal administration.*

17. *The method of claim 1, wherein said administering the inhibitor reduces the activity of a receptor.*

18. *The method of claim 17, wherein said administering the inhibitor reduces an interaction of stem cell factor with a receptor.*

19. *The method of claim 17, wherein the receptor is a receptor tyrosine kinase.*

20. *The method of claim 17, wherein the receptor is c-Kit.*

21. *The method of claim 17, wherein the receptor is found on a hematopoietic progenitor cell, a melanocyte, a germ*

cell, an eosinophil, a lymphocyte, a fibroblast, a myofibroblast, or a mast cell.

22. *The method of claim 1, wherein the stem cell factor originates from a bone marrow cell, a liver cell, an epithelial cell, a smooth muscle cell, or a fibroblast.*

23. *The method of claim 1, wherein administering the inhibitor to a subject results in a direct inhibition of fibroblast activation.*

24. *A composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to stem cell factor.*

25. *A composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8.*

26. *The composition of claim 24, wherein the antibody is a monoclonal antibody or antigen-binding fragment thereof.*

27. *The composition of claim 24, wherein the antibody is a humanized antibody or antigen-binding fragment thereof.*

28. *A method of preparing an isolated monoclonal antibody targeting stem cell factor comprising the steps of providing a peptide comprising a sequence, or a portion of a sequence, selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8, immunizing a host with the peptide, isolating an immune cell from the host, preparing a hybridoma using the immune cell, and isolating the antibody or antigen-binding fragment thereof.*

29. *A method comprising the steps of providing an inhibitor of stem cell factor and administering the inhibitor to a cell or tissue.*

30. *A kit comprising the composition of claim 24, a means for administering the composition to a subject, and instructions for use.*

11. Later on 09/01/2015, the applicant filed amendments to the claims on Form -13 with prescribed fee. The proposed amendments to the claims are shown as below:

1. *An anti-stem cell factor antibody that specifically binds to stem cell factor isoform b relative to stem cell factor isoform a or an antigen-binding antibody fragment that specifically binds to stem cell factor isoform b relative to stem cell factor isoform a.*

2. *The anti-stem cell factor antibody or the antigen-binding antibody fragment of claim 1 wherein the antibody or the antigen-binding antibody fragment specifically binds to:*

a) a protein comprising an amino acid sequence provided by SEQ ID NO: 4 or a peptide fragment thereof,

b) a protein comprising an amino acid sequence that is encoded by a nucleotide sequence provided by SEQ ID NO: 3 or a peptide fragment of said protein; and/or

c) a polypeptide comprising an amino acid sequence provided by SEQ ID NO: 1.

3. *The anti-stem cell factor antibody or the antigen-binding antibody fragment of claim 1 wherein:*

a) the antibody is a monoclonal antibody or the antigen-binding antibody fragment is a fragment of a monoclonal antibody;

b) the antibody is a polyclonal antibody;

c)the antibody is a humanized antibody or the antigen-binding antibody fragment is a fragment of a humanized antibody; or

d) the antibody or antigen-binding antibody fragment is a Fab, a Fab', a F(ab'), a Fv fragment, a scFv fragment, or a linear antibody.

4. A pharmaceutical composition comprising the anti-stem cell factor antibody or the antigen-binding antibody fragment of any one of claims 1 to 3 and a physiologically appropriate solution for administration to a subject.

5. The pharmaceutical composition of claim 4 formulated for administration into an airway of a subject.

6. A peptide comprising a sequence, or a portion of a sequence, provided by SEQ ID NO: 1 for use in a method of preparing an isolated monoclonal antibody targeting stem cell factor, wherein the method comprises the steps of immunizing a host with the peptide, isolating an immune cell from the host, preparing a hybridoma using the immune cell, and isolating the antibody or an antigen-binding fragment thereof.

7. A composition comprising the anti-stem cell factor antibody or the antigen-binding antibody fragment of

any one of claims 1 to 3 and a stem cell factor isoform b polypeptide.

8. A composition comprising:

a) a nucleic acid encoding the antibody or antigen-binding antibody fragment of any one of claims 1 to 3; or

b) a nucleic acid encoding a peptide comprising the sequence provided by SEQ ID NO: 1.

9. A kit comprising the pharmaceutical composition of claim 4 and a means for administering the pharmaceutical composition to a subject.

10. An antibody or antigen-binding fragment thereof that specifically binds to stem cell factor isoform b relative to stem cell factor isoform a for use in the preparation of a medicament for administering to a cell or a tissue.

12. Respondent No. 2 issued a First examination Report (FER) on 20/06/2018. The main objections were as follows:

NON PATENTABILITY:

Claim(s) (1-23, 28-29; 24; 30) are statutorily non-patentable under the provision of clause (i; c; f) of Section 3 for the following reasons:

Claims 1-23 may not be allowable under section 3(i) as they relate to a method of treating a fibrotic or tissue remodeling disease.

Claim 24 may not be allowable under section 3(c) as they relate to an isolated antibody, which may be a naturally occurring substance.

Claims 28-29 may not be allowable under section 3(i) as they

comprise the step of immunizing a host cell.

Claim 30 may not be allowable under section 3(f) as it comprises a mere combination of different integers acting independently of each other.

UNITY OF INVENTION:

Claim(s) 1-30 lack(s) unity of invention as the claims do not relate to a single invention or to a group of inventions linked so as to form a single inventive concept:

The application contains the following group of inventions which do not relate to a single inventive concept as per section 10(5) of the Patents Act, 1970:

Group 1 (Claims 1-23, 29) – related to a method of treating a fibrotic or tissue remodeling disease comprising administering a therapeutically effective amount of a stem cell factor inhibitor to a subject.

Group 2 (Claims 24, 26, 27, 30) – related to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to stem cell factor.

Group 3 (Claim 25) –related to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8.

Group 4 (Claim 28) – related to a method of preparing an isolated monoclonal antibody targeting stem cell factor.

The application has four groups of claims: (1-23), (24, 30), (25-27), (28-29). The common feature between these four groups of claims is that they relate to stem cell factor inhibitor i.e. an antigen or antibody that binds to stem cell factor. The common

feature is the actual the function of the inhibitor and cannot be considered as a technical feature for the purpose of determining the single inventive concept. Even if it were to be conceded that that the stem cell factor inhibitor were to be considered as a common technical feature, it is seen in the prior art that stem cell factor inhibitors are already known (D1, D2). Therefore, these groups of claims lack unity of invention a posteriori and the claims that are considered to relate to distinct inventions have been grouped broadly into four groups.

In addition, claims 1-23 represents inventions wherein inhibitor may be antibody or antigen-binding fragment thereof specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8 , a polyclonal antibody, or even a small interfering RNA. Claim 28 related to preparation of the antibody which bind to SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8, will all represent different inventions. Claim 25 relates to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8, which is two separate inventions. Thus these groups of claims not only relate to multiple inventions in themselves but also have different intents i.e. treatment using inhibition of stem cell factor, a composition comprising antibodies against specific sequence and methods of preparation of isolated monoclonal antibody that bind to different peptides.

Examination in respect of novelty and inventive step is restricted to only the first group i.e. claims 1-23, 29. As all the claims of the first group comprise non-patentable subject matter, no search report is being established for the same.

SCOPE:

Claim(s) 24-27 does/do not define the scope of invention for which the protection is claimed for the following reasons:

Claims 24-27 define the antibodies on the basis of their functional effect. The sequences of these antibodies are not specified. These claims, therefore, are not considered to clearly define the scope of the invention.

OTHER REQUIREMENTS:

Claims 1-23 represents inventions wherein inhibitor may be antibody or antigen-binding fragment thereof specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ IDNO: 1 and SEQ ID NO: 8, a polyclonal antibody, or even a small interfering RNA. Claim 28 related top reparation of the antibody which bind to SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8, will all represent different inventions. Claim 25 relates to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8, which is two separate inventions. Thus these groups of claims not only relate to multiple inventions in themselves but also have different intents i.e. treatment using inhibition of stem cell factor, a composition comprising antibodies against specific sequence and methods of preparation of isolated monoclonal antibody that bind to different peptides. Therefore, Examination in respect of novelty and inventive step is restricted to only the first group i.e. claims 1-23, 29 and product claims have not been examined for novelty and inventive step.

13. It is worth noting that the First Examination Report (FER) explicitly mentions that *the Examination in respect of novelty and inventive*

step is restricted to only the first group i.e. claims 1-23, 29 and product claims have not been examined for novelty and inventive step.

14. A close- look on the FER reveals that "Novelty" and "Inventive step" were not at all considered in respect of any of the claims. The 'summary' and the 'detailed' portions of FER is shown herein below which shows that both in respect of 'Novelty' and 'Inventive step', no objection was taken. Not even in respect of claims 1-23 as alleged in the report. The FER reveals that in respect of "Patentability u/s 3", "Unity of Invention", "Scope" and "Other requirements " all the claims 1-30 have been examined and some or the other objection is communicated in respect of all the claims. But while categorically it is mentioned that "Novelty" and "inventive step" have been considered only in respect of claims 1-23, nothing has been considered, actually. This appears a case of negligence and need special attention to strengthen the quality of examination.

15. The Controller is required to consider the report of examiner u/s 14 of the Patents Act, 1970. If the report was inadequately and improperly prepared which is apparent on the face of records, he should have asked the examiner to rectify the mistake before sending the gist of objection to the applicant.

भाग -1: रिपोर्ट का सारांश
PART-I: SUMMARY OF THE REPORT

क्र. सं. /Sl. No.	अधिनियम के तहत आवश्यकताओं पर विस्तृत टिप्पणियां /Requirements under the Act		दावों की संख्या /Claim Numbers	टिप्पणी /Remarks
1.	धारा 2(1)(ज) के तहत आविष्कार /Invention u/s 2(1)(j)	नवीनता /Novelty	दावे /Claims: NA	हाँ /Yes
			दावे /Claims: NA	नहीं /No
		आविष्कारी कदम / Inventive step	दावे /Claims: NA	हाँ /Yes
			दावे /Claims: NA	नहीं /No

ख. अधिनियम के तहत आवश्यकताओं पर विस्तृत टिप्पणियां /B. Detailed observations on the requirements under the Act:

(1).नवीनता / NOVELTY:

(I) ऊपर उद्धरित दस्तावेज़ के संदर्भ (NA) मे लिये गए प्रकटन के पूर्वानुमान को ध्यान मे रखते हुए, निम्नलिखित कारणों से दावा(वों) (NA) मे नवीनता की कमी है /
Claim(s) (NA) lack(s) novelty, being anticipated in view of disclosure in the document cited above under reference for the following reasons:

(2).आविष्कारी कदम / INVENTIVE STEP:

(I) ऊपर उद्धरित दस्तावेज़(जों) के संदर्भ मे स्पष्ट अध्यापन(नों) को ध्यान मे रखते हुए, निम्नलिखित कारणों से दावा(वों) (NA) मे आविष्कारी कदम की कमी हैं
Claim(s) (NA) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference for the following reasons:

(3).पेटेंट अयोग्यता /NON PATENTABILITY:

16. Further, though Form -13 for amendments of the claims was filed on 09/01/2015, the FER issued dated 20/06/2018 just mentions *"Form 13 (E-18(i)/64/2015-DEL) cannot be allowed as no marked-up copy has been submitted indicating the amendments as per section 57. Claims as originally filed have been considered for examination."*. No substantive view on the allowability/non-allowability of the amendments was communicated to the appellant.

17. After consideration of the response of the FER, a hearing notice was issued with the following objections:

Other Requirement(s)

The amendments in the claims are not allowable under section 59 as the addition of new claims is beyond the scope of the provisions as per the Sec 59 of the Act and also the claims of the specification as amended do not fall wholly within the scope of a claim of the specification before the amendment. The added features of claims, that state anti-stem cell factor antibody that specifically binds to stem cell factor isoform b relative to stem cell factor isoform a or an antigen-binding antibody fragment that specifically binds to stem cell factor isoform b relative to stem cell factor isoform a, are found to be beyond the scope of the claims of the specification before the amendment. The subject matter of amended claims 2-10 also finds no basis in the originally filed

claims.

Therefore, none of the amendments are considered to be allowable.

All the technical objections as raised in the FER are maintained.

Unity of Invention u/s 10 (5)

D1:US20050112698A1D1:US20050112698A1The application contains the following group of inventions which do not relate to a single inventive concept as per section 10(5) of the Patents Act, 1970:

Group 1 (Claims 1-23, 29) – related to a method of treating a fibrotic or tissue remodeling disease comprising administering a therapeutically effective amount of a stem cell factor inhibitor to a subject.

Group 2 (Claims 24, 26, 27, 30) – related to acomposition comprising an isolated antibody or antigen-binding fragment thereof that specifically bindsto stem cell factor.

Group 3 (Claim 25) –related to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8.

Group 4 (Claim28) – related to a method of preparing an isolated monoclonal antibody targeting stem cell factor The application has four groups of claims: (1-23), (24, 30), (25-27), (28-29). The common feature between these four groups of claims is that they relate to stem cell factor inhibitor i.e. an antigen or antibody that binds to stem cell factor. The common feature is the actual the function of the

inhibitor and cannot be considered as a technical feature for the purpose of determining the single inventive concept. Even if it were to be conceded that that the stem cell factor inhibitor were to be considered as a common technical feature, it is seen in the prior art that stem cell factor inhibitors are already known (D1, D2).Therefore, these groups of claims lack unity of invention a posteriori and the claims that are considered to relate to distinct inventions have been grouped broadly into four groups. In addition, claims 1-23represents inventions wherein inhibitor may be antibody or antigen-binding fragment thereof specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ IDNO: 1 and SEQ ID NO: 8 , a polyclonal antibody, or even a small interfering RNA. Claim 28 related to preparation of the antibody which bind to SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ IDNO: 8, will all represent different inventions. Claim 25 relates to a composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8, which is two separate inventions. Thus these groups of claims not only relate to multiple inventions in themselves but also have different intents i.e. treatment using inhibition of stem cell factor, a composition comprising antibodies against specific sequence and methods of preparation of isolated monoclonal antibody that bind to different peptides. Examination in respect of novelty and inventive step is restricted to only the first group i.e. claims 1-23, 29. As all the claims of the first group comprise non-patentable subject matter, no search report is being

established for the same.

Non-Patentability u/s 3

Claims 1-23 may not be allowable under section 3(i) as they relate to a method of treating a fibrotic tissue remodeling disease.

Claim 24 may not be allowable under section 3(c) as they relate to an isolated antibody, which may be a naturally occurring substance.

Claims 28-29 may not be allowable under section 3(i) as they comprise the step of immunizing a host cell.

Claim 30 may not be allowable under section 3(f) as it comprises a mere combination of different integers acting independently of each other.

Scope

Claims 24-27 define the antibodies on the basis of their functional effect. The sequences of these antibodies are not specified. These claims, therefore, are not considered to clearly define the scope of the invention.

Clarity and Conciseness

Claims 1-23 represents inventions wherein inhibitor may be antibody or antigen-binding fragment thereof specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 8, a polyclonal antibody, or even a small interfering RNA. Claim 28 related to preparation of the antibody which bind to SEQ ID NO: 1, SEQ ID NO: 4,SEQ ID NO: 6, and SEQ ID NO: 8, will all represent different inventions. Claim 25 relates to a composition comprising an isolated antibody or antigen-binding fragment thereof that

specifically binds to a peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1and SEQ ID NO: 8, which is two separate inventions. Thus these groups of claims not only relate to multiple inventions in themselves but also have different intents i.e. treatment using inhibition of stem cell factor, a composition comprising antibodies against specific sequence and methods of preparation of isolated monoclonal antibody that bind to different peptides. Therefore, Examination in respect of novelty and inventive step is restricted to only the first group i.e. claims 1-23, 29 and product claim shave not been examined for novelty and inventive step.

18. The learned counsel of the appellant has submitted that pursuant to the hearing held on 22/01/2020 and as per the directions of the Respondent No. 2, the Appellant further revised the claims under Section 57(6) of the Indian Patents Act and retained:

    a. the original composition claims PCT claims 25-27 as claims 1-3 and to further define the said composition claims added new dependent claims 4-6 relation to the composition;

    b. method for preparing an isolated monoclonal antibody targeting stem cell factor as claim 8 (PCT claim 28) and

    c. Kit claim 7 (PCT claim 30).

19. They have submitted a table showing the claim correspondence as follows:

Claim	**PCT claims and/or support in PCT application**
1	claim 25; page 4, lines 7-9; page 37, lines 15-16
2	claim 26; page 21, lines 18-20
3	claim 27; page 23, line 18 to page 24, line 12
4	page 3, lines 4-5; page 15, lines 8-12; page 24, lines 12-27
5	page 4, lines 9-11

6	page 18, lines 28-30; page 23, lines 5-17
7	claim 30
8	claim 28

20. The revised claims submitted after hearing are as follows;

1. *A composition comprising an isolated antibody or antigen-binding fragment thereof that specifically binds to a peptide comprising an amino acid sequence provided by SEQ ID NO: 1.*
2. *The composition as claimed in claim 1, wherein the antibody is a monoclonal antibody or antigen-binding fragment thereof.*
3. *The composition as claimed in claim 1, wherein the antibody is a humanized antibody or antigen-binding fragment thereof.*
4. *The composition as claimed in claim 1, wherein the antibody or antigen-binding fragment thereof comprises a Fab, Fab', $F(ab')_2$, an Fv fragment, diabody, linear antibody, single-chain antibody, an scFv fragment, or a multispecific antibody.*
5. *The composition as claimed in claim 1, wherein the antibody or antigen-binding fragment thereof binds to stem cell factor (SCF) isoform b.*
6. *The composition as claimed in claim 1, wherein the antibody is a chimeric antibody or antigen-binding fragment thereof.*
7. *A kit comprising the composition as claimed in claim 1, a means for administering the composition to a subject, and instructions for use.*
8. *A method of preparing an isolated monoclonal antibody targeting stem cell factor comprising the steps of providing a peptide comprising a sequence, or a portion of a sequence of SEQ ID NO: 1, immunizing a host with the peptide, isolating an immune cell from the host, preparing a hybridoma using the immune cell, and isolating the antibody or antigen-binding fragment thereof.*

21. The operating portions of the Order of respondent no 2 is quoted herein below:

"III. The Applicant's agent submitted the amended claims 1-8 and marked up copy showing the amendments from the original claims 1

to 28 with the written submissions to the hearing. The amended claims 1 to 8 do not meet the requirements of Section 59(1) of the Patents Act, 1970 along with other objections (paragraphs) of the hearing notice as communicated, after considering the arguments put forth by the Applicant's agent…

"The Applicant's agent in the written submissions to the hearing stated that the support exists in the PCT claims and /or support in PCT application but the claims 2 to 4 are newly added claims voluntarily and the applicant's agent has not given any proper explanation or reason for the instant amendment and also has not mentioned by what way these amendments are carried out. The voluntary amendments are also not filed in the prescribed manner. The amendment by way of addition of new claims is not allowed as per the provisions of section 59 (1) of the Patents Act, 1970 as the mere support in the complete specification does not empower the applicant to amend the claims by any way (other than disclaimer, correction or explanation)which is beyond the scope of the provisions of sec 59 of the Patents Act, 1970. Thus, voluntary amendments by way of addition of new claims 4 to 6 are rejected and the arguments in the submissions on support are not tenable and do not meet the raised requirement. Further, the amended claim 8does not meet the requirements of the hearing notice as communicated; as the method claimed in claim 8(original claim 28)is not patentable asper the provisions of clause (i) of section 3 of the Patents Act, 1970. The amended claim 8 (original claim 28) is as following:

> *8. A method of preparing an isolated monoclonal antibody targeting stem cell factor comprising the steps of providing a peptide comprising a sequence, or a portion of a sequence of SEQ ID NO: 1, immunizing a host with the peptide, isolating an immune cell from the host, preparing a hybridoma using the immune cell, and isolating the antibody or antigen-binding fragment thereof*

The applicant's agent has not given any clear explanation or justification how the amended claim 8 (original claim 28) is patentable as per the provisions of clause (i) of Section 3 of the Patents Act, 1970. Hence, the alleged amended claim 8 (original claim 28) of the instant patent application is not patentable as per the provisions of clause (i) of section 3 of Patents Act, 1970 for being a claim for prophylactic method or medicinal/surgical method which claims a step of immunizing a host with the peptide, isolating an immune cell from the host...".Therefore, the alleged amended claim 8(original claim 28)claiming for a method of preparing an isolated monoclonal antibody targeting stem cell factor....is not patentable u/s 3 (i) of the Patents Act, 1970.

IV.In view of the above, the non-allowability of the amended claims 4 to 6 as per the provisions of section 59(1) of the Patents Act, 1970 and the amended claim 8(original claim 28)is not patentable as per the provisions of Section 3(i) of the Patents Act, 1970 and hence, it is hereby decided that the patent application 6001/DELNP/2013isrefused for grant of a patent.

22. In Novartis case[1] Hon'ble Supreme Court held in para 192 and 195 that for an invention to be patentable or not; both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) need be applied. It is equally true for any other sub-clause of section 3 as well. Meaning thereby that the examiners and Controllers do not have liberty to just examine the invention for applicability of section 3 requirements alone, leaving aside the basic question of patentability as provided in section 2(1)(j) of the Patents Act, 1970.

"192. Section 2(1)(j) defines "invention" to mean, "a new product or ...", but the new product in chemicals and especially

[1] Novartis Ag vs Union Of India & Ors available at https://indiankanoon.org/doc/165776436/

pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind". However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation.

195. In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost. The other two appeals are allowed."

23. Here, in the instant case both the tests of "novelty" and 'Inventive step' as provided in section 2(1)(j) of the Patents Act, 1970 has never been conducted. The matter has been decided by respondent no. 2 vide impugned order dated 13/03/2020, refusing the grant of the patent applying sections 3 (i) and 59(1) of the Patents Act, 1970. While trying to substantiate the objection of "unity of invention" he mentions in his order *"Even if it were to be conceded that that the stem cell factor inhibitor were to be considered as a common technical feature, it is seen in the prior art that stem cell factor inhibitors* ***are already known (D1, D2).*** *Therefore, these groups of claims lack unity of invention a posteriori and the claims that are considered to relate to distinct inventions have been grouped broadly into four groups."* [Emphasis added]. Further the examination report does

mention these two citations but for the purpose of unity of invention; further, an analysis whether a common technical feature, i.e. *stem cell factor inhibitors* are already known from D1 and D2 is neither present in FER (shown below) nor in the order of the Controller (quoted earlier).

क्र. सं. / Sl.no	दस्तावेज़ों का विवरण /Details of documents	प्रकाशन तिथि(दिन/माह/वर्ष) / Publication date	उद्धरित दस्तावेज़ का प्रासंगिक विवरण (पृष्ठ व अनुच्छेद संख्या) / Relevant description (page and paragraph no.) of cited document	उद्धरित दस्तावेज़ के प्रासंगिक दावे / Relevant claims of cited document	अभिकथित आविष्कार के दावे /Claims of alleged invention
1	D1:US20050112698A1	26/05/2005			See objection under the heas "UNITY OF INVENTION"
2	D2:US5808002A	15/09/1998			See objection under the heas "UNITY OF INVENTION"

24. Now, the operating portion of the order of the respondent no. 2 considers the hearing submissions filed by the appellant and considers their amended set of claims. He even mentions marked up copy of the original claims.

25. It is evident that the appellant has deleted originally filed claimed claims 1-24, renumbered claims 25, 26, 27, 28 and 30 as claims 1, 2, 3, 8 and 7 respectively. They have inserted dependent claims 4, 5 and 6, showing their dependency on to the principal claim 1 clearly.

26. Respondent no. 2 has considered these amendments and holds that *"The amended claims submitted post hearing are not meeting the requirements under Section 59(1) of the Patents Act, 1970 as the amended claims 4 to 6 are newly added claims and this voluntary amendment is not filed in the prescribed manner as per the Act and Rules. ….Also, as per the marked up copy the original method and composition claims 1 to 24 and 29 are disclaimed which is allowable but in place of that there is addition of new dependent composition claims 4 to 6 which is clearly amendment by way of addition and that is not allowable as per the provisions of section 59 (1) of the Patents Act, 1970.*

27. In Electric and Musical Industries Ltd v Lissen Ltd[2] It was held that *"They further have pointed out that the claims have a particular function to discharge. With every word of this I agree; but I desire to add something further in regard to the claim in a specification.*

The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundaries of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document, and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere. It is not permissible, in my opinion, by reference to some language used in the earlier part of the specification to change a claim which by its own language is a claim for one subject-matter into a claim for another and a different subject-matter, which is what you do when you alter the boundaries of the forbidden territory. A patentee who describes an invention in the body of a specification obtains no monopoly unless it is claimed in the claims. As Lord Cairns said, there is no such thing as infringement of the equity of a patent (Dudgeon v. Thomson, L.R. 3 App. Cas. 34)."

28. In this regard, it will be very relevant to quote the "Notes on clauses" on Amendment of specification of Justice Ayyangar Committee Report on Patents[3]

> *".....I consider that the scope of an amendment before acceptance ought to be wider than that after acceptance because at the former stage the specification is not disclosed to the public. It is then wholly a matter between the applicant for the patent*

[2] In Electric and Musical Industries, Ltd. et al v. Lissen, Ltd. et al: 56 RPC 23

[3] REPORT on the revision of the patents law by Shri Justice N. Rajagopala Ayyangar

and the office, and such amendments as are necessary to afford to the applicant, the benefit of the invention which he has disclosed in his complete specification ought to be available to him. On the other hand, after the acceptance of the application, and its advertisement, the contents of the specification become open to public inspection, and the rights of third parties who have started work on the basis of the claims made or not made, by the applicant in the published specification should be taken into account in defining the scope of the amendment which the applicant or the patentee might be permitted to effect. After a complete specification has been accepted two limitations not applicable to amendments at the earlier stage should be imposed. The first is in regard to the formulation of new claims which were not found in the original specification. Where a complete specification has not been advertised, there would be no question of a dedication of the unclaimed portion of the invention to the public and hence there cannot be any objection to a claim being formulated in respect of an invention disclosed in the specification if by error the claim has not been properly made or formulated. But where the specification has been accepted and advertised, the position is entirely different. In that case unless the claim after amendment would fairly fall within the claim before amendment it should not be permitted. In other words, it should be presumed that all claims not made, except by reason of obvious mistake, in the specification before acceptance are abandoned.

555. The second is a requirement that the invention before and after the amendment should be identical. This requirement would be out of place before acceptance and at that stage an amendment may be allowed so long as the

invention is comprehended within the matter disclosed. A mere shifting of the centre of gravity ought not to preclude an applicant from adjusting that centre until the specification is accepted, and is thrown open to public inspection. After that date, other interests and rights intervene and hence the applicant should be precluded from making a claim for any other inventions by amendments even if such be by way of disclaimer and the amendment would merely shift the centre of gravity (vide May & Baker's case).

29. It is clear from the plain reading of the above quoted notes that Justice Ayyangar Committee Report on Patents[4] also favours the wider scope of amendment before acceptance to that of after acceptance. Though the concept of "what is not claimed is disclaimed" is also upheld, when it talks about the amendments, after acceptance, and when the invention has been made available to public, after its publication.

30. The situation after the Patents (Amendments) Act, 2002, changed drastically when section 11A publication was introduced and when its sub-section (7) was further inserted vide Patents (Amendments) Act, 2005.

11A. Publication of applications[5].—

(1) Save as otherwise provided, no application for patent shall ordinarily be open to the public for such period as may be prescribed.

(7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent

[4] ibid

[5] Available at http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps11.html

for the invention had been granted on the date of publication of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted:

Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent: Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.

31. The concept of publication after acceptance was done away with and publication under section 11A was introduced to precede examination.

32. Further, Sub-section (3) of section 57[6] was also amended as *"Any application for leave to amend an application for a patent or a complete specification or a document related thereto under this section made* ***after the grant of patent*** *and the nature of the proposed amendment may be published."* removing the phrase *"after acceptance" [Emphasis added]*

33. The Manual of Patent Office Practice and Procedure[7] also mentions in paragraph 05.03.15 as:

[6] Available at http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps57.html

[7] Available at http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf

"A claim is a statement of technical facts expressed in legal terms defining the scope of the invention to be protected. No exclusivity is obtained for any matter described in the Complete Specification unless it is claimed in the claims. What is not claimed in the claims (including amended claims) stands disclaimed and is open to public use, even if the matter is disclosed in the description."

34. It is evident from the submission of the appellant that during the course of hearing respondent no. 2 allowed the 'composition' claims and "method of making the composition" and a claim for "kit comprising the composition" to be retained.

35. The objections of respondent no.2 are on claims 4-6 and 8, so let's discuss them in seriatim.

35.1 The principal claim 1 has been amended and is orienting towards *"A composition comprising an isolated antibody or antigen-binding fragment thereof..."* A close- look on the content of Claim 4 which is made dependent on claim1; is just to further define the features of *an isolated antibody or antigen-binding fragment thereof.* Though, the claim has been numbered separately, but the contents of claim 4 just narrow down the scope of claim1, further defining its feature(s) clearly, which is essential as per the teaching of the Patents law. We have seen that each of the words have their reference in the description. Therefore, holding that this claim is just an addition, is not an objective reading of the requirements of the law. If claim 4 is not allowed to be retained, claim 1 will be left totally non- definitive and wider which is not allowed as per the teaching of the law, either.

35.2 With regard to claim 5, we agree with the view of

respondent no. 2 that it cannot be allowed but for a different reason. Not that it's just a new addition and should be disallowed but due to the fact that it does not have an antecedent basis in claim 1 and hence cannot be allowed for the reason that it is going beyond the scope of claim 1.

35.3 With regard to claim 6, we consider that this dependent claim is also qualifying the ingredient of claim 1 i.e. antibody. But for these restrictions and qualifications, the principal claim could have been vague and non-allowable. Therefore this claim also could not be put in the category of new claim.

35.4 Therefore, both claims 4 and 6 cannot be construed as 'New' claim insertions, since they are just qualifying and limiting the scope of already defined subject matter of claim 1. No new feature(s), which was present in description but not claimed earlier, is being claimed through these claims. In the scenario, when a new additional feature was added, through insertion of new claim which was never claimed earlier but was present in description, such claims should have attracted the settled principle of law, i.e. "if not claimed; disclaimed", not otherwise.

35.5 Now with regard to the third objected claim 8 (original claim 28) which is objected as it attracts the provision of section 3(i) of the Patents Act, 1970.

35.6 Let's have a look on the provisions of the Act:

3. (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.

35.7 This clearly means that the inventions which relate to *method of treatment of human beings or similar treatment of animal which renders them free of disease, their economic value or that if their product* is not held patentable as per the teachings of section 3(i) of the Patents Act,1970. In the present case no such process or method is defined. Rather, it defines *"a method of preparing an isolated monoclonal antibody…"* . The particular step, identified in the order of the respondent no. 2 to attract the provisions of section 3(i), is *"immunizing a host with the peptide, isolating an immune cell from the host,"* . This particular step relates to preparation of monoclonal antibody using animal model rather than treating any human being or animal per se. Therefore, this claim does not attract the provisions of section 3(i) of Patents Act 1970 and is therefore, allowable.

Conclusions:

36. Keeping in view the settled principles of law, on amendments of the claims, we agree that no new claim may be allowed. But the whole question is whether the claim inserted in "new". Does it define any "new" feature(s) hitherto not defined in the body of the claims? If the answer is 'yes', then such claims are not allowed to be inserted. We refer to the body of the claims as originally filed, and amended subsequently, in both these sets the claim relating to "*A composition comprising an isolated antibody or antigen-binding fragment thereof* …" are present. The dependent claims inserted to qualify the features already covered in the principal claims and having sufficient basis in the description cannot be held to be "new".

Therefore, we allow the amended set of claims by the appellant except claim 5. We also allow claim 8 for reasons explained in earlier paragraphs.

37. The appellant is directed to file the fresh set of claims, renumbering claims 1,2,3,4,6,7, and 8 of the amendments proposed with hearing submission, vide their letter dated 04/03/2020 as claims 1-7, excluding claim 5, to the respondents no. 2 at the earliest.

38. We have observed that the test of "novelty" and "inventive steps" was never been carried out on any of the claims in the instant application by respondent no. 2.

39. The respondent no.2 is directed to be more cautious while communicating the gist of objections under section 14 to the applicants in future and avoid contradictory statements as in this case. If the test of "novelty" and 'inventive step' was conducted as per respondents no.2 for claims 1-23, the same should have been shown in the First Examination Report (FER); which shows NA/ blank in this case.

40. Therefore, keeping in view the above facts and circumstances, we set aside the impugned order of respondent no 2 dated 13/03/2020. The matter is remanded back to respondent no.2 to decide specific issues of "novelty" and "inventive step".

41. Respondent no.2 is directed to conduct the test of "novelty" and "inventive step" on the present set of claims 1-7 and decide the matter in accordance with law, after providing a fair opportunity to the applicant of being heard, if so required, strictly within 3 months from the date of issuance of this order.

42. Appeal is allowed. No cost.

- Sd/-	**-Sd/-**
(Dr. B.P. Singh) **Technical Member (Patents)**	**(Justice Manmohan Singh)** **Chairman**