
(2021) 02 IPAB CK 0012

In the Intellectual Property Appellate Board

Case No : Original Application No. 11 Of 2017/PT/KOL

Janssen Biotech, Inc

APPELLANT

Vs

Controller Of Patents

RESPONDENT

Date of Decision : 03-02-2021

Acts Referred:

Indian Patents Act, 1970 — Section 57, 59, 117A

Citation : (2021) 02 IPAB CK 0012

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

Bench : Division Bench

Advocate : Debashish Banerjee

Final Decision : Allowed

Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 13/12/2016, passed by the Respondent,

being the Assistant Controller of Patents & Designs, whereby he refused to allow amendments of Appellants's Indian granted patent No. 225434

(Patent application no. 152/KOLNP/2003), filed on Form-13.

2. It is the case of the appellant that After the grant of the subject patent, the Appellant noticed error in the sequence listing and figures 2A, 2B, 3, 4

and 5 which could not be recognized earlier.

As soon as the Appellant discovered the error in the sequence listings and figures, a post grant amendment on Form 13 was filed on January 10, 2014.

Surprisingly, the Respondent vide impugned order dated December 13, 2016 which was communicated by the Respondent on December 16, 2016

(under Section 57 of the Act), erroneously refused the Form 13 filed on January 10, 2014, without appointing a hearing in the matter.

Aggrieved by the impugned order dated December 13, 2016 (which was communicated on December 16, 2016), the Petitioner prefers the instant appeal.

3. The learned counsel of the appellant submits that It is clearly evident from the nature of the amendments carried out to the figures, the amendments

have been made to remove the unintended spaces from the figures in order to bring clarity. The Appellant submits that the spaces were a

typographical error and it is obvious to a person skilled in the art to recognize the said error as explained in more detail subsequently in this synopsis.

The Appellant submits that the amendments were in the nature of minor adjustments to correct spacing issues and explicitly mention sequence ids in

the figures.

Â In the present case, claim 1 refers to SEQ ID NOS. : 7 and 8 which were incorrectly mentioned in the original PCT specification. To correct the

same, Form 13 was filed by the Appellant to correct the sequence listings. The Appellant submits that the amendment to the sequence listings ought to

have been allowed by the Respondent since the correct sequence of the antibody is depicted in figures 4 and 5 of the application as originally filed.

The Appellant submits that no new subject matter has been added and all the amendments requested were only of corrective nature and therefore

were permissible under Section 57 and 59 of the Patents Act.

In view of the foregoing, the Appellant submits that the order of the Respondent refusing the Appellant's application is erroneous in law and is

liable to be set aside. Respondent ought not to have refused the voluntary request for amendment of the figures and sequence listings filed by the

Appellant on Form 13 on January 10, 2014.

The Appellant further invite the attention of this Board to the following points:

The impugned order is vitiated since the Respondent misdirected himself in the appraisal of Section 57 and Section 59 of the Act and failed to

appreciate that the nature of amendments requested on Form 13 filed on January 10, 2014 were corrective in nature and were allowable Section 57 of

the Act and not barred under Section 59 of the Act.

The impugned order is vitiated since it does not contain even a whisper as to how Section 57 or Section 59 has been contravened. The Appellant

submits that impugned order is erroneous inasmuch as it has failed to appreciate that the post-grant amendments to figures 2A, 2B, 3, 4 and 5 and the sequence listing filed which were requested on Form 13 dated January 10, 2014 meets the requirements of Section 57 and is not precluded from allowance under Section 59 of the Act.

4. The learned counsel of the appellant has further clarified the amendments as follows:

As directed by the Honâ??ble Board during the hearing attended in the matter on February 03, 2021, the Appellant wishes to present the following explanation regarding the nature and support for the amendments requested vide Form 13 filed on January 10, 2014.

The Appellant submits that the impugned order is erroneous since the amendments made to the sequence listing and figures 2 A, 2B, 3, 4 and 5 of the specification are within the scope of the as filed specification. The Appellant submits that said amendments have been made to remove the unintended spaces from the figures in order to bring clarity.

The Appellant submits that the spaces were a typographical error and it is obvious to a person skilled in the art to recognise said error because of the following reasons:

The Figure legends on page 6-11 makes no mention of spaces in the figures. Unlike the dots and dashes in the figures, the legends do not define the meaning of any spaces and therefore the skilled person would not expect to see them in the figures.

Moreover, the length of the gap created by the erroneous spaces is the same in number of characters as the length of the overhang that it causes beyond the end of the germline sequence. To the skilled person familiar with sequence alignments (which use a font where each character takes up the same space, e.g., the â??Courierâ?? font in Figure 4), this equal-sized gap and overhang shows that the alignment contains unintended spaces.

Â The skilled person would recognise that the space should not be present because it leads to the final six residues in the TNV14 and TNV15 sequences being said to be identical to no corresponding residues in the germline. This alignment cannot be correct. For example, the incorrect alignment would mean that the CDR3 sequences in the TNV14 and TNV15 antibodies are only 11 amino acids long, in contrast to the 17 amino acid

length of the CDR3 sequences in the other antibodies. The skilled person would realize that this alignment is incorrect because the patent says that

each of the heavy chain CDR3 sequences are [...] of the same length' in these antibodies. (Attention is invited to page 84, last paragraph)

The incorrect alignment is further demonstrated by the fact that the eighth residue in the TNV14 CDR3 is shown to be a glycine (G) which is same as

the glycine in the germline sequence immediately above. If the misalignment was intended, then the glycine TNV14 CDR3 would be shown as a dot

and not as glycine.

Therefore, while the respondent failed to identify the typographical error, the Appellant has rectified the same in order to bring clarity to the claimed

scope of the invention.

The amendments made to Figure 2A are as under:

As filed figure 2A:

The Appellant submits that said figure has been amended only to remove the unintended spaces (highlighted in blue above) and SEQ IDs have been

mentioned to bring clarity, apart from that, no other amendment has been made to the figure as follows:

Amended Figure 2A:

The amendments made to Figure 2B are as under: As filed Figure 2B:

As is evident from the above figure, the unintended spaces highlighted in blue have been removed. Further, the misaligned underlined text has been

aligned properly. Further, Sequence IDs have been mentioned just to bring clarity. Apart from that, no other change has been made to the Figure.

Amended figure 2B is as follows

The amendments made to Figure 3 are as under: As filed Figure 3:

As is evident from the above figure, the unintended spaces highlighted in blue have been removed. Further, the misaligned underlined text has been

aligned properly. Further, Sequence IDs have been mentioned just to bring clarity. Apart from that, no other change has been made to the Figure.

Amended figure 3 is as follows:

The amendments made to Figure 4 are as under: As filed figure 4:

As is evident from the above figure, the unintended spaces highlighted in blue have been removed. Further, the misaligned underlined text has been

aligned properly. Further, Sequence Ids have been mentioned just to bring clarity. Apart from that, no other change has been made to the Figure.

Amended Figure 4:

The amendments made to Figure 5 are as follows:

As filed Figure 5:

As is evident from the above figure, the unintended spaces highlighted in blue have been removed. Further, Sequence Ids have been mentioned just to bring clarity. Apart from that, no other change has been made to the Figure.

Amended Figure 5:

Therefore, in view of the aforesaid, no substantial change has been made to the figures. The figures have been amended by way of correction, merely to correct the typographical errors and align the sequences co-terminously.

Regarding the Amendments made to the Sequence Listings:

The Appellant wishes to invite the attention of the Honâ??ble IPAB towards the below figure, which indicates the amino acid three letter and single letter codes:

The Appellant submits that the Sequence listing has been amended merely to rectify the typographical errors and support for the amendments made can be found in original figures 4 and 5 of the specification.

Further, the Appellant submits that Figures 4 and 5 provide the sequences for the antibodies either by referring to them individually (e.g., as TNV14, TNV15 etc.) or by referring to them collectively (e.g. as ""TNVsâ??). Figures 4 and 5 provides the sequence information for all of the CDRs and FRs in all of the TNV antibodies.

The Amendments made to the sequence listing are discussed as under:

Amendment to SEQ ID NO: 1:

As indicated above, SEQ ID No: 1 corresponds to heavy chain CDR1. The amendment made to SEQ ID NO: 1 includes replacing â??Argâ? by â??Serâ? and Thr by â??Alaâ?. Support for the same can be found in Figure 4, wherein sequence of CDR1 has been provided i.e. â??SYAMHâ?

(S refers to Serine and A refers to Alanine). The sequence listing has been amended to correct the typographical error and to bring it in line with the Specification.

Amendment to SEQ ID NO: 2:

As indicated above, SEQ ID No: 2 corresponds to heavy chain CDR2. Support for the amendments made can be found in following extract from

Figure 4, wherein sequence of CDR2 has been provided (refer below).

Support for the amendments made to position 1, 2, 3, 4, 10, 11 and 17 can be found in figure 4. For e.g:

the addition that â??Xaa at position 1 is selected from Ile, Phe or Valâ?? derives support from the above figure, wherein the first position in germline

sequence is occupied by valine, isoleucine in TNV 14 and Phenylalanine in TNV 15, TNV 148 and TNV 196.

the addition that â??Xaa at position 2 is selected from Ile or Metâ? derives support from the above figure, wherein the second position in germline

sequence is occupied by isoleucine and methionine in TNV 148.

the addition that â??Xaa at position 3 is selected from Ser or Leuâ? derives support from the above figure, wherein the third position in germline

sequence is occupied by Serine and leucine in TNV 14 and TNV 15.

Similarly the support for the amendments to positions 4, 10, 11 and 17 can be found in the above figure.

Amendment to SEQ ID NO: 3:

As indicated above, SEQ ID No: 3 corresponds to heavy chain CDR3. Support for the amendments made can be found in following extract from

Figure 4, wherein sequence of CDR3 has been provided (refer below).

Support for the amendments made to positions 4, 5 and 9 can be found in figure 4. For e.g:

the addition that â??Xaa at position 4 is selected from Ile or Valâ? derives support from the above figure, wherein the fourth position in TNV 14 is

occupied by Isoleucine

(I) and Valine (V) in TNV 15.

the addition that â??Xaa at position 9 is selected from Asn or Tyrâ? derives support from the above figure, wherein the ninth position in germline

sequence is occupied by Tyrosine(Y) and Asparagine (N) in TNV 14.

Amendment to SEQ ID NO: 4:

As indicated above, SEQ ID No: 4 corresponds to light chain CDR1. Support for the amendments made can be found in following extract from Figure

5, wherein light chain sequence of CDR1 has been provided (refer below).

Support for the amendments made to position 7 can be found in figure 5. For e.g: the addition that "Xaa at position 7 is selected from Ser or Tyr" derives support from the above figure, wherein the 7th position in germline sequence is occupied by Serine (S) and Tyrosine (Y) in TNV 148 and TNV 196.

Amendment to SEQ ID NO: 5:

As indicated above, SEQ ID No: 5 corresponds to light chain CDR2. Support for the amendments made can be found in following extract from Figure

5, wherein light chain sequence of CDR2 has been provided (refer below).

Support for the amendments can be found in figure 5 as amino acid sequence of CDR2 relates to DASNRAT, and D corresponds to Aspartate

(Asp) and NRAT corresponds to Asparagine (Asn), Arginine (Arg), Alanine (Ala) and Threonine (Thr) respectively.

Amendment to SEQ ID NO: 6:

As indicated above, the only amendment made to SEQ ID No:

6 is to define that SEQ ID No: 6 corresponds to light chain CDR3. Support for the amendments made can be found in following extract from Figure 5,

wherein light chain sequence of CDR3 has been provided (refer below).

Support for the amendments can be found in figure 5 as amino acid sequence of CDR3 relates to QQRSNWPPFT.

Amendment to SEQ ID NO: 7:

SEQ ID No: 7 has been amended to specify that said sequence corresponds to heavy chain variable region sequences wherein positions 1-30 are

occupied by Framework 1(FR1), positions 31-35 are occupied by CDR 1 sequence, positions 36-49 by Framework 2 (FR2), positions 50-66 by CDR2,

positions 67-98 by Framework 3 (FR3), positions 99-115 by CDR 3, positions 116-126 by J6 region. Support for the amendments made can be found

in Figure 4, wherein all the sequences FR1, FR2, CDR1, CDR2 and CDR3 sequences have been provided (refer below).

the addition that "Xaa at position 28 is selected from Ile or Thr" derives support from the below figure, wherein the 28th position (FR1) is

occupied by Threonine (Thr) in germline sequence and Isoleucine (Ile) in TNV 148.

the addition that "Xaa at position 43 is selected from Lys or Asn" derives

support from the below figure, wherein the 43rd position (8th position in Framework

2 (FR2) as FR2 lies between positions 36-49) is occupied by Lysine(K) in germline sequence and Asparagine (N) in TNV 148.

the addition that Xaa at position 50 is selected from Ile, Phe or Valâ? derives support from the below figure, wherein the 50th position (1st

position in CDR2 as CDR2 lies between positions 50-66) is occupied by Valine(V) in germline sequence, Isoleucine (I) in TNV 14 and Phenylalanine

(F) in TNV 15, TNV 148 and TNV 196.

the addition that Xaa at position 94 is selected from Tyr or Pheâ? derives support from the below figure, wherein the 94th position (28th

position in Frame work

3 (FR3) as FR3 lies between positions 67-98) is occupied by Tyrosine (Y) in germline sequence and Phenylalanine (F) in TNV196.

the addition that Xaa at position 102 is selected from Ile or Valâ? derives support from the above figure, wherein the 102nd position (4th

position in CDR3 as positions 99-115 are occupied by CDR 3) is occupied by Isoleucine (I) in TNV 14 and valine (V) in TNV 15.

Similarly, the support for the amendments in rest of the positions derives support from Figure 4.

Amendment to SEQ ID NO: 8:

The Appellant submits that as indicated above, no substantial amendment has been made to SEQ ID NO 8. SEQ ID NO: 8 corresponds to light chain

variable region sequences as presented in original Figure 5. The amendments made to said SEQ ID only includes the description about the positions

occupied by FR1, CDR1, CDR2, CDR3 and J6 region in SEQ ID No: 8. The amendments indicate that positions 1-23 are occupied by Framework

1(FR1), positions 24-34 are occupied by CDR 1 sequence, positions 35-49 by Framework 2 (FR2), positions 50-56 by CDR2, positions 57-88 by Frame

work 3 (FR3), positions 89-98 by CDR 3, positions 99-108 by J3 region as indicated in Figure 5.

Amendment to SEQ ID NO: 9:

No amendment has been made to SEQ ID No: 9. The only amendment made specifies that the said sequence corresponds to human TNF alpha

monomer sequence.

Â Added SEQ ID NO: 32:

SEQ ID NO: 32 corresponds to signal sequence for heavy chain variable region sequences as presented in original Figure 4. Support can be found in

following extract from Figure 4:

Â Added SEQ ID NO: 33:

SEQ ID NO: 33 corresponds to signal sequence for light chain variable region-sequences as presented in original Figure 5. Support can be found in

following extract from Figure 5:

Added SEQ ID NO: 34:

Â SEQ ID NO: 34 corresponds to heavy chain variable region DNA sequences as presented in original Figure 2A-2B. Support can be found in

following extract from Figure 2A-2B:

Added SEQ ID NO: 35:

SEQ ID NO: 35 corresponds to light chain variable region DNA sequences as presented in original Figure 3. Support can be found in following extract

from Figure 3:

5. The learned counsel for the appellant further submits that

The impugned order contravenes the principles of natural justice since no opportunity was given to the Appellant to present its submissions/ arguments

with respect to the amendments requested on Form 13. It is pertinent to note that the conduct of the Respondent is inequitable since on the one hand

he provided the general public two opportunities of hearing by publishing the amendment two times under Rule 81 (3) (a) read with Section 57 in the

Patent Office Journals dated May 16, 2014 and June 11, 2016 and on the other hand did not provide even a single opportunity of hearing under Rule

129 to the Appellant before refusing the Form 13 filed by the Appellant on January 10, 2014.

The law has been definitively interpreted by the courts of the country including the Honâ??ble IPAB in a number of cases where it has been held

that the doctrine of audi alterem partem is sacrosanct and the decision ought to be revoked on the ground of violating this touchstone alone.

It is pertinent to mention that even though two opportunities were given to the public, not even a single representation was filed by a third party since

the amendments were filed only to correct obvious errors in the sequence listings and figures.

The Appellant submits that the impugned order ought to be set aside since it has been passed in contravention of Rule 129 of the Patents Rules and also in contravention to well established judicial precedents.

The Appellant submits that the impugned order is erroneous and liable to be set aside since the same contravenes well established judicial precedents with respect to permissible amendments.

The Appellant submits that the impugned order has failed to follow the principles enunciated by the Delhi High Court in the matter of AGC Flat Glass

Europe SA vs Anand Mahajan & Ors. (I.A. No. 13519/2007 in CS (OS) No. 593/2007) wherein it was unequivocally held that:

17 The claims can be amended and such amendment may be allowed provided that it is clarificatory or elaborative in nature

and also, that it does not alter the scope of the claim or introduce any new claim in the invention which was not present in the original invention. Thus,

the scope of enquiry in relation to amendments in the patent claim is limited to the extent as to whether it introduces any new claim which extends the

scope of the monopoly rights of the patentee.

The Appellant submits that the impugned order being a non-reasoned order is vitiated since it has been passed in contravention of the principles of

natural justice. The Apex Court has time and again held that reason is the soul of a judgment. In the matter of Competition Commission of India Vs.

Steel Authority of India Ltd. & Anr., the Apex Court held that:

12. At the cost of repetition, we may notice, that this Court has consistently taken the view that recording of reasons is an essential feature of

dispensation of justice. A litigant who approaches the Court with any grievance in accordance with law is entitled to know the reasons for grant or

rejection of his prayer. Reasons are the soul of orders. Non-recording of reasons could lead to dual infirmities; firstly, it may cause prejudice to the

affected party and secondly, more particularly, hamper the proper administration of justice. These principles are not only applicable to administrative or

executive actions, but they apply with equal force and, in fact, with a greater degree of precision to judicial pronouncements. A judgment without

reasons causes prejudice to the person against whom it is pronounced, as that

litigant is unable to know the ground which weighed with the Court in rejecting his claim and also causes impediments in his taking adequate and appropriate grounds before the higher Court in the event of challenge to that judgment...

13. The principle of natural justice has twin ingredients; firstly, the person who is likely to be adversely affected by the action of the authorities should

be given notice to show cause thereof and granted an opportunity of hearing and secondly, the orders so passed by the authorities should give reason

for arriving at any conclusion showing proper application of mind. Violation of either of them could in the given facts and circumstances of the case, vitiate the order itself. [Emphasis supplied]

6. The order of the respondent is as under:

7. We have also noted that the Assistant Controller has written an internal letter Available at

<https://ipindiaservices.gov.in/PatentSearch/PatentSearch/ViewPDF> to another Assistant Controller, informing the publication of the proposed

amendments and seeking his approval for the allowance of Form 13.

8. Let us have a look at the provisions of law concerning amendments:

CHAPTER X Available at <https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps57.html>

AMENDMENT OF APPLICATIONS AND SPECIFICATIONS

Section 57

Amendment of application and specification or any document relating thereto before Controller

(1) Subject to the provisions of section 59, the Controller may, upon application made under this section in the prescribed manner by an applicant for a

patent or by a patentee, allow the application for the patent or the complete specification or any document relating thereto to be amended subject to

such conditions, if any, as the Controller thinks fit:

Provided that the Controller shall not pass any order allowing or refusing an application to amend an application for a patent or a specification or any

document relating thereto under this section while any suit before a court for the infringement of the patent or any proceeding before the High Court

for the revocation of the patent is pending, whether the suit or proceeding

commenced before or after the filing of the application to amend.

(2) Every application for leave to amend an application for a patent or a complete specification or any document relating thereto under this section

shall state the nature of the proposed amendment, and shall give full particulars of the reasons for which the application is made.

(3) 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.

(4) Where an application is published under sub-section (3), any person interested may, within the prescribed period after the publication thereof, give

notice to the Controller of opposition thereto; and where such a notice is given within the period aforesaid, the Controller shall notify the person by

whom the application under this section is made and shall give to that person and to the opponent an opportunity to be heard before he decides the

case.

(5) An amendment under this section of a complete specification may be, or include, an amendment of the priority date of a claim.

(6) The provisions of this section shall be without prejudice to the right of an applicant for a patent to amend his specification or any other document

related thereto to comply with the directions of the Controller issued before the grant of a patent.

Section 59 Available at <https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps59.html>

Supplementary provisions as to amendment of application or specification

(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of

disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no

amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe

matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall

wholly within the scope of a claim of the specification before the amendment.

(2) Where after the date of grant of patent any amendment of the specification

or any other documents related thereto is allowed by the Controller or by the Appellate Board or the High Court, as the case may be,â?

(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;

(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and

(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.

(3) In construing the specification as amended, reference may be made to the specification as originally accepted.

CHAPTER IX Available at <https://ipindia.gov.in/writereaddata/Portal/ev/rules/pr81.html>

AMENDMENT OF APPLICATION, SPECIFICATION OR ANY DOCUMENT RELATING THERETO

Rule 81

Amendment of application, specification or any document relating thereto

(1) An application under section 57 for the amendment of an application for a patent or a complete specification or any document related thereto shall be made in Form 13.

(2) If the application for amendment under sub-rule (1) relates to an application for a patent which has not been granted, the Controller shall determine whether and subject to what conditions, if any, the amendment shall be allowed.

(3) (a) If the application for amendment under sub-rule (1) is made after grant of patent and the nature of the proposed amendment is substantive, the application shall be published.

(b) Any person interested in opposing the application for amendment shall give a notice of opposition in Form 14 within three months from the date of publication of the application.

(c) The procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leaving evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under section 57 as they apply to the hearing of an opposition proceeding.

9. We have verified that the proposed amendments have been published twice in the Patent Office Journals dated on 16/05/2014 and 11/06/2016.

10. It is noted that the respondent has violated the settled principles of law twice. Firstly, he failed to give an opportunity of being heard to the applicant; leave alone fair opportunity. Secondly, order passed by him is void of any reasoning and it cannot be sustained.

11. We have considered the proposed amendments and found that they are well within the provisions of section 57 read with section 59 of the Patents

Act, 1970. We have also considered the affidavit filed by Mr. BRIAN CAREY and are convinced to accept his submissions.

12. We are of considered view that the proposed amendments at para 7 and 8 of the order of respondent i.e. those relating to SEQ ID 10-15 and 16-

35 do not have any relevance and hence we are inclined to accept the Auxiliary Request II submitted by the appellant, wherein they are willing to

delete the proposed amendment relating to Sequences 10-35.

13. Therefore, we set aside the impugned order of the respondent dated 13/12/2016 and direct the respondent to allow the remaining amendments.

The respondent is also directed to take all further necessary procedural measures in accordance with law after such amendment.

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