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

\+ W.P.(C)-IPD 2/2023 & CM 2/2023, CM 3/2023

NATCO PHARMA LIMITED ..... Petitioner

Through: Mr. J. Sai Deepak with Mr. G. Nataraj, Mr. Ankur Vyas, Mr. Shashikant Yadav, Ms. Harshita Aggarwal, Mr. Rahul Bhujbal and Ms. Garima Joshi, Advs.

versus

ASSISTANT CONTROLLER OF PATENTS & DESIGNS ANR. ..... Respondents

Through: Mr. Hemant Singh, Ms. Mamta Jha, Mr. Siddhant Sharma, Ms. Garima Mehta and Mr. Abhay Tondon, Advs.
Mr. Harish V. Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat & Mr. Alexander Mathai Paikaday, Advs. for R-1

CORAM:

HON'BLE MR. JUSTICE C.HARI SHANKAR

J U D G M E N T (O R A L)

% 12.01.2023

1. This is a writ petition under Article 226 of the Constitution of India, whereby the petitioner Natco Pharma Ltd. (Natco) assails order dated 14th December 2022, passed by the Learned Assistant Controller of Patents and Designs, allowing Indian Patent Application no. 4412/DELNP/2007, filed by Respondent 2 - Novartis AG (Novartis) on 8th June 2007.

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2. By consent of learned Counsel for the parties, Mr J Sai Deepak and Mr. Hemant Singh, the Court has heard the matter finally and proceeds to dispose of the writ petition.

3. Novartis has assailed the maintainability of this petition under Article 226, as alternate remedies, by way of rectification and correction of the register of trade marks under Section 71(1)[1] of the Trade Marks Act, is available to the petitioner.

4. At the outset of hearing, therefore, it was made clear by the Court that the Court would not be examining, in the present proceedings, the merits of the impugned order, i.e. the patentability or otherwise of the invention claimed by Novartis. As such, Mr. Sai Deepak, learned Counsel for Natco, too, restricted his challenge to the aspect of procedural irregularity and violation of the principles of natural justice in the passing of impugned order dated 14th December 2022. He has cited the decisions of the Supreme Court in ***Whirlpool Corpn. v. Registrar of Trademarks***[2] and ***Harbans Lal Sahnia v. Indian Oil Corporation***[3] among others, to contend that, where a quasi judicial order is passed in violation of the principles of natural justice or in the teeth of the provisions in that regard as they find place in the relevant statutory instruments, a writ petition under Article 226 of the Constitution would

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[1] **71. Rectification of register by High Court** –
(1) The High Court may, on the application of any person aggrieved –
(a) by the absence or omission from the register of any entry; or
(b) by any entry made in the register without sufficient cause; or
(c) by any entry wrongly remaining on the register; or
(d) by any error or defect in any entry in the register,
make such order for the making of variation or deletion, of any entry therein, as it may think fit.

[2] **(1998) 8 SCC 1**

[3] **(2003) 2 SCC 107**

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Signing Date:15.01.2023 13:18:51

be maintainable.

5. I would advert to the issue of maintainability towards the conclusion of this decision. One may, at the outset, refer to the relevant facts, insofar as they are necessary for the purposes of the limited scope of the present examination.

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6. Following a PCT Application dated 16th January 2003, and claiming priority from US Provisional 60/349660, Novartis filed a National Phase Application No. 1538/CHENP/2004, for grant of a patent titled "Pharmaceutical Compositions comprising Valsartan and NEP inhibitors" which was granted by the Controller of Patents on 13th February 2009 as IN 229051 (IN'051).

7. Subsequently, on 8th June 2007, Novartis filed National Phase Application No.4412/DELNP/2007 (hereinafter "Application No. 4412"), relatable to PCT WO2207/056456 and claiming priority on the basis of four US Provisional Patents No. 60/735093 dated 9th November 2005, 60/735541 dated 10th November 2005, 60/789332 dated 4th April 2006 and 60/8822086 dated 11th August 2006, for a patent titled "pharmaceutical combinations of an Angiotensin Receptor Antagonist and an NEP Inhibitor". At the time when the claims were filed as WO546, there were 85 claims. However, as filed in Application No. 4412, there were 29 claims.

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Signing Date:15.01.2023 13:18:51

8. Application No. 4412, as filed by Novartis, was subjected to examination by the examiner in the office of the Controller of Patents. The examiner issued a first examination report dated 30th January 2015, containing the following objections (to the extent they are relevant):

> "1. Claims" part of the specification should be super scribed with "I /We claim":-.
>
> 2. Claim 1 (and thus dependent claims) are not clear and succinct and sufficiently definitive to the scope of alleged invention in the absence of mention of any significant feature/components/characteristics of said product that reflects technological contribution to establish it as new product. [Requirements of Sec. 2(1 J G) and Sec. 1O]
>
> 3. Title inconsistent with description and claims. Title should be in accordance of claim.
>
> 4. Claims 1-12,13,14-19 are mere new forms of the known compound and do not differ significantly in properties with regard to efficacy. Therefore, these Claims fall within the scope of such clause of section 3(d) of the Patent Act 1970 as amended in 2005.
>
> 5. Claims 12,13-19, 20-21, 22-26,27-29 define a plurality of Distinct inventions.
>
> 6. Claims 12, 13, 25, 27 relates to an independent Invention.
>
> 7. Claim 1 and its dependent claims does not constitute an Invention under section 2[1 (II] of Patents Act 1970 (as amended in 2005) as the claims are lacking in Inventive step in the view of cited Patent documents:
> D1 :W02006086456
> D2: WO 03/059345
> D3: EP·A1-04 43 983
> 04: US-A-5 217 996
> D5:J. Med. Chem. 1995, 38(1 0), 1689-1700"

9. Novartis filed its response to the aforesaid First Examination Report (FER) dated 30th January 2015, on 27th November 2015. By the said report, Novartis amended its claims. As amended, only 17 claims

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Signing Date:15.01.2023 13:18:51

survived.

10. The claims of Novartis were further amended by it on 30th May 2016 to eight claims. Of the said eight claims, the objections of the petitioner are essentially relatable to Claims 1, 3 and 4.

11. At this stage, on 6th September 2016, Natco filed a pre-grant opposition to Application 4412 of Novartis under Section 25(1)[4] of the

[4] **25. Opposition to the patent**. –
(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground –
(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim—
(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or
(ii) in India or elsewhere, in any other document:
Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or sub-section (3) of Section 29;
(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;
(d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.
Explanation. – For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;
(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;
(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;
(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
(h) that the applicant has failed to disclose to the Controller the information required by Section 8 or has furnished the information which in any material particular was false to his knowledge;
(i) that in the case of convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

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Signing Date:15.01.2023 13:18:51

Patents Act, 1970, raising various grounds to oppose Novartis' application.

12. As this Court is not examining the merits of the objections raised by Natco, it is not necessary to burden this decision by a recital of the said grounds. Suffice it to state that on 3rd March 2017, Novartis filed its reply to the pre-grant opposition of Natco.

13. While things stood thus, on 4th/5th February 2019, Novartis instituted CS (Comm) 62/2019 before this Court, alleging infringement, by Natco, of IN'051, by manufacturing and marketing a product consisting of a combination of Valsartan and Sacubitril. The merits of that suit need not detain us. Natco, however, contends that, in the said suit, Novartis had admitted that the claim forming subject matter of Application 4412 was already claimed and protected in IN'051. The merits of that contention, too, need not detain us in the present case.

14. On 6th January 2020, Natco filed an application before the learned Controller in Application 4412 of Novartis, seeking to place the entire record of CS (Comm) 62/2019 before the learned Controller. *Inter alia*, the application sought, as already noted, to aver that, in CS (Comm) 62/2019, Novartis had acknowledged that the invention forming subject matter of Application 4412 already stood claimed and protected in

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(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,

but on no other ground and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.

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Signing Date:15.01.2023 13:18:51

IN'051.

15. On 6th June 2020, Novartis filed a new claim set before the learned Controller, along with three expert affidavits. Natco contends that Claim 4 in the new set of eight claims included the compound claimed in Claim 4 by Novartis in crystalline form which, according to Natco was originally claimed as Claim 3 in Application 4412 and was subsequently deleted in the eight claims which were filed on 30th May 2016, consequent on Natco's objection.

16. On 7th May 2021, Natco applied to the learned Controller for permission to cross examine the three experts whose affidavits had been filed by Novartis on 8th June 2020. The request was disallowed by the learned Controller on 16th September 2021. Aggrieved thereby, Natco moved this Court by way of WP (C)-IPD 91/2021 ***(Natco Pharma Ltd. v. UOI & Ors.)***

17. *Vide* judgment dated 12th July 2022, a Coordinate Single Bench of this Court disposed of WP (C)-IPD 91/2021. This Court, in the said decision, placed reliance on the earlier decision of a coordinate Single Bench of S. Muralidhar, J (as he then was) in ***UCB Farchim SA v. Cipla Ltd.***[5], specifically for the proposition that a pre-grant opposition proceeding is in aid of the examination of the patent application. Having reproduced para 13 of the decision in ***UCB Farchim***[5], to the said effect, the Coordinate Bench proceeded to observe and direct, in paras 18 to 23

[5] **(2010) 42 PTC 425 (Del)**

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Signing Date:15.01.2023 13:18:51

of the decision, thus:

> "18. The language used in Section 25(1) of the Act is in contrast with the language used in Section 25(2) of the Act. A pre-grant opposition is a *`representation by way of opposition'* in writing by *"any person".* Whereas, Section 25(2) of the Act is a *`notice of opposition'* by *"any person interested"*. A Representation under Section 25(1) of the Act does not strictly follow the norms laid down under the Code of Civil Procedure. However, since Rule 55(4) of the Rules contemplates filing a reply statement and evidence, if the applicant wishes to, it can be said that the proceedings is adjudicatory as the same is adversarial in nature.
>
> 19. *The proceeding in a pre-grant opposition and simultaneous examination of a patent application, however, cannot also result in a situation where the pre grant opponent is kept in dark about the developments taking place in the examination process.* For example, when amendments are filed by the Applicant, an immediate decision ought to be taken on allowing or disallowing the amendment so that there is transparency and clarity as to what are the claims being considered by the Controller. A short and brief order should be passed in respect of the amendments which should be uploaded on the website of the Patent Office so that everyone concerned would know the decision on the amendment. In any event, if an amendment is being carried out during the pendency of a pre-grant opposition, the ruling on the amendment ought to be sent to the pre-grant opponent as well. Sometime amendments are carried out during the course of hearings across the table as well, when the patent agent of the Applicant attends the hearing before the Controller. In such a scenario, the Controller ought to examine the said amendments and convey the decision to the Applicant, and if the Opponent is present, even to the Opponent.
>
> 20. In the present writ it is noticed by the Court that there are four amendments on record filed by the Applicant and hence five sets of claims have been filed as late as on June, 2021 much after the completion of the pleadings in the pre-grant opposition.
>
> 21. The Applicant justifies filing of the expert's affidavit on the ground that the Opponent had filed certain additional documents. Be that as it may, the fact is that three substantive affidavits have been filed by the Applicant the Court, an opportunity ought to be granted to the Opponent to rebut the evidence of the Applicant. The Opponent-Natco has agreed to not insist on its prayer seeking cross examination of Applicant's witnesses- Dr. Michael Motto, Dr. Allan S. Myerson and Dr. Gauri Billa, if it is given an opportunity to file affidavits of its

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Signing Date:15.01.2023 13:18:51

own experts in rebuttal. The said arrangement is not objected to by the Applicant. In the above background, and in order to expedite the decision on the application and the pre-grant opposition, the following directions are issued:

i) the Opponent is permitted to file affidavits of its own experts in rebuttal to the three expert affidavits filed by the Applicant, within a period of four weeks.

ii) If any documents are filed by the Opponent along with the said expert affidavits, the same shall be dealt with by the Applicant by way of additional written submissions within one week thereafter, without any further documents being filed by the Applicant.

iii) The Opponent is also permitted to file its additional written submissions within two weeks after filing of additional written submissions by the Applicant. The written submissions filed by both the parties shall be considered by the Controller for final decision in the pre-grant opposition;

iv) Parties shall appear before the Patent Office on 12th September, 2022 at 2:30 p.m. Both the Applicant and the Opponent shall be given one hour each to make their submissions.

v) The situation as it exists today is that there has been no ruling on any of the amendments which have been filed by the Applicant. Thus, before the commencement of oral hearing in the pre-grant opposition, the Controller shall communicate orally to both the parties as to which of the amendments are being allowed and which would be the final set of claims which is being considered for grant.

vi) On the said date, after hearing the parties for one hour each, the final decision on the application/pre-grant opposition shall be given by the Patent Office on or before 15th November, 2022. The final decision rendered shall be communicated to all the parties and shall also be uploaded on the website of the Patent Office;

vii) It is clarified that the hearing of any other opposition proceeding which has already concluded is not being re-opened by this Court;

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Signing Date:15.01.2023 13:18:51

> 22. The observations made in respect of amendments in the present order shall not be applicable to amendments directed by the Controller under Section 15 of the Act.
>
> 23. All contentions of parties are left open. This order shall not be treated as an opinion on the merits of the application or the pre-grant opposition."
>
> (Emphasis supplied)

18. Following the passing of the aforesaid judgment dated 12th July 2022 by this Court, the petitioner filed, before the learned Controller, the affidavit of one Dr. Ramesh Dandala on 9th August 2022. No other documents were filed by the petitioner after the passing of the order dated 12th July 2022.

19. Mr. Hemant Singh points out that, prior to the passing of the judgment dated 12th July 2022, an earlier opportunity of hearing had also been granted by the learned Assistant Controller to both parties on 13th May 2021.

20. On 5th September 2022, the learned Assistant Controller granted an opportunity of personal hearing to both sides. On the said date, the learned Assistant Controller, in accordance with the directions issued by this Court, in its judgment dated 12th July 2022, made the parties aware that he would be considering eight claims as filed by Novartis on 6th June 2020. Following the said hearing, on 20th September 2022, written submissions were filed by both sides.

21. Thus far, it appears that tempers remain unruffled. The controversy emanates from what transpired thereafter.

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Signing Date:15.01.2023 13:18:51

22. On 25th November 2022, the learned Assistant Controller addressed the following notice, *only to Novartis*:

"**Dated: 25/11/2022**

To,

INTTL ADVOCARE Agent for applicant Novartis AG.,

Sub:- Hearing notice under section 14 of the Patent Act 1970 as amended in 2005

Sir,

This is to bring to your notice that a Hearing under section 14 has been appointed on **02.12.2022, at 11. 00 am** at Delhi patent office. You are therefore, required to appear before the Controller for the hearing on said date and time.

Objections

(1) Use claims 4,5 can not be allowable under section 2(1)(j) of the Patent Act 1970 as amended in 2005.

(2) Title inconsistent with description and claims. Title should be in accordance of claim.

(3) Claim 4 fall under section 3(d) of the Patent Act 1970 as amended in 2005.

Sd/-
Yours sincerely
(Dr. Rajendra Lohia)"

As is noted, the notice purports to have been issued under Section 14[6] of the Patents Act.

[6] **14. Consideration of the report of examiner by Controller**. – Where, in respect of an application for a patent, the report of the examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of this Act or of the rules made thereunder, the Controller, before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, shall communicate as expeditiously as possible the gist of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard.

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Signing Date:15.01.2023 13:18:51

23. Following the issuance of the aforesaid notice and as envisaged therein, Novartis presented itself before the learned Assistant Controller on 2nd December 2022, and was heard. Admittedly, Natco was never issued notice of the said hearing and was, therefore, unrepresented.

24. Following the aforesaid hearing, submissions were filed by Novartis before the learned Assistant Controller on 14th December 2022, on which date the impugned order also came to be passed. The covering letter dated 14th December 2022, whereunder the said submissions were filed by Novartis before the learned Assistant Controller, reads as under:

> **"File Reference Na.: 1085/OPT 14th December 2022**
>
> To,
> The Controller of Patents,
> The Patent Office,
> New Delhi.
>
> **Dr. Rajendra Lohiya**
> **Assistant Controller of Patents & Designs**
>
> Respected Sir,
>
> **RE: NOVARTIS AG**
> **Indian Patent Application No.: 4412/DELNP/2007**
> **Filing Date: 08.06.2007**
> **Written Submissions pursuant to hearing under Section 14 of the**
> **Patents Act, 1970 held on 2nd December 2022**
>
> We act on behalf of the Applicant, Novartis AG, in respect of the captioned patent application.
>
> We submit herewith Applicant's written submissions and annexures in response to the hearing notice dated 25.11.2022 issued by the Ld. Controller under Section 14 of the Patents Act, 1970 and hearing held on 02.12.2022.
>
> Kindly take the same on record under intimation to us.

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Signing Date:15.01.2023 13:18:51

Thanking you.

Yours faithfully,
Sd/-
HEMANT SINGH
IN/PA-145
OF INTTL ADVOCARE
AGENT FOR THE APPLICANT"

25. It is necessary to reproduce, *in extenso*, the submissions dated 14th December 2022, filed by Novartis before the learned Assistant Controller under cover of the afore-extracted covering letter, thus:

"**WITHOUT PREJUDICE**

File Reference No.: 1085/OPT **14th December 2022**

To,
The Controller of Patents,
The Patent Office, **Dr. Rajendra Lohiya**
New Delhi **Assistant Controller of Patents & Designs**

Respected Sir,

RE: NOVARTIS AG
Indian Patent Application No.: 4412/DELNP/2007
Filing Date: 08.06.2007
Written Submissions pursuant to hearing under Section 14 of the Patents Act, 1970 held on 2n4 December 2022

This is in furtherance to the hearing held under Section 14 of the Indian Patents Act on December 2, 2022 in respect of the afore-said application.

Our submissions to the objections raised in the hearing notice as advanced in the course of hearing on December 2, 2022 are as follows:

The Ld. Controller has kindly agreed to grant the claims 1-3 and claims 6-8 of the present application in view of the product being a new and inventive compound.

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Signing Date:15.01.2023 13:18:51

As far as the subsisting objections nos. 4 and 5 of the application are concerned, following submissions were advanced as accorded below:

(1) **USE CLAIMS 4 and SNOT ALLOWABLE UNDER SECTION 2(1)(j)**

a) It is respectfully submitted that claims 4 and 5 are not use claims.

b) Section 2(l)(j) defines an invention to mean a *product or* process.

c) Claims 4 and 5 are dependent product claims wherein claim 4 defines that the novel and inventive compound of claims 1-3 can exist in a crystalline form.
Claim 5 is also a composition product claim.

In view of the patent office practice, claim 5 has been revised to read as:

> "A pharmaceutical composition comprising the compound as claimed in any one of claim 1-4 along with the pharmaceutically acceptable carrier"

The objection with regard to claims 4 and 5 not being allowable under Section 2(1)(j) may be withdrawn.

(2) **TITLE**

a) In order to comply with the objection, the title of the invention has been revised to the "***A Dual Acting Compound And Process For Preparing The Same'***.
The Applicant in this regard is enclosing revised form 1, 2 and abstract.

(3) **CLAIM 4 NOT ALLOWABLE, UNDER SECTION 3(d)**

a) In so far as objection with respect to Section 3(d) qua claim 4 is concerned, we respectfully request the Controller to withdraw the same as claim 4 is **dependent** on claim 1 and the Ld. Controller has not raised objection with regard to novelty and inventive step of claims 1-3.

b) It is submitted that the underlying criteria for application of Section 3(d) is that the compound has to

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Signing Date:15.01.2023 13:18:51

be a new form of a known having a known efficacy.
As acknowledged by the Learned Controller, the dual active compound of claims 1-3 is novel and therefore not known.

EXAMPLES OF PATEN1'S GRANTED BY THE INDIAN PATENT OFFICE COMPRISING CLAIM FOR BOTH COMPOUND AND THEIR SALTS/POLYMORPH/SOLVATE UNDER SECTION 10(5)

c) Further, the Applicant is 1enclosing herewith claims of Indian granted patents where the Patent Office has allowed "novel compound and its salt/polymorph/solid dose forms in the same application" in view of Section 10(5) and also has not invoked Section 3(d).

i. **IN 410683**

- Claims 1-6 of the said patent are novel compounds whereas claim 7 is directed to succinate salt of the said novel compound.
- Claim 8 is directed to pharmaceutical composition comprising the said novel compound.

ii. **IN 297581**

- Claims 1 and 2 are directed to specific novel compound.
- Claim 3 is directed to pharmaceutically acceptable mesylate salt of the said compound.

iii. **IN 209251**

- Claims 1-7 is directed to a novel compound and claim 8 is directed to L malate salt of the said novel compound.

iv. **IN 345058**

- The claims are directed to novel compound.
- Claims 4-16 are directed to solid form of the said compound which have been defined through the XRD pattern (claim 4); differentialscanning calorimetry (claims 9-11 and 16); claims 12 and 13

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Signing Date:15.01.2023 13:18:51

define the solvate form of the said novel compound, defined through the XRD pattern; claim 14 defines the acetonitrile hemisolvate form of the said compound.

In view of the submissions advanced as above, the Applicant respectfully submits and requests that the Ld. Controller may withdraw objection nos. 1 & 3 and grant claims 1-8 as currently on record vide amendment dated 06.06.2020.

However, in case the Applicant's submissions as advanced above are not found favour with the Ld. Controller, in deference to the discretion exercised by the Ld. Controller under Section 15, without prejudice to the Applicant's rights and contentions, the Applicant requests for grant of the patent as per direction of the Ld. Controller.

Accordingly, the revised claims are attached as under:

a. claim 4 has been deleted; and
b. claim 5 has been revised l[as now claim 4).

We request the Ld. Controller to grant the patent without any further delay.

Your faithfully,
Sd/-
HEMANT SINGH
IN/PA-145
OF INITL ADVOCARE
AGENT FOR THE APPLICANT"

(Italics supplied)

26. On the very same day, the impugned order came to be passed by the learned Assistant Controller.

27. Natco submits that it was only after the impugned order came to be passed on 14th December 2022 that, on 15th December 2022, i.e. on the next day, (i) the notice dated 25th November 2022 *supra*, issued by the learned Assistant Controller to Novartis granting Novartis an opportunity of hearing on 2nd December 2022 and (ii) the written submissions dated

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Signing Date:15.01.2023 13:18:51

14th December 2022, filed by Novartis before the learned Assistant Controller pursuant to the said hearing, came to be uploaded on the website of the Controller of Patents. No copy of the said submissions, admittedly, was supplied to the petitioner.

28. The present writ petition, as already noted, assails the said order dated 14th December 2022, which grants the patent as applied by Novartis *vide* Application 4412 as IN 414518. The following concluding passages of the impugned order, which deal with the hearing dated 2nd December 2022, the written submissions filed by Novartis on 14th December 2022 and the conclusion of the learned Assistant Controller may be reproduced:

> "Hearing under section 14
>
> A Hearing under section 14 has been conducted on 02.12.2022, at 11.00 am at Delhi patent office,
>
> **Objections :**
>
> (1) Use claims 4,5 can not be allowable under section 2(1)(j) of the Patent Act 1970 as amended in 2005.
>
> (2) Title inconsistent with description and claims. Title should be in accordance of claim.
>
> (3) Claim 4 fall under section 3(d) of the Patent Act 1970 as amended in 2005.
>
> **Applicant's written submissions:**
>
> **TITLE**
>
> (a) In order to comply with the objection, the title of the invention has been revised to the 'A Dual Acting Compound And Process For Preparing The Same'. The

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Signing Date:15.01.2023 13:18:51

Applicant in this regard is enclosing revised form 1, 2 and abstract.

(b) Accordingly, the revised claims are attached as under:
a. claim 4 has been deleted; and
b. claim 5 has been revised l[as now claim 4).

Conclusion

In view of all above mentioned detailed discussion in the light of all the submissions of all opponents and applicant; and arguments before hearing by the applicant and all Opponents, the facts given in the documents submitted by all the parties, the all pre-grant representations are hereby I find claimed compounds are novel, inventive and patentable under Patents Act.

Accordingly, the instant application as titled 'A Dual Acting Compound And Process For Preparing The Same'. is allowed to proceed for grant with finally amended claims 1-7 as filed by the applicant.

There is no order as to the costs."

29. Aggrieved thereby, Natco is before this Court, having invoked the extraordinary jurisdiction which Article 226 of the Constitution of India vests in it.

30. I have heard Mr. J. Sai Deepak, learned Counsel for the petitioner and Mr. Hemant Singh, learned Counsel for the respondent at considerable length and, with consent of parties and learned Counsel, proceed to dispose of this writ petition.

Rival Submissions

31. Mr. Sai Deepak submits that the learned Assistant Controller, in passing the impugned order dated 14th December 2022, has not only infracted the applicable provisions of the Patents Act and the Patent

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Rules, 2003, but has also acted in stark violation of the principles of natural justice, as well as the directions contained in the order dated 12th July 2022 passed by this Court in WP (C)-IPD 91/2021. He additionally submits that the impugned order stands vitiated on account of non-consideration, therein, of the documents filed by the petitioner. In these circumstances, Mr. Sai Deepak submits that the petitioner is entitled to invoke Article 226 of the Constitution of India.

32. Mr. Sai Deepak submits that the grant of an opportunity of unilateral hearing to Novartis, by the learned Assistant Controller on 2nd December 2022, by the notice dated 25th November 2022 *supra*, is not envisaged by any provision either in the Patents Act or in the Patent Rules. Once a pre-grant opposition has been filed and, consequently, a pre-grant opponent has entered the fray, Mr. Sai Deepak's submission is that the said pre-grant opponent, being vitally interested in the outcome of the patent application, has necessarily to be involved in every proceeding that takes place in that regard. He submits that there was no justification, whatsoever, either on facts or in law, for the learned Assistant Controller to, having heard the parties on 5th September 2022 as directed by this Court *vide* its judgment dated 12th July 2022 in WP (C)-IPD 91/2021, grant a further – and, as he would submit, clandestine – unilateral hearing to Novartis on 2nd December 2022. He further points out that the directions in the judgment dated 12th July 2022 were clear and categorical. According to the said decision, the learned Assistant Controller was required, after grant of an opportunity of hearing to the parties, to take a final decision on the objections of Natco as well as the

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

application of Novartis, by 15th November 2022. The learned Assistant Controller breached the said direction. Not only did he do so, submits Mr. Sai Deepak, he, for no fathomable reason, decided to grant a unilateral hearing to Novartis, in which Natco was kept out of the picture. Thereafter, he proceeded to pass the impugned order, which, even for that reason, is completely unsustainable in law.

33. In this context, Mr. Sai Deepak has invited my attention to the submissions dated 14th December 2022, filed by Novartis consequent to the hearing granted on 2nd December 2022, particularly to the following acknowledgement, as contained in the said submissions (which already stand reproduced *in extenso* in para 25 *supra)*:

> "The learned Controller has kindly agreed to grant the Claims 1 to 3 and Claims 6 to 8 of the present application in view of the product being a new and invented compound."

Mr. Sai Deepak submits that this was completely irregular. Prior to the passing of the impugned order dated 14th December 2022, the learned Assistant Controller could not have communicated, to Novartis, any decision to grant Claims 1 to 3 and Claims 6 to 8 of Application 4412, especially as the last hearing was granted behind the back of Natco.

34. In this context, Mr. Sai Deepak has invited my attention to various statutory provisions. He refers, first, to Section 25(1) of the Patents Act, which envisages the grounds on which the application for grant of a patent could be opposed. He, thereafter, proceeds to Rule 55[7] of the

[7] **55. Opposition to the patent**. –

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Patent Rules. Drawing particular attention to Rule 55(5), Mr. Sai Deepak contends that the said provision envisages (i) consideration of the statements and evidence of the applicant (i.e. Novartis), (ii) consideration of the representation including the statement and evidence filed by the opponent (i.e. Natco), (iii) submissions made by the parties and, (iv) after hearing the parties, taking of a decision. The provision, points out Mr. Sai Deepak, allows the learned Controller the choice of one of three decisions which he could take after the above drill is exhausted. The learned Controller could either (a) reject the pre-grant opposition, thereby granting the patent or (b) refuse to grant the patent thereby rejecting the application filed by the patent applicant or (c) direct amendment of the complete specification and other documents filed by the patent applicant to his satisfaction before the patent is granted. In any event, submits Mr. Sai Deepak, the provision does not envisage a further unilateral hearing by the Controller, to one of the parties alone and to the exclusion of the other, before taking any of these decisions. The decisions have, according to Mr. Sai Deepak, to be the sequitur and consequence to the

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(1) Representation for opposition under sub-section (1) of Section 25 shall be filed in Form, 7(A) at the appropriate office with a copy to the applicant, and shall include a statement and evidence, if any, in support of the representation and a request for hearing, if so desired.

(1-A) Notwithstanding anything contained in sub-rule (1), no patent shall be granted before the expiry of a period of six months from the date of publication of the application under Section 11-A.

(2) The Controller shall consider such representation only when a request for examination of the application has been filed.

(3) On consideration of the representation if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment, he shall give a notice to the applicant to that effect.

(4) On receiving the notice under sub-rule (3), the applicant shall, if he so desires, file his statement and evidence, if any, in support of his application within three months from the date of the notice, with a copy to the opponent.

(5) On consideration of the statement and evidence filed by the applicant, the representation including the statement and evidence filed by the opponent, submissions made by the parties, and after hearing the parties, if so requested, the Controller may either reject the representation or require the complete specification and other documents to be amended to his satisfaction before the patent is granted or refuse to grant a patent on the application, by passing a speaking order to simultaneously decide on the application and the representation ordinarily within one month from the completion of above proceedings.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

hearing envisaged by the opening words in Rule 55(5). No intervening unilateral hearing is permissible.

35. Mr. Sai Deepak further submits that the discipline of Rule 55 cannot be sacrificed on the ground that grant of the patent would be delayed, were the prescribed procedure to be followed. He submits that a certain amount of delay is inherent in the entire procedure of application and grant of a patent. That cannot, however, submits Mr. Sai Deepak constitute a basis for adopting of a procedure, before granting the patent, which is not envisaged by the provisions either of the Patents Act or the Patents Rules.

36. Mr. Sai Deepak also places reliance on the decision of Muralidhar J in ***UCB Farchim SA***[5] on which Mr. Hemant Singh has also relied. He draws my attention to the following passage from the said decision:

> "13. In the first instance a distinction has to be drawn between a pre-grant opposition and a post-grant opposition. While a pre-grant opposition can be filed under Section 25 (1) of the Patents Act at any time after the publication of the patent application but before the grant of a patent, a post-grant opposition under Section 25(2) of the Patents Act has to be filed before the expiry of one year from the date of the publication of the grant of patent. A second significant difference, after the amendment of 2005, is that a pre-grant opposition can be filed by "any person "whereas a post-grant opposition under Section 25(2) can be filed only by "any person interested". It may be noticed that the application for revocation of a patent in terms of Section 64 of the Patents Act can also to be filed only by "any person interested". In other words, the post-grant opposition and the application for revocation cannot be filed by just about any person who is not shown to be a person who is "interested". A third significant difference is that the representation at the stage of pre-grant is considered by the Controller himself. Rule 55 of the Patents Rules requires the Controller to consider the "statement and evidence filed by the applicant" and thereafter either refuse to grant the patent or require the complete specification to be amended to his satisfaction. Of course, in

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

> that event notice will be given to the applicant for grant of patent who can file his reply and evidence. *This Court finds merit in the contention that the pre-grant opposition is in fact "in aid of the examination" of the patent application by the Controller.* The procedure is however different aspect as far as the post-grant opposition is concerned. Therein terms of Section 25 (3), the Controller has to constitute an Opposition Board consisting of such officers as he may determine and refer to such Opposition Board the notice of opposition along with other documents for its examination and recommendations. After receiving the recommendations of the Opposition Board, the Controller gives the patentee and the opponent an opportunity of being heard. The Controller then takes a decision to maintain, amend or revoke the patent. The fourth major difference between the pre-grant and the post-grant opposition is that while in terms of Section 117 A an appeal to the IPAB is maintainable against the order of the Controller in a post-grant opposition under Section 25(4) of the Patents Act, an appeal has not been expressly been made available against an order made under Section 25(1) of the Patents Act."
>
> (Emphasis supplied)

Mr. Sai Deepak submits that the afore-extracted passage from ***UCB Farchim***[5] clarifies that the exercise of pre-grant opposition, and its consideration, was in aid of examination of the patent application. That being so, he submits that there could be no question of keeping the pre-grant opponent out of the picture at any stage relating to the examination of the patent application. Sub-rules (3) to (5) of Rule 55 of the Patent Rules, he submits, have to be interpreted and understood in the light of the said enunciation of law in ***UCB Farchim***[5]. The pre-grant opposition being a step in aid of the examination process, he submits that the pre-grant opponent is also entitled to be heard at every stage and in every proceeding prior to grant of the patent.

37. Any other procedure, he submits, has the pernicious potentiality of throwing open flood gates for mischief which, according to Mr. Sai

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Deepak, has actually taken place in the present case.

38. Mr. Sai Deepak has also invited my attention to the judgment dated 12th July 2022 passed by this Court in WP (C) IPD 91/2021, particularly to para 19 thereof. He submits that a holistic reading of para 19 of the decision clearly indicates that, in the matter of amendment of the claims as filed by the Patent Applicant, there can be no question of the opponent being kept in the dark. Transparency, regarding the grant of amendment to the claims, he submits, is clearly envisaged by para 19 of the said decision.

39. In this context, Mr. Sai Deepak reiterates his contention that the impugned order is also liable to be faulted for not having taken into consideration the record of CS (Comm) 62/2019, which was filed by Natco before the learned Controller on 6th January 2020. The direction, by this Court, in its judgment dated 12th July 2022, to the learned Assistant Controller to take into account all the documents filed by Natco, he submits, would also embrace the documents relating to CS (Comm) 62/2019. However, he submits that the learned Assistant Controller has not, in the impugned order, taken stock of Natco's contentions predicated on the said document, *inter alia* including the contention that, in the proceedings in CS (COMM) 62/2019, Novartis had admitted that the claim in Application 4412 already stood claimed and protected in IN'051.

40. Apropos the judgments which were placed on record by Mr.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Hemant Singh appearing for Novartis, Mr. Sai Deepak submits that they are clearly distinguishable. Specifically referring to the decision in ***Haryana Pesticides Manufacturers Association v. Willowood Chemicals Pvt Ltd***[8], on which considerable reliance was placed by Novartis in its written submissions, Mr. Sai Deepak submits that the facts of the said case were clearly distinguishable. Unlike the position which obtained in ***Haryana Pesticides***[8], in which the notice issued by the Controller to the patent applicant was a specific notice envisaging amendment of the claims in the application, Mr. Sai Deepak submits that the notice dated 25th November 2022 could not, read any which way, be regarded as a notice requiring Novartis to amend its claims. Rather, he submits that the notice, as worded, envisaged a continued examination of the claims of Novartis in Application 4412. The facts that obtained in ***Haryana Pesticides***[8], he submits, therefore, are clearly distinguishable from those which obtained in the present case. Besides, submits Mr. Sai Deepak, the decision in ***Haryana Pesticides***[8], while noting Rule 55 of the Patents Rules, does not really return any finding on the effect of the said Rule, thereby remaining *sub silentio* in that regard.

41. In this context, Mr. Sai Deepak also points out that the impugned order, too, while referring to the hearing notice dated 25th November 2022 and the hearing which took place on 2nd December 2022, does not purport to state that the notice was only for the amendment of the claims. Mr. Sai Deepak also placed reliance, in this context, on the judgment of a Coordinate Single Bench of this Court in ***Best Agro Life Ltd v. Deputy***

[8] **2022 SCC OnLine Del 2848 : (2022) 5 HCC (Del) 467**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Controller of Patents[9], in which the Coordinate Single Bench had exercised Article 226 jurisdiction against the order passed by the learned Deputy Controller of Patents and Designs which, as in the present case, dismissed the pre-grant opposition and allowed grant of patent, on the ground that the order had been passed without considering vital grounds or documents. *Mutatis mutandis*, submits Mr. Sai Deepak, the same position would obtain in the present case as well as on the ground of lack of grant of hearing on the proposed amendments to the claim.

42. In these circumstances, Mr. Sai Deepak submits that the impugned order, being in the teeth of the provisions of the Patents Act and the Patents Rules as well as violative of the principles of natural justice, deserves to be quashed and set aside.

43. Mr. Sai Deepak also placed reliance on the report of the Ayyangar Committee on Revision of the Patents Law, by Hon'ble Mr. Justice N. Rajagopala Ayyangar, an eminent former Judge of the Supreme Court, and has referred to paragraphs 210 and 213 therein, which read as under:

> "210. *Stated broadly an opposition proceeding constitutes an extension of the investigation undertaken by the Examiner*. No doubt there are some grounds open in an opposition proceeding which are not the subject of scrutiny by the Examiner, for instance the ground of prior public user but these are matters of mere detail. What I desire to emphasise is that the history of the patent legislation of the U.K. shows that new matters for examination, and necessarily for opposition have been added from time to time and *there has never been any change in the reverse direction, of diminishing the scope of examination or opposition*. It is in the light of this history that I consider the proposal of the Committee a retrograde one. I might at this stage refer to the extension of the grounds of opposition in the U.K. by the Patents Act of 1949 by which an objection on the score of

[9] **2022 SCC OnLine Del 1982**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

"obviousness" or "lack of subject-matter" was brought in. This was based on the acceptance of the recommendation of the Swan Committee. In their second interim report the Committee referred to the representations made to them that the scope of the grounds of opposition ought to be enlarged, to comprehend "subject matter". They accepted the force of these representations and expressed themselves thus:-

> "To grant a patent, even though it may be subsequently revoked, for something which quite obviously possesses no inventive merit whatever, is *prima facie* contrary to public policy and contrary to the purpose of the patent law, whose object has always been to encourage genuine inventions without imposing undue restraint upon normal industrial development. Against this, it is urged by those who object to any extension of the Comptroller's powers in this direction, that little or no harm is done by the continuance of such a practice. We are not convinced of the truth of this plea. The evidence we have heard satisfies us of the fact that people are deterred by the risk that legal proceedings for infringement may involve so serious an expense to the defendant as to deter him from challenging the patent. Thus, an obviously invalid patent may act as a formidable deterrent, and discourage a manufacturer from pursuing research, or from adopting improvements in methods of manufacture which involve nothing more than the application of the normal technique and skill of those experienced in the art."

> "The Patent Offices of the principal industrial countries, particularly those of the United States, Germany, Sweden and Holland have power to refuse applications for patents, which, in their opinion, are lacking in subject matter....Several witnesses have expressed the view that patents granted by the Patent Offices of countries which in addition to making a wide investigation for novelty, take the question of subject-matter into account have a higher validity value and therefore a better chance of commercial exploitation than the patents granted in countries where the question of subject matter is not considered.... Incidentally it may be observed that the investigation for novelty, which today is an accepted and valued feature of our patent system, was when first proposed before the Fry Committee of 1900, strongly opposed by a number of witnesses as likely to be an expensive and dangerous innovation....As a logical corollary to our recommendation

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

> that the Comptroller should have power to reject an application on the ground of lack of subject-matter, it follows that he should similarly have power to refuse the grant of a patent on the same ground in opposition proceedings."
>
> *****
>
> 213. *In cases where an opposition is entered, the grant of a patent would necessarily be delayed, but the question is one of balancing the benefit which accrues to the public from a successful opposition eliminating a possible invalid patent and the inconvenience or hardship caused to an applicant for a legally patentable invention not being quickly sealed because of an opposition. In considering this it has to be borne in mind that under the law the rights of a patentee start from the publication of the complete specification though a suit for infringement could not be filed till the patent is granted.* After setting off the one against the other, patent laws in most of the countries of the World which follow the examination system, have provided for an opposition as conducive to public interests and I am unable to see any condition in India to militate against the application of this rule. I consider that the views of the Committee were greatly coloured by those assumptions none of which I consider well founded – first, that a very large number of applications were opposed; secondly, that most, if not all, of them were unsuccessful and thirdly, these oppositions were *mala fide*, and that this procedure has been utilised to blackmail *bona fide* applicants, particularly those with slender resources, the assumption being that the parties who raised the opposition were rich corporations who blocked the immediate grant of patents by demanding improper concessions as a ground for withdrawing their opposition. I do not find from any of the memoranda submitted to the Committee any representation regarding *mala fide* use of opposition proceedings."
>
> (Emphasis supplied)

44. He also cited the judgment of the High Court of Bombay in ***Neon Laboratories Pvt. Ltd. v. Troikaa Pharma Limited***[10]**.**

45. Responding to the submissions of Mr. Sai Deepak, Mr. Hemant Singh initially submitted, relying on the judgments of Coordinate

[10] **2010 SCC Online Bom 1799**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Benches of this Court in ***UCB Farchim***[5], ***Mylan Laboratories Ltd v. UOI***[11] and ***Haryana Pesticides***[8], that, in view of the alternate remedy of rectification available to the petitioner, this writ petition is not maintainable. Mr. Hemant Singh also submits that the decision in ***Haryana Pesticides***[8] covers this case both on facts as well as in law.

46. On the merits of the arguments of Mr. Sai Deepak, Mr. Hemant Singh submits that Sections 14 and 15[12] of the Patents Act have to be read together. The exercise of consideration of the report of the examiner, and the objections contained therein, as initially raised pursuant to the filing of Application 4412 by Novartis, he submits, stood exhausted only when the impugned order came to be passed.

47. Mr. Hemant Singh has drawn my attention to Sections 14 and 80[13] of the Patents Act, both of which envisage a notice being given to the patent applicant. Mr. Hemant Singh submits that the exercise which takes place between the submission of an application for grant of a patent and the ultimate grant thereof proceeds along two parallel channels, one relating to the examination of the patent by the examiner and, later, the Controller, and the subjective satisfaction of each regarding the issue of

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[11] **2019 (80) PTC 374 (Del)**

[12] **15. Power of Controller to refuse or require amended applications, etc., in certain cases**. – Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may refuse the application or may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application and refuse the application on failure to do so.

[13] **80. Exercise of discretionary powers by Controller**. – Without prejudice to any provision contained in this Act requiring the Controller to hear any party to the proceedings thereunder or to give any such party an opportunity to be heard, the Controller shall give to any applicant for a patent, or for amendment of a specification (if within the prescribed time the applicant so requires) an opportunity to be heard before exercising adversely to the applicant any discretion vested in the Controller by or under this Act:

Provided that the party desiring a hearing makes the request for such hearing to the Controller at least ten days in advance of the expiry of the time-limit specified in respect of the proceeding.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

whether the claims were required to be amended or could be allowed to stand as they were, and the second relating to the filing of pre-grant opposition and its considerations by the Controller. These channels, he submits, are clearly distinguishable from each other. He submits that it would be erroneous in law to conflate these two distinct proceedings, which take place during the consideration of an application seeking grant of a patent.

48. In the exercise of examination of the patent application with respect to the objections raised by the examiner, or by the Controller himself thereafter, specifically with respect to the requirement of amending the specifications as filed, Mr. Hemant Singh submits that the Patents Act does not envisage involvement of the pre-grant opponent. The amendment of the claims in the application, he submits, is an exercise between the Controller and the patent applicant. It is for that reason, submits Mr. Hemant Singh, that involvement of the pre-grant opponent, who objects to the grant of the patent, is not envisaged either by Section 14 or by Section 80 of the Patents Act.

49. On a conjoint reading of Sections 15 and 80 of the Patents Act and Rules 20, 28(a) and 55 of the Patents Rules, Mr. Hemant Singh submits that the position that emerges is that the learned Controller can take a decision to reject the opposition filed by the pre-grant opponent to the patent and, thereafter, allow amendment of the claim by the claimant, in which exercise the pre-grant opponent is not required to be involved. He submits that Mr. Sai Deepak is in error in regarding the notice dated 25th

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

November 2022 as relatable to the objections filed by Natco to the grant of the patent as applied by Novartis. He submits that the said notice was in continuation of the Section 14 proceedings which had initially emanated out of the objections raised by the examiner in the First Examination Report dated 30th January 2015.

50. Mr. Hemant Singh has also taken me through the various sub-rules of Rule 55 of the Patents Rules. He seeks to contradistinguish sub-rules (3) and (5) of the Rule and submit that the manner in which Mr. Sai Deepak is seeking to interpret the Rule would result in conflation of these provisions. Mr. Hemant Singh submits that Natco can have no legitimate grievance, as it was heard on a number of occasions and was also granted a detailed hearing on 13th May 2021 and 5th September 2022, in which Natco's objections were heard threadbare. He submits that as many as 260 pages of the impugned order are devoted to a consideration of the objections of Natco and it cannot, therefore, be said that the said objections were not bestowed the consideration that they deserve.

51. Mr. Hemant Singh further submits that Rule 55, being in the nature of a rule, cannot trump the provisions of the Patents Act, *inter alia* of Sections 14, 15 and 80. A conjoint reading of Sections 14, 15 and 80 of the Patents Act, he submits, would make it clear that the legislature did not envisage participation of anyone other than the patent applicant, in the matter of objections either raised by the examiner or by the Controller himself regarding the aspect of grant of the patent or any amendment which was required to be made to the claims as submitted for such grant

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

by the patent applicant. In fact, submits Mr. Hemant Singh, this was a matter which lay entirely within the satisfaction of the Controller. The pre-grant opponent, objecting to the grant of the patent, has no locus to interfere in that regard. After hearing the objection, if the Controller feels that the complete specifications were required to be amended, that, submits Mr. Hemant Singh, is an exercise between the Controller and the patent applicant. The patent applicant is required, in such a case, to satisfy, not the pre-grant opponent, but the Controller, *qua* his subjective satisfaction regarding the nature of the claims which were sought to be patented, and the need, or otherwise, to amend them. It is for this reason, submits Mr. Hemant Singh, that the legislature has, advisedly, restricted the grant of hearing, in Sections 14 (which is required to be read with Section 15 in his submission) and Section 80 of the Patents Act to the applicant and to no one else.

52. On facts, submits Mr. Hemant Singh, no prejudice has resulted to Natco, as would justify any legitimate challenge to the impugned order. He submits that Natco had objected mainly to Claims 1, 4 and 5 of the set of Claims as filed by Novartis on 6th June 2020. On all objections raised by Natco, Mr. Hemant Singh submits that both Natco and Novartis were heard at length by the learned Assistant Controller. If the decision that has resulted consequent to such hearing is, according to Natco, erroneous or otherwise objectionable, the remedy in that regard, he submits, would be by way of a rectification petition and not by way of writ proceedings under Article 226 of the Constitution of India.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

53. It cannot, submits Mr. Hemant Singh, be said that the learned Assistant Controller infracted the provisions of the Act or otherwise proceeded in violations of principles of natural justice, in such a manner as would justify the present writ proceedings and interdiction, therein, by this Court, with the impugned order dated 14th December 2022.

54. Referring to the notice dated 25th November 2022, Mr. Hemant Singh submits that the notice was, properly read, restricted only to Claims 4 and 5 of the Claims as filed by Novartis on 6th June 2020. Natco had, even prior thereto, been heard at length on all its objections and could not, therefore, be entitled to any further audience at that stage. The reference to "objections", in the notice dated 25th November 2022, he submits, has to be understood in the backdrop of the notice itself. The objections, as envisaged in the notice, were that (i) Claims 4 and 5 could not be allowed under Section 2(1)(j) of the Patents Act, (ii) the title of Claim 5 was inconsistent with the description of the claim and (iii) Claim 4 was hit by Section 3(d) of the Patents Act.

55. The decision taken by the learned Assistant Controller, consequent to the aforesaid notice dated 25th November 2022 and the hearing that followed on 2nd December 2022, was only to allow deletion of Claim 4 and amendment of the title of Claim 5. In that view of the matter, Mr. Hemant Singh submits that Natco could not be said to have suffered any prejudice, whatsoever, by the hearing that took place on 2nd December 2022 or the proceedings that followed thereafter.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

56. Mr. Hemant Singh has also referred to Rule 28(A) of the Patents Rules, read with Rule 28 thereof. Rule 28(A), read with Rule 28, too, he submits, envisages the grant of an opportunity of hearing only to the applicant who applies for grant of the patent, regarding the amendment of the specifications in the application seeking such grant.

57. Inasmuch as the impugned order has been passed in accordance with the discipline of Sections 14, 15 and 80 of the Patents Act as well as Rules 28 and 28(A) of the Patents Rules, and does not in any manner infract Rule 55 thereof, Mr. Hemant Singh submits that the allegation, of Natco, regarding the impugned order being procedurally invalid, has no legs to stand on.

58. Referring to the judgment dated 12th July 2022, passed by this Court in WP (C)-IPD 91/2021, Mr. Hemant Singh submits that, in para 22 of the said decision, this Court made it clear that the observations regarding amendments, in the preceding paragraphs of the decision, would not apply to amendments under Section 15 of the Patents Act. Inasmuch as the notice dated 25th November 2022, and the amendments of the Claims of Novartis, as earlier submitted on 14th December 2020, were relatable to Section 15 of the Patents Act, and were made to the satisfaction of the learned Assistant Controller, he submits that the impugned order was also in accordance with the judgment dated 12th July 2022 and the directions contained therein.

59. Mr. Hemant Singh also disputes Mr. Sai Deepak's contention that

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

documents filed by Natco were not taken into consideration by learned Assistant Controller. While contending that the said ground would, appropriately, be available to be urged only in rectification proceedings, Mr. Hemant Singh submits that the direction, in the judgment dated 12th July 2022, was for the learned Assistant Controller to take into consideration the expert affidavit which Natco would choose to file thereafter, along with any documents filed with the said affidavit. He submits that no independent documents were filed by Natco after the passing of the judgment dated 12th July 2022. Natco only filed an affidavit dated 9th August 2022 of Dr. Ramesh Dandala which, he submits, the impugned order has taken into consideration. He also submits that the proceedings relating to CS (Comm) 62/2019 have also been considered by the learned Assistant Controller and invites attention, in this context, to the findings in that regard as contained in the impugned order.

60. Mr. Hemant Singh further relies on the judgment of the Supreme Court in ***K L Tripathi v. SBI***[14], to contend that any examination of the plea of violation of the principles of natural justice would require consideration of three factors; firstly the scheme of the Act and the Rules, secondly, the facts of the case and, thirdly, the issue of whether any prejudice had resulted to the opposite party by reason of the alleged failure to comply with the principles of natural justice. He also relies on the judgment of Muralidhar J (as he then was), sitting singly in this Court, in ***Snehlata C. Gupte v. UOI***[15], which reiterates the mandate of

[14] **(1984) 1 SCC 43**
[15] **2010 (43) PTC 813**

Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Rule 55(5) of the Patents Rule and holds that, in view of the said provision and Section 43 of the Patents Act, which requires proceedings for grant of a patent to be expeditiously decided, the learned Assistant Controller was legally required to simultaneously decide the application of Novartis for grant of the patent and the objections of Natco filed by way of response thereto.

61. Mr. Hemant Singh submits that the requirement of simultaneous decision on the application for grant of patent as well as on the objections filed by way of response thereto fosters the purpose of expeditious disposal of the application seeking grant of the patent. He also submits that, if the provisions of the Act and Rules are to be interpreted in the manner in which Mr. Sai Deepak would seek to interpret them, it could result in repeated oppositions against an application seeking a patent, which would unconscionably delay the grant thereof. In the present case itself, he submits, as many as ten oppositions had been filed, one after the other, to the grant of the patent for which Novartis had applied. As such, he submits, the exercise conducted by the learned Assistant Controller was not only in keeping with the provisions of the Act and the principles of natural justice and fair play, but also furthered the requirement of expeditious disposal of Novartis' application for grant of the patent.

62. He points out that 16 years have already passed since the application was filed and, if the impugned order were to be interdicted, it may well result in the application being rendered an exercise in mere futility.

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Signing Date:15.01.2023 13:18:51

63. Mr. Sai Deepak advanced brief concluding submissions with respect to Section 80 of the Patents Act. He draws attention to the fact that the provision, as enacted, is "without prejudice to any provision contained in this Act requiring the Controller to hear any party to the proceedings thereunder or to give such party an opportunity to be heard". As such, he reiterates his contention that, once the pre-grant opponent had entered the fray, Rule 55(5) clearly required him to be granted a hearing before a decision was taken even to amend the claims as submitted by the patent applicant. That requirement stood saved by the opening words of Section 80 of the Patents Act. As such, he submits that the reliance, by Novartis, on Section 80, is misplaced.

64. Mr. Sai Deepak finally submits, with respect to Section 15 of the Patents Act, that Section 15, as statutorily enacted, does not envisage, specifically, grant of a hearing to either party. At the same time, he submits, the provision could not be so applied as to extend the courtesy of hearing to one party and decline such courtesy to the other.

65. Mr. Sai Deepak also submits that the impugned order does not consider Natco's contention that no patent for the crystalline form of the Valsartan-Sacubitril complex could be legitimately sought. He submits that this objection did not stand addressed merely by allowing deletion of Claim 4 in the claim set filed by Novartis as, simultaneously, the impugned order allowed the modification of the title of Claim 5 which, as modified, was broadened by removal of reference to use. He also submits that no limitation to the crystalline form of Valsartan-Sacubitril

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

combination was included in Claim 1 as sought by the Natco. Thus, he submits, it would be erroneous for Novartis to contend that Natco had suffered no prejudice on account of non-compliance, by the learned Assistant Controller, with due procedure.

Analysis

I. Compliance with *audi alteram partem*

66. *Audi alteram partem*, and all other principles of natural justice have, over a period of time, become sanctified in our legal lore. It is well settled that, even if a statutory provision, the application of which can result in prejudice to a party does not expressly spell out the requirement of compliance with the principles of natural justice, the Court has necessarily to read the principles of natural justice into such provision unless the provision expressly excludes such principle. One may refer, in this context, to the judgment of the Supreme Court in ***D.K. Yadav v. J.M.A. Industries Ltd***[16], in which it was held that save and except where the terms of a "particular statute or statutory rules or orders having statutory flavour .... exclude the application of the principles of natural justice expressly or by necessary implication", in all other respects, the principles of natural justice would apply. In ***Liberty Oil Mills v. U.O.I.***[17], the Supreme Court held that it was not "permissible to interpret any statutory instrument so as to exclude natural justice, unless the language of the instrument leaves no option to the Court". In ***U.O.I v. Tulsiram***

[16] **(1993) 3 SCC 259**
[17] **(1984) 3 SCC 465**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Patel[18], following its earlier decision in ***Swadeshi Cotton Mills v. U.O.I.***[19], the position in law was enunciated thus:

> "100. In ***Swadeshi Cotton Mills***[19] Chinnappa Reddy, J., in his dissenting judgment summarized the position in law on this point as follows:
>
> > "The principles of natural justice have taken deep root in the judicial conscience of our people, nurtured by ***State of Orissa v. Binapani Dei***[20], ***A.K. Kraipak v. Union of India***[21], ***Mohinder Singh Gill v. Election Commissioner of India***[22], ***Maneka Gandhi v. Union of India***[23] etc. etc. They are now considered so fundamental as to be 'implicit in the concept of ordered liberty' and, therefore, implicit in every decision-making function, call it judicial, quasi-judicial or administrative. *Where authority functions under a statute and the statute provides for the observance of the principles of natural justice in a particular manner, natural justice will have to be observed in that manner and in no other. No wider right than that provided by statute can be claimed nor can the right be narrowed. Where the statute is silent about the observance of the principles of natural justice, such statutory silence is taken to imply compliance with the principles of natural justice. The implication of natural justice being presumptive it may be excluded by express words of statute or by necessary intendment. Where the conflict is between the public interest and the private interest, the presumption must necessarily be weak and may, therefore, be readily displaced*."
>
> 101. *Not only, therefore, can the principles of natural justice be modified but in exceptional cases they can even be excluded.* There are well-defined exceptions to the *nemo judex in causa sua* rule as also to the *audi alteram partem rule.* … So far as the *audi alteram partem* rule is concerned, both in England and in India, it is well established that *where a right to a prior notice and an opportunity to be heard before an order is passed would obstruct the taking of prompt action, such a right can be excluded. This right can also be excluded where the nature of the action to be taken, its object and purpose and the scheme of the relevant statutory provisions warrant its exclusion; nor can the audi alteram partem rule be invoked if importing it would have*

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[18] (1985) 3 SCC 398
[19] (1981) 1 SCC 664
[20] (1967) 2 SCR 625
[21] (1969) 2 SCC 262
[22] (1978) 2 SCR 272
[23] (1978) 1 SCC 248

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

> *the effect of paralysing the administrative process or where the need for promptitude or the urgency of taking action so demands*, as pointed out in ***Maneka Gandhi's case*** at page 681."
>
> (Emphasis supplied)

Mangilal v. State of M.P.[24] held, further, as under:

> "10. …It has always been a cherished principle. Where the statute is silent about the observance of the principles of natural justice, such statutory silence is taken to imply compliance with the principles of natural justice where substantial rights of parties are considerably affected. *The application of natural justice becomes presumptive, unless found excluded by express words of statute or necessary intendment*…"
>
> (Emphasis supplied)

Following these precedents, a Full Bench of this Court, in ***Andaleeb Sehgal v. U.O.I.***[25] held that it was "clear as crystal that the principles of natural justice are presumed to be attracted unless they are expressly excluded or its exclusion can be inferred or deduced by necessary implication".

67. On the aspect of reading, into statutory provisions, the principles of natural justice, especially *audi alteram partem*, where the statute is either silent or ambivalent in that regard, the law is, therefore, settled. Where a statute *expressly excludes* the application of *audi alteram partem*, the Court cannot read the requirement into the statute by judicial fiat. Such exclusion is not, however, not to be presumed, where it is absent. Absent express exclusion of *audi alteram partem* by the statute, the presumption is that the requirement is included in it. It is only where the language of the statute leaves, to the Court, no option but to exclude,

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[24] **(2004) 2 SCC 447**
[25] **AIR 2011 Del 29 (FB) : (173) 2010 DLT 296 (FB)**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

in its application, the *audi alteram partem* principle, that the Court can legitimately do so.

68. To this, I may add that the *audi alteram partem* doctrine, for its compliance, requires hearing of *both sides*, where the lis is adversarial. Hearing of one side in the absence of the other is not only antithetical to *audi alteram partem*; it is a veritable affront to the principle.

II. *Audi alteram partem* and its applicability to the Patents Act and Patents Rules in the backdrop of the present controversy

69. Where an opposition is filed to an application seeking grant of a patent, the proceedings become adversarial. Due compliance with the principles of natural justice, in the case of adversarial proceedings, necessarily requires both parties to be involved in the proceedings at every stage. It is antithetical to the principles of the natural justice, as well as *audi alteram partem* doctrine, to tolerate a situation in which even a single hearing can take place, in an adversarial judicial or quasi-judicial proceedings, merely by hearing one party and excluding the other party therefrom. It may be an entirely different situation where both parties are called upon to participate in the proceedings and one or the other party remains absent. The judicial or quasi-judicial authority enjoys the latitude, in such circumstances, to proceed in the absence of the absent party. Else, the proceedings have necessarily to include, at all stages, participation of both parties.

70. There is no provision either in the Patents Act or in the Patents

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Rules, which *expressly* envisages exclusion of the objector, who objects to an application, seeking grant of a patent, at any stage of the proceedings.

71. Mr. Hemant Singh had drawn pointed attention to Sections 14 and 80 of the Patents Act to contend that this provision only requires notice to be issued to the applicant which has applied for grant of a patent. He sought to submit that, where an opposition is filed to an application seeking grant of a patent, the proceeding travels in along two parallel paths, one being the path which decides and adjudicates on the objection and the other which deals with examination of the patent application and consideration of the objections raised by the examiner in his report or, later, by the Controller of his own will and volition. The requirement of participation, by the objector, in Mr. Hemant Singh's submission, is only in the former proceedings and not in the later. Where an application seeking grant of a patent is opposed, Mr. Hemant Singh would seek to submit that the entitlement of the objector opposing such grant is only to have his objection heard and decided, for which there is an exhaustive procedure prescribed in the Patents Act and the Patents Rules. That procedure, in his submission, has scrupulously been followed in the present case by the learned Assistant Controller.

72. I confess my inability to agree with Mr. Hemant Singh.

73. I find myself, rather, in agreement with Mr. Sai Deepak in his contention that the entire dynamics of the proceedings change once an objector files an opposition to the grant of a patent. Once an opposition

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

is filed, the stakeholders in the proceedings are not one but two – the patent applicant seeking grant of the patent and the pre-grant opponent opposing such grant. The proceedings become adversarial. The adversaries have rival, and competing, rights. They are equal stakeholders. Neither can be given precedence, or priority, over the other. Ergo, both adversaries have to be involved in the proceedings at every stage. The proceedings cannot be allowed to take place merely involving one of the stakeholders and excluding the other. There is, to reiterate, no provision either in the Patents Act or in the Patents Rules, which envisages expressly or by necessary implication, the exclusion of the pre-grant opponent, opposing the grant of the patent, at *any* stage in the proceedings before the Controller of Patents.

74. Equally, I am unable to convince myself that the proceedings before the Controller follow two distinct paths. The proceedings cannot be analogized to a railway track, where the two paths run on a parallel lines and do not converge, save and except when the patent is ultimately granted or refused. Once a pre-grant opponent objects to the application seeking of a patent, every decision which impacts such grant, or the extent to which the application is granted, results in serious civil consequences, both to the applicant seeking grant as well as to the pre-grant opponent opposing such grant. The right to oppose the grant of a patent is just as sacrosanct as the right to seek grant of a patent. The public interest involved in ensuring that patentable inventions are patented, cannot be accorded a greater degree of sanctity than the public interest involved in ensuring that the non-patentable inventions are not

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

allowed to be patented. Allowing patenting of inventions which already stand claimed, or disclosed, in prior art, results in evergreening. Evergeening, in its turn, results in serious commercial abuse. In pharmaceutical patents, especially, additional care has to be taken to ensure that, by being allowed to evergreen a patent beyond its expiry, the patent holder does not keep others, who may seek to deal in the patented product, out of the market. The ultimate sufferer, in such a situation, would be the ailing public, who seek access to the product. Where the invention, for which a patent is being sought, already stands disclosed or claimed in prior art, allowing a claim for a later patent, which does not significantly differ from such prior art, or which stands disclosed in such prior art, would result in evergreening of a patent beyond its normal life span. It is for that reason, specifically in the case of pharmaceutical patents, as recognized by the Supreme Court in ***Novartis AG v. U.O.I.***[26], that Section 3(d) of the Patents Act was amended to require the applicant, in the case where the later patent was merely a new form of a known substance, to demonstrate additional efficacy of the new form over and above the existing prior art.

75. A note of caution: These observations are not intended in any manner to reflect an opinion, even tangential, on merits of Novartis for a patent application in the present case. They are only intended to explain why the participation of both sides is necessary at all stages during the consideration of an application seeking grant of a patent, till the patent is ultimately granted or refused.

[26] **(2013) 6 SCC 1**

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

III. The scope of amendment; Section 59 of the Patents Act

76. Section 59 of the Patents Act is also instructive in this regard. The provision relating to amendment of the application and specification are contained in Chapter 10 of the Patents Act. While Sections 57 and 58 relate to the right of a patent applicant to amend the complete specifications or the documents filed with an application seeking grant of a patent before the Controller or before the High Court, and the power of the Controller of Patents to direct or permit such amendment, the scope of such amendment is delineated in Section 59(1). Section 59(1) provides, and prescribes, that

(i) amendment of an application seeking grant of a patent, or of the specifications therein is permissible by way of (a) disclaimer, (b) correction and (c) explanation,

(ii) the amendment would necessarily require incorporation of actual fact,

(iii) the amendment, if it claims or describes matters which are not in substance disclosed or shown in the pre-amended specification or does not fall within the scope of the claim in the pre-amended specification, would not be allowed.

77. Several considerations, therefore, govern the issue of whether to grant or allow a prayer for amendment as well as whether an amendment of the claim is necessary at all. The words "disclaimer", "correction" and "explanation" are themselves wide in their ambit. If anything, the word

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

"correction" can include a wide variety of changes that an applicant seeking to amend the specification in a patent may choose. Even in the present case, as the facts recited towards beginning of this judgment disclose, the claims as originally filed were amended several times. This itself indicates that amendment is not a mere ministerial exercise, but seriously affects and results in civil consequences to the parties before the Controller, i.e. the applicant seeking to amend the claim as well as the objector who objects to the claim.

78. Both parties have, therefore, to be heard before the amendment is allowed or rejected.

IV. Sections 14, 15 and 80 of the Patents Act

79. Mr. Hemant Singh invoked Sections 14, 15 and 80 of the Patents Act, to urge to the contrary. He also sought to contend that Rule 55 of the Patents Rules could not be interpreted in a manner contrary to the provisions of the Patents Act.

80. There can be no cavil whatsoever with the proposition that Rule 55 of the Patents Rules, being a Rule framed in exercise of the powers conferred by Section 159(1)[27] of the Patents Act, has to be read in consonance therewith.

81. I am unable, however, to agree with the manner in which Mr.

[27] **159. Power of Central Government to make rules**. –
(1) The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Hemant Singh would seek to interpret Sections 14, 15 and 80 of the Patents Act. Section 14 provides that, when the examiner's report, on an application seeking grant of a patent, is adverse to the applicant, or suggests amendments to the application, the Controller would communicate, to the patent applicant, the gist of the examiner's objections and, if the applicant so requests, hear him in the matter before taking a decision.

82. Read as it stands, Section 14 only caters to the procedure to be followed in dealing with the FER of the examiner. It does not envisage any *subsequent* objections to the patent application which the Controller may himself raise, or any amendments to the specifications which the Controller may deem appropriate or necessary. Section 15, on the other hand, caters to this latter eventuality, and provides that, where the Controller feels that the patent application does not comply with the Patents Act or Patents Rules, he may either (i) refuse the application or (ii) require the application to be amended to his satisfaction before he grants the patent.

83. Noticeably, while Section 14 requires the Controller to hear the patent applicant before acting thereunder, Section 15 does not say so.

84. Mr. Hemant Singh sought to submit that Sections 14 and 15 were to be read in tandem, and deal with the same eventuality. Plainly read, they do not seem to do so. Section 14 applies only where the examiner has objections to the grant of the patent, and stipulates how the objections should be dealt with. *Per contra*, Section 15 deals with objections, not of

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

the examiner, but of the Controller himself. The power to object to the grant of the patent vests independently in the examiner and the Controller though, ultimately, the Controller decides both. Ergo, if, for example, the examiner has no objections, but the Controller, on examining the claim and specifications, does find them to be deficient in one or more respect, or requiring amendment, he would act *not under Section 14*, but *only under Section 15*.

85. That distinction, however, does not appear, in the facts of the present case, to be of any particular significance. Mr. Hemant Singh submits that the notice dated 25th November 2022 was in continuation of the original objections raised by the examiner to Novartis' patent. Arguendo, I would proceed on the basis that it is. Even so, there is no provision which permitted the learned Assistant Controller to hear Novartis' alone, on 2nd January 2022, behind the back of Natco, and proceed in the matter.

86. The attempt of Mr. Hemant Singh to contradistinguish the *examination of the application by the examiner and the Controller* under Sections 14 and 15, and the *evaluation of the objections raised by the pre-grant opponent to the grant of the patent* appear, *insofar as they relate to the procedure to be followed in that regard*, to be misguided. Undoubtedly, Sections 14 and 15 of the Patents Act refer to objections raised by the patent office, by the examiner and/or the Controller, whereas Section 80 deals with objections raised by the pre-grant opponent. In either case, they are objections, however, and both are required to be adjudged in accordance with Rule 55 of the Patents Rules,

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

which refers both to the objections of the Controller and the objections of the pre-grant opponent. In Rule 55, therefore, both objections converge; the "parallel paths" charted out by Mr. Hemant Singh, therefore, meet in the Rule.

87. Thus far, indeed, the judgement dated 12th July 2022 in WP (C) IPD 91/2021 is also clear and unequivocal. Para 19 of the said judgement clearly observes that "The proceeding in a pre-grant opposition and simultaneous examination of a patent application …. cannot result in a situation where the pre grant opponent is kept in the dark about the developments taking place in the examination process". Keep the pre-grant opponent abreast of the developments taking place in the examination process, by its very nature, would require involvement of the pre-grant opponent in the decision-making exercise. Compliance with the requirement of transparency, with the pre-grant opponent, of the developments in the examination process can hardly be ensured by conducting the exercise in his absence and merely informing him of the outcome.

88. I am, therefore, unable to subscribe to the submission of Mr. Hemant Singh that the exercise of examination of the application seeking grant of a patent and of assessing the validity of the objections raised against such grant, are parallel proceedings, which take place before the learned Controller of Patents, and which have different demographics. At the cost of repetition, once an objector enters the fray and objects to the application, the proceedings converge. They become consolidated

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

proceedings, which would involve, within their total scope, the consideration of the objections to the grant of the patent, whether raised by the examiner or by the Controller himself, as well as the objections raised by the opponent who objects to the grant of the patent. It would be completely unrealistic to pigeonhole these proceedings into two parallel compartments and allow one to proceed by involving both parties and other to proceed keeping the pre-grant opponent out of the picture.

V. Rule 55 of the Patents Rules

89. This position is also apparent from Rule 55 of the Patents Rules. Rule 55 of the Patent Rules flows from Section 25(1) of the Patents Act. Section 25(1) allows any person to oppose an application seeking grant of a patent which has not been granted. It proceeds to provide, in Clauses (a) to (k), the grounds on which the opposition could be raised and clarifies that the opposition cannot be made on any other ground. Once such an opposition is made, Section 25(1) mandatorily requires the Controller to, on the person opposing the grant of a patent seeking a hearing, hear such opponent and dispose of the opposition "in such manner and within such period as may be prescribed". "Prescribed" is defined, in Section 2(u), to the extent relevant, as "prescribed by rules under the Patents Act. For the purposes of the present controversy, therefore, the words "as may be prescribed" implied in Section 25(1) of the Patents Act, refer to prescription by the Patents Rules. That, therefore, brings into application Chapter VI of the Patents Rules, which deals with proceedings for to grant of patents and, specifically, Rule 55 which deals with the "opposition to the patents".

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

90. Rule 55(1) sets out the manner in which the opposition is required to be filed by the opponent before the Controller. Rule 55(1A) proscribes grant of a patent before the expiry of six months from the date of publication of the application seeking grant of the patent. Rule 55(2) requires the Controller to consider the opposition set up by the opponent opposing the grant of the patent only when a request for the examination of the application has been filed.

91. Sub rules (3) to (5) of Rule 55 proceed to set out the manner in which the Controller is to proceed thereafter. Rule 55(3) envisages the issuance of a notice, by the Controller, to the applicant seeking grant of the patent, if he is of the opinion that the application merits refusal or that the specifications require amendment. That this exercise is, however, not intended to be unilateral, is apparent from Rule 55(4) which requires the applicant seeking grant of the patent to, on receiving a notice from the Controller under Rule 55(3), not only file his statement in evidence supporting the application seeking grant of the patent within three months *but to provide a copy of such statement in evidence to the opponent*. The participation of the opponent even in proceedings emanating from the Controller's objections under Rule 55(3), therefore, stands expressly recognized by Rule 55(4). Rule 55(4), therefore, itself, in a manner of speaking, answers the contention of Mr. Hemant Singh that the examination, by the Controller, of the requirement of amending the patent application or specifications therein, is not required to involve the objector objecting to such grant. Even where the opinion that the

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

patent specifications are required to be amended is that of the Controller under Rule 55(3), the patent applicant is required, under Rule 55(4), not only to answer to such objection but also to provide copy of the response to the opponent, thereby automatically involving the opponent in the exercise.

92. This position, if anything, is further underscored by Rule 55(5). Once the Controller forms an opinion that the patent specifications are required to be amended, communicates the said opinion to the applicant under Rule 55(3), and the applicant files a response thereto under Rule 55(4) with a copy to the pre-grant opponent, Rule 55(5) comes into play. Rule 55(5) requires the controller to consider (i) the statement in evidence filed by the patent applicant, (ii) the representation including the statement in evidence filed by the opponent and (iii) the submissions made by the parties, and, if so requested, to hear the parties. As such, even at this stage, the statutory scheme envisages hearing of both parties. The involvement of the pre-grant opponent at every stage, therefore, is a statutory requirement. Inasmuch as there is no provision in the Patents Act which forbids such involvement, Rule 55(5) does not, in any manner, infract the provisions of the Patents Act.

93. Rule 55(5) proceeds to empower the Collector, once this exercise is carried, to follow, as learned Counsel for the parties agree *ad idem*, to adopt one of three alternative courses of action. He may either (i) reject the opposition of the pre-grant opponent, or (ii) refuse to grant to patent thereby rejecting the application of the patent applicant or (iii) direct or

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

require the complete specification and other documents to be amended to his satisfaction. Once the Controller decides to adopt one of these three alternative courses of action, the Controller is required, by Rule 55(5), to pass a speaking order, simultaneously deciding the application and the objections of the pre-grant opponent.

94. Clearly, Rule 55(5) envisages involvement of both parties in the entire drill. In other words, from the time of filing of the reply, by the patent applicant under Rule 55(4), to the notice issued under Rule 55(3) till the taking of the final decision either to allow or reject the patent or require the specification to be amended, both the parties had to be involved and both parties had to be heard. *No intervening unilateral hearing of the applicant, excluding the pre-grant opponent, is envisaged by Rule 55(5) at this stage. In so proceeding, therefore, the learned Assistant Controller clearly exceeded his authority under Rule 55(5), and acted in a manner foreign to the Rule.* The exercise that has been conducted by the learned Assistant Controller in the present case, of issuance a unilateral notice, on 25th November 2022, only to Novartis excluding Natco from the proceedings at that stage, granting a unilateral hearing to Novartis without the participation of Natco and thereafter, passing the order granting the patent on 14th December 2022 is, in my considered opinion, alien to the scheme of Rule 55 of the Patents Rules and cannot be sanctioned by any provision of the Patents Act, as there is no provision in the Act which allows such a procedure to be followed.

95. I am fortified, in the view that I have taken, by S. Muralidhar, J (as

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

he then was) in para 13 of ***UCB Farchim***[5], already reproduced in para 36 *supra*.

96. Muralidhar, J. has, in the afore-noted decision, clearly held that pre-grant opposition proceedings are in aid of the examination of the patent application by the Controller. This observation, too, belies the submissions of Mr. Hemant Singh that the opposition proceedings, and the examination of the patent application by the Controller, can be confined to two separate compartments, distinct from and uninvolved, with each other. They have to be dealt together and even for this reason, both parties have to be involved at every stage of the said process.

VI. <u>The Ayyangar Committee Report</u>

97. Paras 210 and 213 of the Ayyangar Committee report on patents also underscore this position. In para 210, it is clearly opined that "an opposition proceeding constitutes an extension of the investigation undertaken by the examiner".

98. Para 213 also goes on to answer the submissions of Mr. Hemant Singh that, if Rule 55 of the Patents Rules is to be interpreted in such a fashion, the exercise of grant of a patent may become unconscionably delayed. As has been observed in para 213 of Ayyangar Committee report, "the question is one of the balancing the benefits which accrues to the public from a successful opposition eliminating a possible invalid patent and the inconvenience of hardship caused to the applicant for legally patentable invention quickly sealed because of an objection". As

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

such, it is not possible to accord between the applicant seeking grant of a patent and the objector opposing such grant, greater precedence to either one over the other.

VII. ***Haryana Pesticides***[8]

99. In such circumstances, I am of the opinion that the judgment of the coordinate Bench in ***Haryana Pesticides***[8], cannot come to the aid of Novartis. In the said decision itself, the coordinate Bench has expressly termed as "relevant", the notices dated 20th June 2019 and 25th November 2019, issued by the Controller, which read thus:

> "Notice dated 20th June 2019
>
> "(5) SCOPE: Claims: 1-27 does/do not define the scope of invention for which the protection is claimed for the following reasons:
>
> a. The compositions stated in claims should be clearly defined w.r.t the ratio/percentage of the components used.
>
> b. The expressions "of 2.50-5.00% w/w.","1.50-3.00% w/w. "preferably" alone or in combination thereof "," group consisting of combination products "," natural polysaccharides. "are broad in scope and make the scope of claims broader than is justified by the description.
>
> c. The scope of claims 1-27 is **unclear and indefinite** with respect to the expressions "present in an effective amount, plurality of anti freezing agents, fillers, anti-foaming agent, dispersing/wetting agents, viscosity modifiers, biocide and solvents alone or in combination thereof selected from the group consisting of combination products....etc" which are not all supported and disclosed in the present application. The extremely large number of possibilities which are covered by the claims make it impossible to determine the **exact scope of the invention.** Therefore, the above claims *should be redrafted to clearly define the scope of protection*

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

sought to restrict the scope of the invention as per requirement u/s 10 of the Act.

d. Claims 27 define a product (novel fungicidal composition) in terms of the process (known procedure) used to produce that product. The technical features of that product will be the same when compared to the same product produced by a different process. The instant claims are not allowed."

(Italics supplied)

Notice 25th November 2019

"Scope

1.a. The expressions "alone or in combination thereof "," group consisting of combination products", "natural polysaccharides." are **broad in scope** and make the scope of claims **broader** than is justified by the description.

b. The scope of claims 1-25 is **unclear** and **indefinite** with respect to the expressions plurality of anti freezing agents, fillers, anti-foaming agent, dispersing/wetting agents, viscosity modifiers, biocide and solvents alone or in combination thereof selected from the group consisting of combination products....etc" which are not all supported and disclosed in the present application. The **extremely large number of possibilities** which are covered by the claims **make it impossible to determine the exact scope of the invention.** *Therefore, the above claims should be redrafted to clearly define the scope of protection sought to restrict the scope of the invention as per requirement u/s 10 of the Act*."

(Italics supplied)

100. Para 25 of the report underscores the importance of these notices, thus:

"25. Since the amendments were made at the asking of the Controller and in the course of examination of application under Section *14*, hence no notice was issued by the Controller to the petitioner. Further it is important to note *petitioner never raised any objection to the amended claim nos.1-25 when it submitted its written submissions dated 28.01.2020.* The amended claim nos.*1-25* were subject matter of hearing notice dated 25.11.2019 issued to both the parties, fixing the hearing of Controller's objection as well as pre-grant opposition."

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

101. Thereafter, the coordinate Bench goes on to hold that as the amendments were made at the asking of the Controller in course of the examination of the application, no notice was issued by the Controller to the petitioner.

102. Unlike the present case, therefore, the notice issued to the claimant in ***Haryana Pesticides***[8] was unquestionably a notice by the Controller calling on the applicant to amend his claims.

103. Paras 26 and 27 of the report, on which considerable reliance was placed by Mr. Hemant Singh, read thus:

> "26. The Patents Act, 1970 and Patents Rules, 2003 envisage: ***a)*** voluntary amendment sought to be made by an applicant in a specification or a patent document and ***b)*** the amendment of the specification required to be made by the Controller to his satisfaction. For a voluntary amendment the procedure prescribed is under Section *57(1)* and *57(2)* of the Patents Act, 1970 which involve filing of application in the manner prescribed in Rule *81* and *82* of the Rules of Form-13 with payment of prescribed fee vide entry no.*20* of *Table-1* of the *first* schedule of the Patents Rules 2003. Such procedure does not apply to the amendment made in the specification to comply with the direction of the Controller issued before the grant of Patent under Section *14, 15* and Rule *55(5)*.
>
> 27. A bare perusal of the claims would reveal there was never any addition nor expansion to the ***scope*** of claim nos.*1-25* while bringing it down to claim nos.*1-19*. Rather six claims were ***deleted*** and rest were only ***merged*** in claim nos.*1-19*, hence, there appears to be no violation of principles of natural justice."

104. I am unable to discern, from paras 26 and 27 of the report in ***Haryana Pesticides***[8], any finding to the effect that, after hearing both parties on the sustainability of the objections to the claim of the patent

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

claimant, whether at the instance of the controller or at the instance of the objector, a unilateral proceeding, merely hearing one party to the exclusion of the other, is permissible. Para 26 of the report sets out the fact situation by noting that the amendments were made at the asking of the Controller and in the case of the examination of the application under Section 14 and that hence, no notice was issued by Controller to the petitioner. It does not contain any expression of opinion of the law in that regard. Para 27 of the report goes on to distinguish between a voluntary amendment sought to be made by an applicant in a specification or a patent document and an amendment of the specification at the instance of the Controller to his satisfaction. All that it says is that the procedure in respect of a voluntary amendment is contained in Sub rules 1 and 2 of Section 57 of the Patents Act, which involve filing of the application as prescribed under Rules 81 and 82 with payment of prescribed fee *vide* Entry 20 of Table I to the First Schedule of the Patents Rules and that this procedure does not apply to the amendment made in the specification to comply with the direction of the Controller issued before the grant of patents under Sections 14 and 15 of Rules 55(5).

105. Rule 55(5) of the Patents Rules has not come up for specific examination by the coordinate Bench in ***Haryana Pesticides***[3], as Mr. Sai Deepak correctly pointed out.

106. In view of my opinion, already expressed hereinabove, Rule 55(5) does, as it is enacted, envisage participation by both sides in the entire

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Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

exercise, from the point of submission, by the patent applicant, of a reply under Rule 55(4) to the notice under Rule 55(3), till the final decision to grant or refuse the patent or require the patent specification applications to be amended.

107. The objector objecting to the application cannot be excluded from these proceedings at any point.

VIII. The "prejudice" argument

108. One of the contentions that was advanced by Mr. Hemant Singh was that Natco has not really suffered any prejudice in the present case, as would justify interference by this Court especially under Article 226 of the Constitution of India. Here, too, I confess my inability to agree with Mr. Hemant Singh. The aspect of prejudice cannot be viewed merely by referring to Claims 4 and 5 of the claim set filed by Novartis before the learned Controller. It has to be borne in mind that, prior to 14th December 2022, there was no decision either on Application 4412 filed by Novartis, or the pre-grant objections filed by Natco thereto. It was for the first time, therefore, that a decision was taken by the learned Assistant Controller, on any aspect of controversy before him, on 14th December 2022. As such, the aspect of prejudice has to be viewed with respect to the entire order and not merely with respect to the deletion of Claim 4 or the modification of the title of Claim 5. The patentability of Claim 1 of the claim set filed by Novartis was seriously opposed by Natco. As I have already observed, the merits of opposition are not a matter to be considered in the present petition. However, once such an

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

opposition has been voiced and that opposition was decided for the first time on 14th December 2022, any courtesy of hearing extended prior thereto, to Novartis without notice to Natco, is, by itself, sufficient to vitiate the decision, as it would fly in the teeth of the *audi alteram partem* principle.

109. The objections raised by Natco against the patentability of Claim 4, in the claim set filed by Novartis on 6th June 2020 did not stand entirely answered by merely deleting Claim 4. Mr Sai Deepak's submission is that the crystalline form of the Valsartan-Sacubitril composition was also subsumed in Claim 1 of the Claim Set filed by Novartis on 6th June 2020. Prior to 2nd December 2022, both Claims 4 and Claim 1 were claimed by Novartis before the learned Assistant Controller. Even if the submission of Mr. Hemant Singh that the proceedings on 2nd December 2022 were restricted only to the allowability of Claims 4 and 5 of the clam set filed by Novartis is to be accepted, the fact of the matter remains that, as Natco was kept out of the proceedings on 2nd December 2022, Natco lost the opportunity to point out to the learned Controller that, in fact, the crystalline form of the Valsartan-Sacubitril formulation was also subsumed in Claim 1 of the claim set filed by Novartis.

110. I reiterate here that I am not intending, in any manner, to examine the correctness of this objection. All that I intend to point out is that the opportunity to demonstrate, to the learned Assistant Controller, that what was claimed in Claim 4 was also claimed in Claim 1, was lost to Natco,

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

as it was kept out of the proceedings on 2nd December 2022. In that background, given the fact that it was for the first time on 14th December 2022, that the learned Assistant Controller pronounced on any of the aspects of the controversy, including the patentability of Claim 1 of the claim set filed by Novartis on 6th June 2020, the unilateral proceedings, which took place on 2nd December 2022, in which Novartis was heard and Natco was kept out of the proceedings, in my view, seriously prejudices Natco's interest.

111. This, therefore, cannot be taken as one of those cases in which absence of prejudice can be cited as a ground to discountenance the requirement of the compliance of principle of natural justice.

IX. Other disquieting aspects

112. In this context, the submissions of Mr. Sai Deepak also do raise certain other disquieting features of the procedure, which was followed by the learned Assistant Controller.

113. As Mr. Sai Deepak correctly pointed out, consequent to the hearing on 2nd December 2022, Novartis filed written submissions before the learned Assistant Controller on 14th December 2022. On the very same day, the impugned order came to be passed. This itself raises a serious question mark as to the manner in which the proceedings were conducted. It is difficult to understand how written submissions were filed by Novartis on 14th December 2022 and the impugned order came to be passed on the very same day on which the submissions were filed.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

114. Further, Mr. Sai Deepak points out that the written submissions specifically averred that the learned Assistant Controller had already communicated, to Novartis, his decision to allow Claims 1 to 3 and Claims 6 to 8 of the claim set filed by Novartis on 6th June 2020. This, again, is disquieting. The *a priori* communication of the decision that the learned Assistant Controller formally pronounced on a later date, to the Novartis, in whose favour the decision was being taken, behind the back of Natco, was seriously prejudicial to natural justice and fair play.

115. In the present case, the seriousness of the matter is underscored by the fact that the notice dated 25th November 2022, as well as the submissions of Novartis dated 14th December 2022, were uploaded on the website of the Controller of Patents only a day after the impugned order came to be passed on 14th December 2022. This, too, reveals an entirely unsatisfactorily states of affairs, especially given the seriousness of the *lis* between the parties.

X. Breach of order dated 12th July 2022

116. The learned Assistant Controller has also, in the process, plainly breached the order dated 12th July 2022. Direction (v), in para 21 of the order, required the learned Assistant Controller, *before the commencement of oral hearing in the pre-grant opposition*, to orally communicate, to the parties, the amendments which were being allowed and the final set of claims which were being considered for grant. The hearing on the pre-grant objections was to take place *thereafter*.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Direction (vi) further required the learned Assistant Controller to hear the parties for an hour each on the pre-grant objections of Natco and to pronounce his decision on or before 15th November 2022.

117. The learned Assistant Controller has, unfortunately, complied with these directions, but in reverse. He heard the parties on 15th November 2022. He did not, however, as directed by this Court, pronounce his decision on or before 15th November 2022. Nor did he deem it appropriate or necessary to seek any extension of time from this Court in that regard. Apparently *suo motu*, and for reasons which are totally unfathomable, the learned Assistant Controller, on 22nd November 2022, issued a notice *only to Novartis*, fixing a further hearing on 2nd December 2022. In that hearing, Natco was excluded. Thereafter, he pronounced to pass the impugned order on 14th December 2022. The deletion of Claim 4, and the amendment of the title of Claim 5, was allowed for the first time in the said order. He, thereby, again breached the direction, of this Court, to inform both sides of the amended claims which were finally going to be taken into consideration by him *before finally hearing arguments on Natco's pre-grant opposition*.

118. Assuming, for a minute, that the learned Assistant Controller was empowered to again allow amendment of the claims after the hearing of 15th November 2022 – as he has – the very least that the learned Assistant Controller was required to do, for some semblance of compliance with the directions issued by this Court to be forthcoming, was to hear the parties once again on the amended claims. He, however, did not deem it

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

necessary to do so. Instead, he followed a procedure *sui generis* after 15th November 2022, completely foreign to that directed by this Court. The specific direction, of this Court, that the parties were *first* required to be notified the amended claims *before* final hearing on the pre-grant opposition, thereby, also stood defeated.

119. The procedure followed by the learned Assistant Controller also transgresses the opening sentences in para 19 of the order dated 12th November 2022 which read thus:

> "The proceeding in a pre-grant opposition and simultaneous examination of a patent application, however, cannot also result in a situation where the pre-grant opponent is kept in dark about the developments taking place in the examination process. For example, when amendments are filed by the Applicant, an immediate decision ought to be taken on allowing or disallowing the amendment so that there is transparency and clarity as to what are the claims being considered by the Controller."

120. Para 22 of the order dated 12th July 2022 does not, in any manner, detract from the impact of the directions issued by this Court. In any event, the notice dated 22nd November 2022 was issued under Section 14; not under Section 15. If it is to be taken as having issued both under Sections 14 and 15, para 22 of the order dated 22nd November 2022 would be rendered nugatory, as all amendments are relatable either to Section 14 or 15.

121. Thus,

(i) Natco and Novartis were both heard by the learned Assistant Controller on 5th September 2022, and apparently the matter was kept pending for orders,

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

(ii) despite the expiry of 15th November 2022, being the *terminus ad quem* fixed by the Court (*vide* the judgement dated 12th July 2022) for passing of the said decision by learned Assistant Controller, no such decision was passed,

(iii) rather, 10 days later, on 25th November 2022, the learned Assistant Controller chose to send a notice only to Novartis keeping Natco out of the picture, calling Novartis to attend a hearing on 2nd December 2022,

(iv) during the hearing on 2nd December 2022, the learned Assistant Controller intimated Novartis that he had already decided to allow Claims 1 to 3 and Claims 6 to 8,

(v) thereafter, on 14th December 2022, written submissions came to be filed by Novartis before the learned Assistant Controller without providing any copy thereof to Natco and

(vi) on the same very day, the impugned order came to be passed, allowing the amendment of the claims and granting the amended claims of Novartis.

122. As to why the learned Assistant Controller acted as he did, one can only remain in a state of wonderment.

123. In my considered opinion, the procedure followed by the learned Assistant Controller is completely antithetical to the most fundamental notions of natural justice and fair play. While this Court does not desire to adversely comment on the proceedings being followed or on the justification of the allegations made by Mr. Sai Deepak in that regard, the

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

Court is constrained to observe that especially given the seriousness of the issue involved and the fact that the patent which was in stake is a breakthrough pharmaceutical patent, intending to cater to cardiovascular therapy, such a procedure could not have been followed by the learned Assistant Controller.

124. As Mr. Sai Deepak correctly contends, if the Court is to lend its imprimatur to such a procedure, it would open floodgates for misuse as, after hearing both sides on the opposition and objections to the patent application, the Controller or the Assistant Controller could unilaterally hear one of the parties in the absence of the other and proceed to take a decision. What may transpire during such hearing would remain entirely a matter of conjecture. Such a procedure cannot be permitted, if the rule of law is to be observed.

125. In view of the aforesaid discussion, I do not deem it necessary to return any finding on the aspect of non-consideration of the material filed by the petitioner as, in my view, that is actually a ground which cannot by itself constitute the basis for invoking writ jurisdiction of this Court.

XI. Maintanability; availability of Article 226

126. For the reasons as aforesaid, I am not inclined to accept the submissions of Mr. Hemant Singh that, in this case, the remedy under Article 226 of the Constitution of India is not available to the petitioner. The infirmity in the procedure followed by the learned Assistant Controller, and the transparent violation of the principles of natural

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

justice and fair play that has resulted as a consequence thereof, in my view, justify invocation of Article 226 of the Constitution of India, in the light of the principles enunciated in ***Whirlpool***[2] and ***Harbans Lal Sahnia***[3]**,** among other decisions. I may also observe, in this context that, in somewhat similar circumstances, and seized with an analogous dispute, this Court has already upheld the invocability of Article 226, in ***Best Agro Life***[9].

Conclusion

127. For all the aforesaid reasons, the impugned order dated 14th December 2022, passed by the learned Assistant Controller of Patents is quashed and set aside. Novartis' Application 4412/DELNP/2007is remanded to the learned Assistant Controller for reconsideration. The reconsideration shall start from the point of the notice issued by the learned Assistant Controller on 25th November 2022. The said notice shall be deemed to have been issued to Novartis and Natco and both parties would be heard thereon.

128. After following the said procedure, the learned Assistant Controller is directed to take a fresh decision on both on the application for registration as filed by Novartis as well as on the objection of Natco thereto. Needless to say, the decision would be taken in accordance with the principles of natural justice and fair play and keeping in mind the dictates of the law in that regard. The learned Assistant Controller would also remain uninfluenced by the impugned decision.

Signature Not Verified
Digitally Signed By:SUNIL SINGH NEGI
Signing Date:15.01.2023 13:18:51

129. Given the nature of the controversy, the learned Controller is requested, if possible, to decide the matter himself or to assign this exercise to an Officer other than the learned Assistant Controller who has passed the impugned order. I make it clear that, by so observing, I do not intend to cast any aspersion on the Officer, who has passed the impugned decision. However, given the nature of the dispute, the importance of controversy, the stakes involved and the principle that justice should not only be done but also seen to have been done, and following the example set by the Supreme Court in ***P.V. Narasimha Rao v. State (CBI/SPE)***[28], it would be advisable that this matter is heard by a different Officer.

130. In order to avoid any confusion, it is clarified that the exercise to be undertaken by the learned Assistant Controller would cover (i) the merits of Application 4412 filed by Novartis seeking grant of patent, (ii) any objection to the claims, which may have been expressed by the Examiner or by the Controller as well as the issue of whether the claims are required to be amended and (iii) the objection raised to Natco against the application of Novartis.

131. The writ petition stands allowed accordingly, with no orders as to costs. Miscellaneous pending applications also stand disposed of.

C.HARI SHANKAR, J

JANUARY 12, 2023
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