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

\+ C.A.(COMM.IPD-PAT) 22/2021

ALLERGAN INC ..... Appellant

Through: Mr. Ankush Verma, Mr.Debashish Banerjee, Mr. Vineet Rohilla, Mr.Rohit Rangi, Mr.Venkatesh Naik, Mr.Tanveer Malhotra, Advs.

versus

THE CONTROLLER OF PATENTS ..... Respondent

Through: Mr. Harish Vaidyanathan Shankar, CGSC, Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat, Mr. Alexander Mathai Paikaday, Advs.

CORAM:
HON'BLE MR. JUSTICE C.HARI SHANKAR

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

% 20.01.2023

1. On 13th August 2012, the appellant submitted Patent Application No. 7039/DELNP/2012 to the Patent Office, New Delhi, for grant of a patent for "INTRACAMERAL SUSTAINED RELEASE THERAPEUTIC AGENT IMPLANTS". The application contained the following 20 claims:

> "1. A method for treating an ocular condition comprising the steps of:
>
> providing at least two biodegradable sustained release implants containing at least one therapeutic agent;
>
> implanting the at least two biodegradable sustained release implants into the anterior chamber of an eye; and
>
> treating the ocular condition,
>
> wherein the at least two biodegradable sustained release implants release about100 ng per day of the at least one bioactive agent for a period greater than about 1month.

2. The method according to claim 1 wherein the ocular condition is glaucoma.

3. The method according to claim 1 wherein the ocular condition is elevated intraocular pressure.

4. The method according to claim 1 wherein the sustained release implant releases about 70% of the at least one therapeutic agent over the first month.

5. The method according to claim 1, wherein the at least one therapeutic agent is selected from the group consisting of latanoprost, bimatoprost and travoprost and their salts, esters and prodrugs.

6. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 30% therapeutic agent.

7. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 5% to about 70% poly(D,L-lactide).

8. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 5% to about 40% poly (DL-lactide-co-glycolide).

9. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 5% to about 40% polyethylene glycol.

10. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 30% therapeutic agent, 65% poly(D,L-lactide),and 5% polyethylene glycol.

11. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 30% therapeutic agent, 65% poly(D,L-lactide), and 5% polyethylene glycol.

12. The method according to claim 1 wherein the at least two biodegradable sustained release implants comprise about 20% therapeutic agent, 55% poly(D,L-lactide),10% poly(DL-lactide-co-glycolide), and 5% polyethylene glycol.

13. The method according to claim 1 wherein the implanting step is accomplished using an applicator.

14. The method according to claim 1 wherein the at least two biodegradable sustained release implants are settled out in the

inferior angle within 24 hours of implanting within the anterior chamber.

15. A method for treating glaucoma in an eye comprising the steps of:

providing at least two biodegradable sustained release implants containing at least one therapeutic agent;

implanting the at least two biodegradable sustained release implants into the anterior chamber of the eye;

allowing a sufficient time for the at least two biodegradable sustained release implants to settled out in the inferior angle;

allowing a sufficient time for the at least two biodegradable sustained release implants to release the at least one therapeutic agent; and

treating glaucoma,

wherein the at least two biodegradable sustained release implants release about 100 ng per day of the at least one bioactive agent for a period greater than about 1 month.

16. The method according to claim 15 wherein the sufficient time for the at least two biodegradable sustained release implants to release the at least one therapeutic agent is greater than about 42 days.

17. The method according to claim 15, wherein the at least one therapeutic agent is selected from the group consisting of latanoprost, bimatoprost and travoprost and their salts, esters and prodrugs.

18. The method according to claim 15 wherein the at least two biodegradable sustained release implants comprise about 30% therapeutic agent, 65% poly(D,L-lactide), and 5% polyethylene glycol.

19. The method according to claim 15 wherein the at least two biodegradable sustained release implants comprise about 20% therapeutic agent, 55% poly(D,L-lactide),10% poly(DL-lactide-co-glycolide), and 5% polyethylene glycol.

20. The method according to claim 15 wherein the sufficient time for the at least two biodegradable sustained release implants to settled out in the inferior angle is about 24hours."

2. On 6th November 2017, the Controller of Patents wrote to the

attorneys of the appellant, objecting to the application as filed. Among the objections which were raised by the Controller was an objection that the Claims in the patent application were not patentable as they related to the method of treatment of human beings/animals, in respect of which Section 3(i)[1] of the Patents Act, 1970 (the Patents Act) forbore grant of patent.

3. Pursuant to the aforesaid First Examination Report (FER), the appellant, submitted a set of amended Claims, reducing the number of claims from the earlier 20 to 5. The amended Claims read thus:

> "l. An intracameral implant comprising:
>
> (i) 5-40% wt of a therapeutic agent;
> (ii) 10-60% wt of a poly-(D, L lactide) with an inherent viscosity of 0,25-0,35dl/g;
>
> (iii) 5-20% wt of a poly-(D.L lactide) with an inherent viscosity of 0, 16-0, 24 dl/g:
>
> (iv) 5-40% wt of a poly-(DL-lactide-co-glycolide) which has a molar ratio of D, L glycolidc:lactide of 73:27 to 77:23 and an inherent viscosity of 0,16-0,24 dl/g;
>
> and
>
> (v) 0-15% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol.
>
> 2. An intracameral implant as claimed in claim 1, comprising:
> (i) 20% wt of a therapeutic agent;
>
> (ii) 45% wt of a poly-(D,L lactide) with an inherent viscosity of 0,25-0,35 dl/g;
>
> (iii) 10% wt of a poly-(D,L lactide) with an inherent viscosity of 0,16-0,24 dl/g;

[1] **3. What are not inventions**. – The following are not inventions within the meaning of this Act, –
(i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;

(iv) 20% wt of a poly-(DL-lactide-co-glycolidc) which has a molar ratio of D,L glycolide:lactide of 73:27 to 77:23 and an inherent viscosity of 0,16-0,24 dl/g;

and

(v) 5% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol.

3. An intracameral implant as claimed in any preceding claim, wherein the therapeutic agent is a prostamide.

4. An intracameral implant as claimed in any preceding claim, wherein the prostamide is bimatoprost,

5. An intracameral implant as claimed in any preceding claim for use in a method of treating an ocular condition, the method comprising the steps of:

- providing at least two biodegradable implants as defined in any preceding claim; and

- implanting the implants into the anterior chamber of the eye."

4. The appellant was, thereafter, issued a notice of personal hearing on 29th July 2019, which reiterated several of the objections contained in the FER and, on the aspect of whether the appellant was entitled to amend his claims as it had chosen to do, noted thus:

"**Other Requirement(s)**

1. As originally filed claims pertain to a "Method for treating an ocular condition (glaucoma)" which involves providing biodegradable sustained release implants with different portions of the release of therapeutic agents or implant of therapeutic agents.

But the amended set of claims pertain to

An intracameral implant comprising:

(i) 5-40% wt of a therapeutic agent;

(ii) 10-60% wt of a poly-(D, L lactide) with an inherent viscosity of 0,25-0,35 dl/g;

(iii) 5-20% wt of a poly-(D,L lactide) with an inherent viscosity of 0,16-0,24 dl/g;

> (iv) 5-40% wt of a poly-(DL-lactide-co-glycolide) which has a molar ratio of D, L glycolide:lactide of 73:27 to 77:23 and an inherent viscosity of 0, 16-0,24 dl/g; and
>
> (v) 0-15% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol. Etc.,
>
> Therefore, *such type of "compositions of intracameral implant" does not have support in the as originally filed claims, and further the same "intracameral implants" has not been claimed either in WIPO (International) claims or while entering in the national phase,* so it is of the opinion that disclaimed claims can't be allowable for further proceedings, hence the voluntary amendments made by the applicant/agent are not allowable u/s 59(1) of the Patents Act."
>
> (Emphasis supplied)

5. Thereafter, the appellant was granted a hearing by the learned Controller of Patents on 27th August 2019. Consequent thereupon, the impugned order has come to be passed by the learned Controller on 30th March 2020.

6. The impugned order runs into 16 pages. Mr. Ankush Verma, learned Counsel for the appellant points out that the discussion and findings of the learned Controller are limited to the concluding pages 15 and 16 of the impugned order, as the first fourteen pages refer to the Claims as filed, the FER, the objections raised, reply thereto, and the amendments proposed. Pages 15 and 16 of the impugned order, which contained, in sum, the basis for rejecting the appellant's amended Claims, read thus:

> "**The Applicant/Agent provided a written note of submission on 10/10/2019 along with necessary documents**.
>
> In addition to the above, the objection regarding beyond the scope of the invention u/s 59 is as follows in detail,
>
> In view of the as originally filed claims it is crystal clear that the subject matters of the present invention pertain to 1. "A method for

treating an ocular condition comprising the steps of", 2. "A method for treating glaucoma in an eye comprising the steps of". With preferable amount of agents/components along with preferable intervals of time durations etc.,

But the amended set of claims pertain to

An intracameral implant comprising:

(i) 5-40% wt of a therapeutic agent;

(ii) 10-60% wt of a poly-(D, L lactide) with an inherent viscosity of 0, 25-0,35dl/g;

(iii) 5-20% wt of a poly-(D,L lactide) with an inherent viscosity of 0,16-0,24 dl/g;

(iv) 5-40% wt of a poly-(DL-lactide-co-glycolide) which has a molar ratio of D, L glycolide:lactide of 73:27 to 77:23 and an inherent viscosity of 0, 16-0,24 dl/g; and

(v) 0-15% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol. Etc.,

Therefore, *such type of "compositions of intracameral implant" does not have support in the as originally filed claims, and further the same "intracameral implants" has not been claimed either in WIPO (International) claims or while entering in the national phase,* so it is of the opinion that disclaimed claims can't be allowable for further proceedings, hence the voluntary amendments made by the applicant/agent are not allowable u/s 59(1) of the Patents Act."

Section 59 is reads as follows,

59. Supplementary provisions as to amendment of application or specification.-*(1)* No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.

Therefore, while considering the amendments of the present invention the set of amended claims does not fall within the scope

> of the as originally filed claims as per the any clauses of the section 59(1) of the Patents Act, hence as the amended sets of claims are not allowable u/s 59 of the Act, it is of the opinion that there is no need to discuss the rest of the objections/sections with respective to the hearing notice for the present invention.
>
> Therefore, In view of the above findings on the facts of the case and upon consideration of written submission of the agent of the applicants, objection regarding section 59 of the Patents Act is still maintained, hence I hereby refuse the said invention/application (7039/DELNP/2012) u/s 15 of the Patents Act.
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> Dated 30/03/2020."

7. Clearly, therefore, the learned Controller has not examined the aspect of patentability of the claims of the appellant as amended, as he has proceeded on the premise that the appellant was not entitled, in the first place, to amend the Claims as it had chosen to do. This finding is predicated on Section 59(1)[2] of the Patents Act.

8. The reasons for rejecting the amendments to the Claims, as proposed by the appellant, as contained in the personal hearing notice (and as extracted, verbatim, in the impugned order), and the final reasons adduced by the learned Controller for doing so are not identical. The notice of personal hearing proposed rejection of the request, by the appellant, to amend its claims, for the following reason:

> "Therefore, such type of "compositions of intracameral implant" does not have support in the as originally filed claims, and further the same "intracameral implants" has not been claimed either in wipo (International) claims or while entering in the national phase, so it is of the opinion voluntary amendments made by the applicant/agent are not allowable u/s 59(1) of the Patents Act."

9. This passage, therefore, envisages two grounds to hold that the

[2] Reproduced in the impugned order as extracted in para 6 *supra*

appellant was not entitled to amend its Claims as sought, *viz.* that (i) the amended Claims which claimed "composition of Intracameral Implants" did not "have support in the as originally filed Claims", (ii) "Intracameral Implants" had not been claimed either in the WIPO (International) claims i.e. the PCT Claims or while entering the National Phase.

10. As against this, the final decision of the learned Controller reads thus:

> "Therefore, while considering the amendments of the present invention the set of amended claims does not fall within the scope of the as originally filed claims as per the any clauses of the section 59(1) of the Patents Act, hence as the amended sets of claims are not allowable u/s 59 of the Act, it is of the opinion that there is no need to discuss the rest of the objections/sections with respective to the hearing notice for the present invention."

11. The learned Controller has, therefore, essentially restricted the decision to reject the amendments to the Claims, as proposed by the appellant, as impermissible under Section 59(1) of the Patents Act, to the ground that the "set of amended Claims does not fall within the scope of the as originally filed claims as per the any clauses of the Section 59(1) of the Patents Act".

12. Insofar as the failure of the appellant to seek a claim to patent "compositions for intracameral implant" in the PCT application or while entering the national phase, learned Counsel for both sides are *ad idem* that this discrepancy was owing to a difference in the patentability regime in the US and in India. Method claims are patentable in the US, whereas they are not patentable in India, by virtue of Section 3(i) of the Patents Act. The original PCT claim, as filed in the US, which was for methods for treating ocular ailments

using the intracameral implants was, therefore, patentable in the US, but would not have been patentable in India. As Mr. Vaidyanathan himself acknowledges, it is only after the original patent application is filed that the patentee proceeds to file national phase applications for the patent in the countries designated in the original PCT application. Different countries have, however, different patent regimes, and it would be impractical, nay impossible, to expect that the claims in the original PCT application, as filed (in this case, in the US), would be patentable in every designated country. This is precisely what happened in the present case. The method claim for treating of ocular ailments using intracameral implants was patentable in the US and was, indeed, granted a US patent. In India, however, such a method claim could not be patented, by virtue of Section 3(i). It was for this reason that the appellant amended its claim to a product patent.

13. Whether such an amendment could have been allowed, under the Patents Act, would be presently examined. The learned Controller has held in the negative and has, therefore, effectively shut the door on the appellant, seeking patenting of its invention, at the very inception. Before proceeding to examine the justifiability of the impugned order *vis-à-vis* Section 59(1) of the Patents Act, it would be appropriate, first, to examine whether the learned Controller was justified in additionally citing, as grounds for rejecting the petitioner's request to amend its claims, (i) non-claiming of the process patent in the original international PCT application, filed in the US, and (ii) the process claim not having been made at the stage of entry into the national phase, i.e., at the time of the National Phase application in India.

14. The answer, in my view, has to be in the negative. The

appellant legitimately sought a method patent in its original international PCT application as patents laws in the US, where it was filed, allowed patenting of method patents. No fault can, therefore, be found with the appellant on that score. Insofar as the filing of the National Phase application is concerned, Section 138(4)[3] of the Patents Act deems an international PCT application designating India to have the effect of filing of a patent application for grant of the patent in India *and also requires the title, description, claim and abstracted drawings filed in the international application to be taken as the complete specification for the purposes of the Patents Act*. At the time of entering the National Phase, therefore, there could be no occasion for the appellant to amend the Claims as originally filed in the PCT application in the US.

15. This position is also acknowledged by Mr. Harish Vaidyanathan Shankar as well, appearing for the learned Controller of Patents. The appellant could not, therefore, be faulted, either, for the National Phase application filed by it not having the amended product claims for the implants. These grounds for rejecting the request of the appellant to amend its claims, as originally envisaged were, therefore, without merit. Apparently for that reason, they do not figure as grounds of rejection in the final decision of the learned Controller.

16. It remains, therefore, to be examined whether the amendment of the claims, as sought by the appellant, was otherwise not permissible

[3] **138. Supplementary provisions as to convention applications**. –

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(4) An international application filed under the Patent Cooperation Treaty designating India shall have effect of filing an application for patent under Section 7, Section 54 and Section 135, as the case may be, and the title, description, claim and abstract and drawings, if any, filed in the international application shall be taken as complete specification for the purposes of this Act.

under Section 59(1)[4] of the Patents Act. The learned Controller has held in the negative, and Mr Vaidyanathan echoes the view.

Analysis

17. By way of a brief reiteration, owing to the proscription engrafted in Section 3(i) of the Patents Act, the claims in the PCT application of the appellant, as originally filed in the US, could not be granted in India, as they were in the nature of process/method claims. This, therefore, was one of the grounds on which, legitimately, the Controller of Examination, objected to the appellant's application, in the FER dated 6th November 2017. That, again, was the reason why the appellant sought to amend the claims, as proposed in its reply dated 2nd August 2018 to the FER and later, once again in response to the notice of personal hearing issued to the appellant.

18. Mr. Harish Vaidyanathan, however, submits that the learned Controller was justified and correct in law in holding that the appellant was not entitled to amend its claims in the manner in which it had chosen to do, as such amendment was specifically debarred under Section 59(1) of the Patents Act.

19. Section 59(1) is, to say the least, a peculiarly worded provision. Pared down to its essentials, the provision states that

(i) no patent application would be made except by way of disclaimer, correction or explanation,

[4] **59. Supplementary provisions as to amendment of application or specification**. –
(1) No amendment of an application for a patent or a complete specification or any document related thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.

(ii) no amendment of the application would be allowed except for the purpose of incorporation of actual fact, and

(iii) (to quote verbatim) "no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended, would not fall wholly within the scope of a specification before the amendment".

20. I have quoted this last component (iii) of Section 59(1) verbatim, as it is this component which has been invoked by the learned Controller and with which, therefore, we are essentially concerned in the present case.

21. Mr. Ankush Verma, learned Counsel for the appellant submits that the learned Controller was in error in treating the amended claims of the appellant as beyond the scope of the original claims as filed before the patent office. He has, with commendable clarity, sought to demonstrate this in the following manner:

(i) The original claims pertained to methods for treating ocular conditions using intracameral implants with specific and unique compositions and constituents which, according to the appellant, were inventive *vis-à-vis* prior art.

(ii) All that the appellant had done was to substitute the original claims, which were for the method of treating the ocular conditions using the said implants, by claims for the

implants themselves.

(iii) The amended claims sought, therefore, to claim the very implants, for the method of use of which the original claims had been filed. In fact, para [0002] of the complete specifications effaces, to an extent, the artificial distinction between the method of using the implants for ocular therapy and the implants themselves. It reads thus:

> "**[0002]** The present invention *relates to intracameral sustained release implants and* methods of making and using the same."

(iv) That the implants themselves were also subject matter of the claims even as originally filed is further apparent from paras [0007], [0008], [0027], [0031] and [0039] of the complete specifications (which remained unaltered) which read thus:

> **"[0007]** In another embodiment, the at least two biodegradable sustained release implants comprise about 5% to about 70% poly(D,L-lactide). In other embodiments, the at least two biodegradable sustained release implants comprise about 5% to about 40% poly(DL-lactide-co-glycolide). In yet other embodiments, the at least two biodegradable sustained release implants comprise about 5% to about 40% polyethylene glycol.
>
> **[0008]** In still other example embodiments, the at least two biodegradable sustained release implants comprise about 30% therapeutic agent, 65% poly(D,L-lactide), and 5% polyethylene glycol or about 20% therapeutic agent, 55% poly(D,L-lactide), 10% poly(DL-lactide-co-glycolide), and 5% polyethylene glycol.
>
> *****
>
> **[0027]** *Described-herein are intracameral implants including at least one therapeutic agent.* The implants described herein are placed in the anterior chamber of an eye, but are not anchored to the ocular tissue. Rather, the implants are held in place by currents and gravity present in the anterior chamber of the eye. The implants are preferably polymeric, biodegradable and provide sustained release of at least one therapeutic agent to both the trabecular meshwork (TM) and associated ocular tissues,

and the fluids within the anterior chamber of the implanted eye.

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[0031] *Described herein are intracameral sustained release therapeutic agent implants that provide continuous release of the therapeutic agent thereby avoiding the peak and trough therapeutic .agent levels that occur in the aqueous humor with topical dosing.* The steady state drug concentrations achieved in the aqueous humor with the implants described herein can significantly lower the IOP fluctuation during the day and night unlike conventional topical administration of drugs.

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[0039] *The implants described herein* are made of polymeric materials to provide maximal approximation of the implant to the iridocorneal angle. In addition, the size of the implant.' which ranges from a diameter, width or cross-section of about 0.1 mm to about 1 mm, and lengths from about 0.1 mm to about 6 mm, enables the implant to be inserted into the anterior chamber using an applicator with a small gauge needle ranging from about 22G to about 30G."

(v) All details of the implants were disclosed in the complete specifications filed with the original claims. Reliance was specifically placed, for this purpose, on paras [0027], [0028], [0046], [0047] and [0054] which may be thus reproduced:

"[0027] Described-herein are intracameral implants including at least one therapeutic agent. The implants described herein are placed in the anterior chamber of an eye, but are not anchored to the ocular tissue. Rather, the implants are held in place by currents and gravity present in the anterior chamber of the eye. The implants are preferably polymeric, biodegradable and provide sustained release of at least one therapeutic agent to both the trabecular meshwork (TM) and associated ocular tissues, and the fluids within the anterior chamber of the implanted eye.

[0028] Direct intracameral or anterior intravitreal administration of sustained release implants or therapeutic agent delivery systems, as set forth herein, are effective in treating an array of ocular conditions outlined herein. On

such condition is glaucoma characterized by elevated intraocular pressure which can be treated as described herein by bypassing the robust scleral drug clearance mechanisms (e.g. topical drops).

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[0046] In one embodiment, an intracameral implant according to the present description has a formulation of 30% therapeutic agent, 45% R203S poly(D,L-lactide), 20% R202H poly(D,L-lactide) and 5% PEG 3350. In another embodiment, the formulation is 20% therapeutic agent, 45% R203S poly(D,L-lactide), 10% R202H poly(D,L-lactide), 20% RG752S poly(DL-lactide-co-glycolide), and 5% PEG 3350. The range of concentrations of the constituents that can be used are about 5% to about 40% therapeutic agent, about 10% to about 60% R203S, about 5% to about 20% R202H, about 5% to about 40% RG752S, and O to about 15% PEG 3350. Specific polymers may be omitted, and other types added, to adjust the therapeutic agent release rates. The polymers used are commercially available

[0047] The polymers used to form the implant have independent properties associated with them that when combined provide the properties needed for sustained release of at least one therapeutic agent once implanted. For example, R203S poly(D,L-lactide) has an inherent viscosity, or mean viscosity, of about 0.25 to about 0.35 dl/g whereas R202H poly(O,L-lactide) has a lower inherent viscosity of about 0.16 to about 0.24 dl/g. As such, the polymer compositions described herein can have a mixture of higher and lower molecular weight poly(D,L-lactide). Likewise, RG752S poly(DL-lactide-co-glycolide) has a molar ratio of D,L- lactide:glycolide of about 73:27 to about 77:23 and an inherent viscosity of about 0.16 to about 0.24 dl/g. The polyethylene glycol used herein can have a molecular weight for example of about 3,000 to about 3,500 g/mol, preferably about 3,350 g/mol. Polymers having different inherent viscosities and/or molecular weights can be combined to arrive at a polymeric composition appropriate for sustained release of a particular therapeutic agent or agents.

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[0054] The therapeutic agents that can be used with the implants described herein are prostaglandins, prostaglandin analogues, and prostamides. Examples include prostaglandin receptor agonists including prostaglandin E, (alprostadil), prostaglandin E2 (dinoprostone), latanoprost and travoprost. Latanoprost and travoprost are prostaglandin prodrugs (i.e. 1-isopropyl esters of a

prostaglandin):however, they are referred to as prostaglandins because they act on the prostaglandin F receptor, after being hydrolyzed to the 1-carboxylic acid. A prostamide (also called a prostaglandin-ethanolamide) is a prostaglandin analogue, which is pharmacologically unique from a prostaglandin (i.e. because prostamides - act on a 01fferent cell receptor [the prostamide receptor] than do prostaglandins), and is a neutral lipid formed a as product of cyclo-oxygenase-2 ("COX-2") enzyme oxygenation of an endocannabinoid (such as anandamide). Additionally, prostamides do not hydrolyze in situ to the 1-carboxylic acid. Examples of prostamides are bimatoprost (the synthetically made ethyl amide of 17-phenyl prostaglandin F2a) and prostamide F20. Other prostaglandin analogues that can be used as therapeutic agents include, but are not limited to, unoprostone, and EP2/EP 4 receptor agonists."

The manner in which the specifics of the implants stood disclosed in these paras of the complete specifications, as explained by Mr Ankush Verma, may be depicted thus, in a tabular fashion:

Amen-ded Claim No.	**Amended Claim**	**Para No. of Com-plete Specifica-tions wherein Amended Claim disclosed**	**Relevant text of complete specification**
1	An intracameral implant comprising: (i) 5-40% of a therapeutic agent; (ii) 10-60% of a poly-(D,L lactide) with an inherent viscosity of 0,25-0,35 dl/g (iii) 5-20% wt of a poly-D,L lactide) with	[0046]	"The range of concentrations of the constituents that can be used are *about 5% to about 40% therapeutic agent*[5], 45% R203S poly (D,L-lactide), 10% R202H poly (D,L-lactide), 20% RG752S poly (DL-lactide-co-glycolide) and 5% PEG 3350. The range

[5] Disclosing feature (i) of amended Claim 1

	an inherent viscosity of 0,16-0,24 dl/g (iv) 5-40% wt of a poly-(DL-lactide-co-glycolide) which has a molar ratio of D,L glycolide:lactide of 73:27 to 77:23 and an inherent viscosity of 0,16-0,24 dl/g; and (v) 0-15% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol	[0047]	of concentrations that can be used are about 5% to about 40% therapeutic agent, about *10% to about 60% R203S*[6], about *5% to about 20% R202H*[7], about *5% to about 40% RG 752S*[8], and *0 to about 15% PEG 3350*[9].” “… For example, *R203S poly (D,L-lactide) has an inherent viscosity, or mean viscosity, of about 0.25 to about 0.35 dl/g*[10] whereas *R202 poly (D,L-lactide) has a lower inherent viscosity of about 0.16 to about 0.24 dl/g*[11]. … Likewise, *RG752S poly (DL-lactide-co-glycolide) has a molar ratio of D,L-lactide:glycolide of about 73:27 to about 77:23 and an inherent viscosity of about 0.16 to about to about 0.24 dl/g*[12]. *The polyethylene glycol used herein can have a molecular weight for example of about 3,000 to 3,500 g/mol, preferably about 3,350 g/mol*[13].
2	An intracameral implant as claimed in claim 1,	[0046]	“In another embodiment, *the*

[6] Disclosing feature (ii) of amended Claim 1 (with Footnote 9)
[7] Disclosing feature (iii) of amended Claim 1 (with Footnote 10)
[8] Disclosing feature (iv) of amended Claim 1 (with Footnote 11)
[9] Disclosing feature (v) of amended Claim 1 (with Footnote 12)
[10] Disclosing feature (ii) of amended Claim 1 (with Footnote 5)
[11] Disclosing feature (iii) of amended Claim 1 (with Footnote 6)
[12] Disclosing feature (iv) of amended Claim 1 (with Footnote 7)
[13] Disclosing feature (v) of amended Claim 1 (with Footnote 8)

	comprising: (i) 20% wt of a therapeutic agent; (ii) 45% wt of a poly-(D,L lactide) with an inherent viscosity of 0,25-0,35 dl/g; (iii) 10% wt of a poly-(D,L lactide) with an inherent viscosity of 0,16-0,24 dl/g; (iv) 20% wt of a poly-(DL-lactide-co-glycolide) which has a molar ratio of D,L glycolide:lactide of 73:27 to 77:23 and an inherent viscosity of 0,16-0,24 dl/g; and (v) 5% wt of a polyethylene glycol having a molecular weight of 3,000-3,500 g/mol.		*formulation is 20% therapeutic agent, 45% R203S poly (E,L-lactide), 10% R202H poly (D,L-lactide), 20% RG752S poly (DL-lactide-co-glycoside) and 5% PEG 3350.*[14]*"*
3	An intracameral implant as claimed in any preceding claim, wherein the therapeutic agent is a prostamide.	[0054]	"*The therapeutic agents that can be used with the implants described herein are* prostaglandins, prostaglandin analogues, *and prostamides.*"
4	An intracameral implant as claimed in any preceding claim, wherein the prostamide is bimatoprost.	[0054]	"… Examples of prostamides are bimatoprost (the synthetically made ethyl amide of 17-phenyl prostaglandin $F_{2\alpha}$) and prostamide $F_{2\alpha}$."
5	The intracameral implant as claimed in claims 1 to 4	[0027]	"Described herein are intracameral implants

[14] Disclosing amended Claim 2

	as and when used in the treatment of an ocular condition by implanting said implants into the anterior chamber of the eye.		including at least one therapeutic agent. *The implants described herein are placed in the anterior chamber of an eye,* but are not anchored to the ocular tissue."
		[0028]	"*Direct intracameral or anterior intravitreal administration of sustained release implants or therapeutic agent delivery systems*, as set forth herein, are effective in treating an array of ocular conditions outlined herein."

Thus, all details and particulars of the implants, as claimed in the amended claims, were fully disclosed in the complete specifications accompanying the original claims. The only difference was, in his submission that the original claims were for the method of using the said implants, whereas the amended claims were for the implants themselves. It could not, therefore, in his submission, be said that the amendments were claiming any claims which were beyond the scope of the claims as originally applied for.

22. A reading of the above table discloses, that indeed, the implants forming subject matter of the methods for which the claims had originally been filed, with all their peculiarities and characteristics, were indeed disclosed in the complete specifications accompanying the original claims. This is apparent from the tabular statement in para

21 *supra*. By way of example, amended Claim 1(ii) claimed "10-60% wt of a poly-(D,L lactide) with an inherent viscosity of 0.25-0.35 dl/g". This amended Claim stood fully disclosed in the complete specifications of the original claims as filed, as

(i) Para [0046] of the complete specifications accompanying the original claims (which remained unchanged in the amended claims) disclosed the intracameral implant having a formulation of "10% to about 60% R203S", and

(ii) Para [0047] disclosed that "R203S poly (D,L-lactide) has an inherent viscosity, or mean viscosity, of about 0.25 to about 0.35 dl/g".

As the above table shows, this position is replicated in respect every one of the amended Claims. Each claim stands fully disclosed in the complete specifications accompanying the unamended claims.

23. Mr. Harish Vaidyanathan does not, fairly, dispute this factual position.

24. Mr. Vaidyanathan's contention is, however, that the amendments sought by the appellant did not, thereby, become allowable under Section 59(1). For this purpose, he reverts to the last part of Section 59(1), which reads "… the effect of which would be that *the specifications as amended* would claim or describe matter not in substance disclosed or shown in the specifications before the amendment, or that *any claim of the specification as amended* would not fall wholly within the scope of a claim of the specification before the amendment". Thus, submits Mr Vaidyanathan, this concluding part of Section 59(1) envisages two types of amendments. The first was the amendment of the complete specification and the second was

the amendment of the claims themselves. Insofar as the amendment of complete specifications are concerned, Mr. Vaidyanathan's contention is that Section 59(1) proscribed allowing of such amendment of the complete specifications in the original application, where the amended complete specification claimed or described matter not is substance disclosed or shown in the pre-amended complete specifications. The scope of allowability of amendments *of claims*, however, he submits, is more restricted. Section 59(1) proscribes amendment of claims where the amended claim did not fall wholly *within the scope of the pre-amended claim*.

25. Mr. Vaidyanathan's contention is, therefore, that, while examining the permissibility of an amendment which sought to amend the claims as originally applied for, the authority, or the Court, would have to examine the amended claims *vis-à-vis* the original claims. The complete specifications accompanying the original claims, he submits, is entirely immaterial in such consideration. The complete specifications accompanying the original claims would be relevant only if the amendment sought were of the complete specifications. Where the amendment sought is of the claims, all that has to be seen, he submits, is whether the amendment would be within the scope of the original claim. The amendment cannot be allowed merely because the amended claims are within the scope of the pre-amended complete specifications (except, possibly, where the amendment was by way of a correction of the claim).

26. Mr Vaidyanathan contends, therefore, that the concluding part of Section 59(1) allows amendment of the claim/claims, in the patent application, if the amended claims are within the scope of the

unamended claims, and allows amendment of the specifications if the amended specifications are disclosed or shown in the unamended specifications. The provision does not, therefore, allow the patent application to amend the claims as originally filed if the amended claims are not within the scope of the pre-amended claims, even if they are disclosed in the complete specifications. The plea of Mr Verma that the amended claims stand disclosed in the complete specifications and that, therefore, the amendments should be allowed to be incorporated is, therefore, according to Mr Vaidyanathan, contrary to the scheme of Section 59(1).

27. In this context, Mr. Vaidyanathan has placed reliance on Section 10 of the Patents Act, titled "Contents of Specifications". He has particularly drawn attention to Section 10(4)(c)[15], and submits that the provision, which sets out the requirements of a complete specification in a patent application, envisages the ending of the complete specifications with the actual claim or claims defining the scope of the invention. As such, he submits that the claim or claims are only a part of, and cannot be equated with, the complete specifications. Resort to the pre-amended complete specifications, to examine whether amendment sought *to a claim* should, or should not, be allowed, therefore, he submits, is completely impermissible as it would conflate the claim and the specifications, which is directly in the teeth of Section 10(4) of the Patents Act.

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[15] **10. Contents of specifications**. –

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(4) Every complete specification shall –

(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) end with a claim or claims defining the scope of the invention for which protection is claimed.

(d) be accompanied by an abstract to provide technical information on the invention:

28. Mr. Vaidyanthan has also placed reliance, in this context, on the judgment of a Co-ordinate Bench of this Court in ***Nippon A and L Inc v. Controller of Patents***[16], particularly on para 40 thereof, which reads thus:

> "40. A perusal of Section 59(1) shows that an amendment of an application, specification or any document related thereto would be permissible only if the following conditions are satisfied:
>
> (i) the amendment has to be by way of disclaimer, correction or explanation;
>
> and
>
> (ii) the amendment has to be for the purpose of incorporation of actual facts;
>
> and
>
> (iii)(a) the effect of the amendment ought not be to amend the specification to claim or describe any matter which was not disclosed in substance or shown in the originally filed specification;
>
> and
>
> (iii)(b) the amended claims have to fall within the scope of claims as originally filed."

29. Having heard learned Counsel for both sides and applied my mind to the rival contentions advanced at the Bar, I have to observe that the submissions of Mr. Vaidyanathan, seen purely and strictly in the light of the statutory provisions, are attractive. However, any interpretation of Section 59(1) along the lines suggested by Mr Vaidynathan would, in my mind, result in creating an artificial distinction between the claims in a patent and the complete specifications that accompany it, and would also discriminate between

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[16] **2022 SCC OnLine Del 1909**

applications for amendment of claims and applications for amendment of specifications, according them treatment which is completely different, which would militate against the very ethos and philosophy of the Patents Act.

30. Literal construction with faithful adherence to the plain words of the statute is, after the decisions in ***Shailesh Dhairyawan v. Mohan Balkrishna Lulla***[17], ***Richa Mishra v. State of Chhatisgarh***[18] and, most recently, ***X v. Principal Secretary, Health & Family Welfare Department, GNCTD***[19], no longer the golden rule of interpretation, having given way to the principle of purposive interpretation. This would be especially so in the case of statues dealing with intellectual property, the main aim and object of which is preservation of intellectual property rights. Avowedly, as held in ***Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries***[20], "the object of patent law is to encourage scientific research, new technology and industrial progress".

31. Fostering of inventiveness is, therefore, the very *raison d'etre* of patent law, to which end any meaningful interpretation of the provisions of the Patents Act must aspire. Placing unduly restricted, pedantic, or hypertechnical interpretations on provisions of the Patents Act, in a manner which would discourage inventiveness and entrepreneurship would, therefore, be counter-productive to its purpose. It would be completely impermissible, therefore, for the provisions of the Patents Act to be so interpreted as to render a possibly inventive invention non-patentable.

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[17] **(2016) 3 SCC 619**
[18] **(2016) 4 SCC 179**
[19] **AIR 2022 SC 4917**

32. If the interpretation which the learned Controller has placed on Section 59, and which is, to an extent, also espoused by Mr. Vaidyanathan, is to be accepted, the result would be that the appellant would be foreclosed from seeking a patent in respect of the implants which, according to it, are a result of the appellant's own inventiveness and which are intended to cure a wide variety of ocular ailments. In such circumstances, the Court is also required to keep in mind public interest, being one of the cardinal aims of patent law, especially where the patent is pharmaceutical or therapeutic in nature.

33. Section 59 disallows amendment of an application for a patent or the complete specification therein, where the amended claim "would not fall wholly within the scope of a claim of the specification before the amendment". In the present case, the original 20 claims of the appellant were for various methods of using the intraocular implants of various compositions and constitutions, claimed to have been invented by the appellant, for treating a wide variety of ocular ailments. As Mr. Verma pointed out, as many as 60 of the 97 paragraphs of the disclosure in the complete specifications in the patent application submitted by the appellant dealt with the implants themselves, their composition and constitution. Of the remaining 37 paragraphs, 15 paragraphs dealt with the method of treatment, 16 paragraphs dealt both with the nature of implants and the method of treatment and 6 were neutral/formal paragraphs. A large part of the complete specifications in the subject patent, therefore, dealt with the implants themselves, and their peculiar compositional constitution.

[20] **(1979) 2 SCC 511**

34. The 20 claims for which the patent application was originally submitted sought patenting of the method for using the aforesaid implants in treating ocular ailments. As method/process claims cannot be patented in Indian law by virtue of Section 3(i) of the Patents Act, the appellant sought to amend the claims seeking, instead, to patent the implants themselves, being the inventions for the application of which the original method/process patent claim had been filed. This Court is not presently concerned with whether the implants were, in fact, inventions within the meaning of Section 2(j)[21] of the Patents Act or, whether, in their creation *vis-à-vis* prior art, any inventive step within the meaning of Section 2(ja)[22] was, or was not, involved. It would be for the learned Controller, while examining the patentability of the said amended claims, to examine whether they satisfy all the pre-requisites of patentability as envisaged by the Patents Act.

35. The question which is before this Court, for the present, is whether the appellant should be completely foreclosed from seeking a patent in respect of the said implants merely because the original application, as filed by the appellant, sought a patent not for the implants but for the method in which the implants were to be used, whereas the amended claims seek patents for the implants themselves, rather than the method of their usage, *even if all details of the implants, and every particular of the amended claims stand completely disclosed in the complete specifications accompanying the original claims*.

36. Any such view, in my considered opinion, would be completely

[21] (j) "invention" means a new product or process involving an inventive step and capable of industrial application;

[22] (ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a

contrary to the very ethos of the Patents Act, as well as the most elementary principles of patent claim construction. ***Bishwanath Prasad Radhey Shyam***[19] spoke thus, on patent claim construction, *vis-à-vis* the complete specifications:

> **"43.** As pointed out in ***Arnold v. Bradbury***[23] the proper way to construe a specification is not to read the claims first and then see what the full description of the invention is, but *first to read the description of the invention, in order that the mind may be prepared for what it is, that the invention is to be claimed*, for the patentee cannot claim more than he desires to patent. In ***Parkinson v. Simon***[24] Lord Esher, M.R. enumerated that as far as possible the claims must be so construed as to give an effective meaning to each of them, but *the specification and the claims must be looked at and construed together*.
>
> **44.** The learned trial Judge precisely followed this method of construction. He first construed and considered the description of the invention in the provisional and complete specifications and then dealt with each of the claims, individually. *Thereafter, he considered the claims and specifications as a whole*, in the light of the evidence on record."
>
> (Emphasis supplied)

The principle was enunciated, with even greater precision, in the judgement of the Division Bench of this Court authored by S. Ravindra Bhat, J. (as he then was), in the following passage from ***Merck Sharp & Dohme Corporation v. Glenmark Pharmaceuticals***[25]:

> "48. At this juncture, the Court notes that: -
>
> *"the construction of claims is not something that can be considered in isolation from the rest of the specification, Claims are intended to be pithy delineations of the scope of monopoly, and they are drafted in light of the much more detailed text of the description. A specification must be read as a whole, just as any document is. It must moreover be read as having been addressed to a person acquainted*

person skilled in the art;

[23] **(1871) 6 Ch A 706**

[24] **(1894) 11 RPC 483**

[25] **(2015) 63 PTC 257 (Del-DB)**

> *with the technology in question. So it must take account of that person's state of knowledge at the time."*
>
> (*see,* Cornish, Llewelyn and Aplin, Intellectual Property, Seventh Ed, Sweet and Maxwell, pages 182-3)."
>
> (Italics in original; underscoring supplied)

37. Dichotomizing the claims and the accompanying specifications is, therefore, contrary to the most fundamental canons of patent law. That, however, is precisely what the Court would be lending its imprimatur to, were it to accept the interpretation that Mr Vaidyanathan seeks to place on Section 59(1).

38. This is not a case in which there is a wide divergence between the claims for which the patent had originally been sought, and the claims as amended subsequently. The amended claims were in respect of the very same implants for the method of use of which the original claims have been filed. Every detail of the implants, as contained in the amended claims, was in fact disclosed in the original claims as filed. This is apparent from the tabular statement in para 22 *supra*. In fact, the complete specifications, holistically read, clearly indicate that the appellant was effectively claiming both the implants as well as their method of use as its inventions.

39. The question is, therefore, whether, in such circumstances, this Court should uphold the decision of the learned Controller to throw out, at the very threshold, the application of the appellant, on the ground that the amended claims were not within the scope of the originally filed claims.

40. A hyper-technical view, in that regard, in my opinion, would not be justified, given the philosophy behind the Patents Act. If,

indeed, the implants are inventive, the appellant, as the claimed inventor, ought to be given a chance to have the implants patented. If, however, the learned Controller finds, on examination, that the implants are not inventive or stand otherwise disentitled to a patent under the Patents Act for any reason whatsoever, the appellant's application would naturally stand disallowed. The application cannot, however, be thrown out without examination at the very threshold.

41. Referring back to Section 59(1), what the Section proscribes is permitting of an amendment of the claim where the amended claim would not *fall wholly* within *the scope of the pre-amended claim*. Interestingly, even this last part of Section 59(1) uses two expressions. It states that "no amendment of a complete specification shall be allowed, the effect of which would be … that any *claim* of the specification as amended would not fall wholly within the *scope of a claim* of the specification before the amendment." What the Section compares, therefore, is the *amended claim* with the *scope of the pre-amended claim*. Where the amended claim does not fall within the scope of the pre-amended claim, the amendment would not be allowed.

42. The exact ambit of the scope of a claim in a patent has been the subject of judicial decisions, to which I have already adverted. As I have already noted, the claims and complete specifications in a patent have to be read together and as a whole. The claims have to be understood in the light of the complete specifications. They form an integrated whole, and cannot be treated as two distinct parts of one document. The claim by itself, and *de hors* the complete specifications which accompany it, cannot convey, to the Court, the exact scope of

the claim.

43. The very use of the expression "scope of a claim" in the concluding part of Section 59(1) would, therefore, in my considered opinion and keeping in mind the avowed purpose of the Patents Act, require taking into consideration the complete specifications of the pre-amended claim, and not merely a textually cabined reading of the pre-amended claims themselves, *de hors* the complete specifications.

44. While, therefore, examining whether the amended claim falls wholly within the scope of the specification in the pre-amended claim, therefore, the Court, in my opinion, cannot eschew, from consideration, the complete specifications in the pre-amended claim.

45. Particularly in a case such as this, in which the pre-amended claim was for the method of using certain implants for treating ocular ailments, *and* all details of the said implants were forthcoming in the complete specifications in the pre-amended claims, *and* the amendment was only to substitute the method of using the implants with the implants themselves, it would be a travesty, in my opinion, to shut out the appellant from seeking a patent in respect of the implants merely on the ground that the amendment was not permissible under Section 59(1).

46. The view that I have taken also harmonises with paras 53 to 55 of the decision of the Co-ordinate Bench in ***Nippon***[15], which reads thus:

> "54. The import of these paragraphs of the Ayyangar Committee Report has been considered by the IPAB in ***Tony Mon George v. v. Controller General of Patents, Designs & Trademarks***[26] *supra* and it has held that *the Report favours wider scope of amendment*

[26] **2020 SCC OnLine IPAB 988**

before acceptance to that after acceptance. The IPAB concluded that if the amended claims define any "new" features, hitherto not defined in the body of the claims, then they should not be allowed but if they are clarificatory or disclaim earlier claimed features, they can be allowed. The relevant observation of the IPAB is as under:

> "36. Keeping in view the settled principles of law, on amendments of the claims, we agree that no new claim may be allowed. But the whole question is whether the claim inserted in 'new'. Does it define any 'new' feature(s) hitherto not defined in the body of the claims? If the answer is 'yes', then such claims are not allowed to be inserted. We refer to the body of the claims as originally filed, and amended subsequently, in both these sets the claim relating to 'a composition comprising an isolated antibody or antigen-binding fragment thereof …' are present. The dependent claims inserted to qualify the features already covered in the principal claims and having sufficient basis in the description cannot be held to be 'new'. Therefore, we allow the amended set of claims by the appellant except Claim 5. We also allow Claim 8 for reasons explained in earlier paragraphs."

55. A perusal of the paragraphs of the Ayyangar Committee Report clearly shows that the purport and intention of this Report *was to give broader and wider permissibility for amendment of claims and specification prior to the grant and restrict the same post of the grant and advertisement thereof*. The Report is also categorical in its observation that the invention before and after amendment need not be identical in case of amendment before acceptance "*so long as the invention is comprehended with the matter disclosed*".

56. When this standard, as contemplated by the Ayyangar Committee Report, is applied to Section 59 of the Act as it stands today, it becomes clear that *amendments to a patent specification or claims prior to grant ought to be construed more liberally rather than narrowly*. The purport and spirit of Article 123 of the European Patent Convention is not too different. In effect, the legislative material and the statutory provisions require that nothing new should be permitted to be inserted in the specification or claims. *So long as the invention is disclosed in the specification and the claims are being restricted to the disclosures already made in the specification, the amendment ought not be rejected, especially, at the stage of examination prior to grant*."

(Emphasis supplied)

47. The amendment that was sought in the present case was at a pre-grant stage. As such, in the facts of the present case, where the

amendment merely sought patenting of claims relating to the very same implants, for the method of use of which the claims had originally been filed, I am of the opinion that the learned Controller ought to have allowed the amendments which the appellant sought, and to have examined the claims as so amended, and their patentability, on merits, and should not have shut out the appellant merely on the somewhat tenuous ground that the appellant was not entitled to amend its claims in view of Section 59(1) of the Patents Act.

Conclusion

48. For the aforesaid reasons, the impugned order dated 30th March 2020, passed by the learned Controller, is quashed and set aside. The prayer, of the appellant, for permission to amend its claims, as advanced before the learned Controller, stands allowed. The amended claims of the appellant (as set out in para 3 *supra*) are remanded to the learned Controller for consideration of their patentability afresh, keeping in mind the Patents Act and all principles applicable in relation thereto.

49. The decision would be taken by the learned Controller in keeping with the principles of natural justice and following due procedure in that regard as also after grant of an opportunity of hearing to the appellant.

50. It is clarified that the present judgement is restricted to the aspect of permissibility of the amendments which were sought by the appellant in the original claims. This Court has not expressed any view on the patentability of the amended claims. The learned

Controller would examine the patentability of the amended claims uninfluenced by any of the observations contained in this judgment.

51. The appeal stands allowed in the aforesaid terms with no order as to costs.

C.HARI SHANKAR, J

JANUARY 20, 2023
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