2024:DHC:7217

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

Reserved on: August 13, 2024
% Pronounced on: September 20, 2024

\+ **C.A.(COMM.IPD-PAT) 403/2022**

BIOTYX MEDICAL (SHENZHEN) CO. LTD .....Appellant
Through: Ms. Julien George, Mr. Amitavo Mitra, Ms. Shruti Jain and Mr. Ayush Saxena, Advs.

Versus

THE ASSISTANT CONTROLLER OF PATENTS AND DESIGNS .....Respondent
Through: Mr. Harish Vaidyanathan Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Alexander Mathai Paikaday and Mr. Krishnan V., Advocates.

CORAM:
HON'BLE MR. JUSTICE SAURABH BANERJEE

J U D G M E N T

1. This judgment addresses the issue of refusal of the Indian Patent Application No.201817029244 titled "ABSORBABLE IRON-BASED ALLOY IMPLANTABLE MEDICAL DEVICE" [hereinafter '***subject application***'] filed as a national phase entry of PCT application on 3rd August, 2018 with a priority date of 8th January, 2016, which involves an absorbable iron-based alloy implanted medical device. The subject application has been refused by the Assistant Controller of Patents and

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Designs [hereinafter '***controller***'] under *Section 15* of the Patent Act, 1970 [hereinafter '***the Act***'] by the impugned order dated 10th July, 2020.

2. The subject application details an absorbable iron-based alloy implantable medical device, which includes an iron-based alloy substrate, a degradable polymer coating, and a zinc-containing protector arranged on the surface of the Iron-based alloy substrate. The zinc-containing protector is selected from Zinc and/ or a Zinc alloy, or a mixture of Zinc and/or a zinc alloy and a degradable binder. The weight percentage of the Zinc and/or zinc alloy in the mixture is greater than or equal to 20% and less than 100%. The zinc-containing protector is capable of delaying the corrosion of the iron-based alloy substrate during the early stage of implantation, such that the iron-based alloy substrate essentially avoids corrosion during the early stage of implantation and the clinical mechanical property requirements for the device in the early stage of implantation can be satisfied.

3. Though the Hearing Notice issued by the controller dated 11th November, 2019 had objections qua novelty (prior claiming) and inventive step under *Section 2(1)(j)* of the Act and the subject matter eligibility objections under *Section(s) 3(d)* and *3(f)* of the Act, *however*, vide the impugned order the subject application was rejected.

4. Now, the moot question before this Court concerns the grounds of objection under *Sections 2(1)(j), 13(1)(b) and (ja)* of the Act. For this, the prior art(s) cited by the controller supporting the objections are reproduced as under:-

D1: 201817020284 (prior claiming, priority date 18/11/2015)

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D2: WO 2008/034031 A2 20/03/2008
D3: WO 2015/062546 A1 07/05/2015
D4: Haiyan Chen et al.: "Microstructure, corrosion properties and biocompatibility of calcium zinc phosphate coating on pure iron for biomedical application," MATERIALS SCIENCE AND ENGINEERING C., vol. 34, 01st January 2014 (2014-01-01), pages 201-206, XP055609252, CH ISSN: 0928-4931, DOl: 10.1016/j.msec.2013.09.010
D5: SATHIYANARAYANAN SETAL: "Inhibition of iron corrosion in 0.5M sulphuric acid by metal cations", APPLIED SURFACE SCIENCE, ELSEVIER, AMSTERDAM, NL, vol. 252, no. 23, 30th September 2006 (2006-09-30), pages 8107-8112, XP024893713, ISSN: 0169-4332, DOl: 10.1 016/J.APSUSC.2005.1 0.028 [retrieved on 2006-09-30]

5. Based on the submissions made by the learned counsel for appellant as also the learned CGSC and on a perusal of the pleadings alongwith the document on record, given herein below are the broad contents of the impugned order for rejecting the subject application of the appellant and the contentions raised by the parties as under:-

Novelty u/*Sections 2(1)(j) and 13(1)(b)* of the Act:

5.1. According to the controller, Claims 1 to 13 of the subject application have been prior claimed in the prior art document D1 and lack novelty under *Section 2(1)(j)*[1] of the Act along with under *Section 13(1)(b)*[2] of the Act.

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[1] "***invention***" means a new product or process involving an inventive step and capable of industrial application;

[2] *(1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining* ***whether the invention so far as claimed in any claim of the complete specification-***

(a) xxx xxx

(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a

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5.2. *However*, as per the learned counsel for appellant Claim 1 of the prior art document D1 is distinct from Zinc/ Zinc alloy claimed in the subject application as also the impugned order has failed to elucidate how or why zinc/ zinc alloy protective layer of the present invention is equivalent (*physically and functionally*) to Zinc Hydroxide or Zinc Oxide.

5.3. *Per contra*, learned CGSC for the respondent submitted that since the subject matter of Claim 1 and its dependent Claims 2 to 12 are anticipated by Claims 1 to 13 of the prior art document D1, there is a lack of novelty under *Sections 2(1)(j) and 13(1)(b)* of the Act.

5.4. To determine the issue of novelty and to check whether the claims of the subject application has been claimed in any claim of D1, the inevitable step is to first and foremost claim comparison of the prior art document D1 with the subject application, for which the relevant extract thereof is reproduced as under:-

Claims of D1	**Claims of the subject application**
1. An absorbable iron-based alloy implanted medical device, comprising an iron-based alloy substrate and a degradable polymer disposed on the surface of the iron-based alloy substrate, *wherein the absorbable iron-based alloy implanted medical device further comprises an alkaline protector disposed on the surface of the iron-*	1. An absorbable iron-based implanted medical device, comprising: an iron-based substrate (11) and a degradable polymer (13) disposed on the surface of the iron-based substrate, *further comprising a zinc-containing protector (12) disposed on the surface of the*

specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

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based alloy substrate. 2. xxx xxx 3. xxx xxx 4. The absorbable iron-based alloy implanted medical device according to claim 1, wherein the alkaline protector comprises at least one alkaline substance; and the alkaline substance is selected from the group consisting of sodium hydroxide, potassium hydroxide, magnesium hydroxide, *zinc hydroxide*, magnesium oxide, *zinc oxide*, sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, calcium carbonate, sodium phosphate, sodium hydrogen phosphate, potassium phosphate, potassium hydrogen phosphate, calcium phosphate, calcium hydrogen phosphate, sodium pyrophosphate, trisodium monohydrogen diphosphate, potassium pyrophosphate, tripotassium monohydrogen diphosphate, calcium pyrophosphate, calcium hydrogen diphosphate, sodium polyphosphate, potassium polyphosphate, calcium polyphosphate, ammonium polyphosphate, hydroxyapatite, carbonated hydroxyapatite, sodium borate, potassium borate, calcium borate, sodium oxalate, potassium oxalate, calcium oxalate, trisodium citrate, sodium dihydrogen citrate, tripotassium citrate, potassium	*iron-based substrate (11), wherein the zinc-containing protector (12) is Zinc and/or a zinc alloy, or a mixture of the Zinc and/or the zinc alloy* and a degradable adhesive; and in the mixture, the weight percentage of the Zinc and/or zinc alloy is in the range of 20 percent to 100 percent.

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dihydrogen citrate, calcium citrate, calcium hydrogen citrate, sodium tartrate, potassium tartrate, calcium tartrate, ethylene diamine tetraacetic acid tetrasodium, ethylene diamine tetraacetic acid tetrapotassium, ethylene diamine tetraacetic acid calcium, sodium ethoxide, potassium ethoxide, calcium ethoxide, urea and hexamine.	

5.5. A thorough analysis of the Claims of the prior art document D1 with that of the subject application to find whether both of the claims overlap and result in prior claiming reveals that the Claims of the prior art document D1 describe a medical device with an iron-based alloy substrate and various types of alkaline protectors (including Zinc Oxide or Zinc Hydroxide) and degradable polymers whereas the claims of the subject application cover a similar device with a zinc-containing protector (Zinc and/ or a Zinc alloy, or a mixture of Zinc and/or Zinc alloy) instead of an alkaline protector.

5.6. Therefore, it is clear that the prior art claims focus on alkaline protectors (Zinc Oxide/ Zinc Hydroxide), while the subject application claims a zinc-containing protector (Zinc and/or a Zinc alloy, or a mixture of Zinc and/ or the Zinc alloy). With this difference in the type of protector (Zinc vs Alkaline) and the additional configurations or features introduced in the claims of the subject application, it appears that the subject application does not overlap with the prior art claims.

6. As such, since it would not fall under the purview of *Section 13(1)(b)*

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of the Act, the controller has erred in recognising the differences between the Claims of the prior art document D1 and the claims of the subject application, which resulted in the wrong conclusion.

Inventive step under *Section 2(1)(ja) of the Act*:

7.1. As per controller, Claims 1 to 13 of the subject application lack inventive step under *Section 2(1)(ja)*[3] of the Act, in light of the prior art documents D2 to D5.

7.2. The closest prior art D2 discloses an iron stent comprising a coating of polyester comprising particles of Zinc Oxide dispersed in the polyester matrix, and Zinc Oxide particles can be present closer to the metallic surface, and antioxidant is present to reduce the rate of corrosion and the antioxidant is present in an amount of up to 50% of the coating. The polymeric coating comprises a drug (Claims 1 to 16, figures, description). Further, the prior art document D2 discloses an endoprosthesis coated with an antioxidant which can reduce (e.g., inhibit) erosion (e.g., corrosion) and can allow for control of biodegradation of metallic endoprosthesis materials and also discloses the possibility of applying the corrosion inhibitor in different manners in order to modulate the corrosion.

7.3. Qua the prior art document D3, even though it is silent about the presence of Zinc in an absorbable iron-based alloy stent, it discloses an absorbable iron-based alloy stent comprising an iron-based alloy substrate and a degradable polyester in contact with the surface of the substrate.

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[3] "***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 person skilled in the art;

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7.4. It is also well known in the prior art that Zinc ions can be used to inhibit iron corrosion (prior art documents D4 and D5). Hence, based on the combined teaching of the prior art documents D2 to D5 and referring to ***Sankalp Rehabilitation Trust v Hoffman La Roche***[4] the controller had decided that the subject application to be within the capacity of a Person Skilled in the Art [hereinafter '***PSITA***'] who is willing to make trial and error experiments based on prior art teachings. The relevant extract from the impugned order entailing the aforesaid IPAB order is reproduced as under:-

> *"When there is a design need or market pressure to solve a problem and (there) are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense...." The aforementioned IPAB order concludes that non–obviousness "demands that the claimed invention be sufficiently removed from the prior art", and that non-obvious enquiry is "a more aggressive sentry."*

7.5. Learned counsel for appellant, attacking each of the prior arts independently submitted that the prior art documents D2 to D5 cited by the controller in the impugned order were irrelevant to the subject application. In any event, the impugned order has failed to provide reason or rationale as to how the teachings of the cited prior art documents D2 to D5 can be combined to provide a clearly identifiable and actionable roadmap to motivate a PSITA to reliably arrive at the present invention. Accordingly, a PSITA of the field of the present invention, being presented with the prior art documents D2 to D5 either alone or in any combination thereof, will not be able in any manner

[4] OA/8/2009/PT/CH Order 250 of 2012 dated 02/11/2012

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to reach the present invention, there is no motivation, teaching, or suggestion to arrive at the present invention from the cited prior art. Without appreciating the above, the controller has wrongly proceeded to reject a novel and inventive invention.

7.6. *Per contra*, the CGSC representing the respondent defending the impugned order, submitted that the reasons for refusal qua inventive step under *Section 2(1)(ja)* of the Act have been provided sufficiently in the impugned order, and that too after considering the written hearing submission of the appellant and disclosure of the prior art D2 to D5 and the subject application.

8. Regarding the issue of inventive step in the subject application, it is a known fact that this issue has been highly disputed since/ throughout the evolution of patent law and various steps/ tests have been formulated for the inventive step assessment by Court/s, one such being by the Hon'ble Supreme Court in ***Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries Ltd.***[5] wherein the relevance of the patentability standard-inventive step was identified and based thereon, it has directed to analyse the same strictly and objectively by keeping the level of the PSITA at a higher level.

9. Hon'ble Division Bench of this Court in ***Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd. 2015***[6] then laid down the *five-step test* as under:-

> *Step 1: Identify a person skilled in the art (PSITA).*
> *Step 2: Determine the inventive concept embodied in the patent.*
> *Step 3: Attribute to a skilled but unimaginative person what*

[5] (1979) 2 SCC 511
[6] DHC:9674-DB

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was common general knowledge in the art at the priority date.
Step 4: Identify the differences between the prior art and the alleged invention to ascertain whether these differences are merely ordinary applications of law or entail various complex steps involving both theoretical and practical applications.
Step 5: Assess whether these differences, viewed in the context of the known invention constituted steps that would have been obvious to the skilled person while avoiding a hindsight approach.

10. Needless to say, what was held in both the aforesaid decisions, ***Biswanath Prasad Radhey Shyam (supra)*** as also in ***Hoffmann-La Roche Ltd (supra)***, have also been followed and reiterated by various Court/s across India.

11. *Additionally,* there are multiple inventive assessment tests prevailing internationally, one of which is the *problem-solution approach* adopted/ followed by the European Patent Office [hereinafter '***EPO***'] and the other one being the test formulated in the ***Graham v. John Deere Co.***[7] in the United States Patent and Trademark Office [hereinafter '***USPTO***'], which are compatible with the legislative intentions of each jurisdiction. The issue qua inventive step or obviousness assessment tests prevailing in other jurisdictions have been discussed by this Court in ***Avery Dennison Corporation vs. Controller of Patents and Designs***[8].

12. In India, the Manual of Patent Office Practice and Procedure, 2019 reiterates the *five-step test* promulgated by the Hon'ble Division Bench of

[7] 383 U.S. 1 (1966)
[8] 2022/DHC/004697

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this Court in ***Hoffmann-La Roche Ltd. & Anr. (supra)***.

13. What, thence has to be seen is whether the controller in the impugned order has proceeded to, in fact, correctly analysed the *five-step test* though without referring to that and if so, it can be said to be sufficient and in accordance with what is prescribed by law.

14. In the considered opinion of this Court, the linkage between the said *five-step test* and the impugned order are as under:-

Step 1: Identify a person skilled in the art (PSITA):

Though the controller has indeed referred to PSITA on more than one occasion, *however*, the basis thereof is not clear as the PSITA relevant to the subject application has not been identified in the impugned order.

Step 2: Determine the inventive concept embodied in the patent:

The controller has been able to identify the key inventive feature of the invention as the subject application of zinc based protective layer (Zinc/ Zinc alloy) in direct contact with an iron-based substrate to control corrosion, as opposed to Zinc Oxide particles in a polymer matrix in prior art document D2. The same was admitted by the appellant during the course of hearing before this Court.

Step 3: Attribute to a skilled but unimaginative person what was common general knowledge in the art at the priority date:

The controller through prior art documents D4 and D5 established that the use of Zinc ions to inhibit the corrosion of iron was part of common general knowledge before the priority date of the subject

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application in combination with prior art documents D2 and D3. This was despite that the appellant widely argued in the hearing that, the Zinc ions work differently in elemental Zinc/ Zinc alloys while showing anti-corrosion properties compared to Zinc oxide. As such, it is felt appropriate that there has to be a more detailed prior art search to check whether there were any further relevant prior art concerning elemental Zinc/ Zinc alloys.

Step 4: Identify the differences between the prior art and the alleged invention to ascertain whether these differences are merely ordinary applications of law or entail various complex steps involving both theoretical and practical applications:

The controller has distinguished the prior art documents from the subject invention with the presence of elemental Zinc/ Zinc alloy based protective layer for corrosion inhibition in the subject invention contrary to the prior arts. The same was admitted by the appellant during the course of hearing before this Court.

Step 5: Assess whether these differences, viewed in the context of the known invention constituted steps that would have been obvious to the skilled person while avoiding a hindsight approach:

The controller after referring to ***Sankalp Rehabilitation Trust (supra)***, concludes that it would be obvious to try for a PSITA to reach the subject application in light of prior art documents D2 to D5 as also that it establishes that there is no surprising technical effect exhibited by the subject application compared to prior art documents D2 to D5. However, since the same lacks detailed technical evaluation of whether

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specific configuration of elemental Zinc-based protective layer as opposed to Zinc Oxide in a polymer matrix in prior art documents, leads to an unexpected result.

15. In effect, the controller in the impugned order mainly assumes that the Zinc substitution is predictable, albeit without probing further as to whether there could be a non-obvious technical advantage in the specific configuration as given in the subject application. Taking the same into consideration, the controller has examined the inventive step in the subject application without referring to the *five-step test* promulgated by the Hon'ble Division Bench of this Court in ***Hoffmann-La Roche Ltd. & Anr. (supra)*** as above.

16. In view of the aforesaid, it would be judicious for this Court to conclude that the impugned order actually lacks a proper methodology and insufficient scientific reasoning as it gives a scattered analysis. All this raises a concern/ doubt over the very genesis thereof. More so, since the (impugned) order of the controller has to be clearly a scientifically reasoned order. If not, such an impugned order will be in violation of ***Manohar v. State of Maharashtra & Ors.***[9] which, reiterating the settled position of law qua the relevance for *principle of natural justice*, has held that application of mind and recording of reasoned decision are the basic elements of natural justice. Thus, the impugned order herein required a more detailed and reasoned analysis of the inventive step by the controller, especially, while the

[9] AIR 2013 SC 681

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subject application was being rejected for the same reasons under *Section 2(1)(ja)* of the Act.

17. Consequently, since the impugned order lacks sufficient scientific reasoning and clarity regarding the inventive step of the invention under *Section 2(1)(ja) of* the Act as also since the controller has erred in adjudicating the novelty of the invention under *Sections 2(1)(j)* and *13(1)(b)* of the Act, the impugned order cannot sustain in the eyes of law and is liable to be set aside.

18. Accordingly, the appeal is disposed of with the following directions:

(i) The impugned order dated 10th July, 2020 passed by the respondent is set aside and the Patent Application No.201817029244 of the appellant is restored to its original number and is remanded to the controller for limited consideration of the inventive step by applying a recognised inventive step assessment test with sufficient scientific reasoning; and

(ii) The controller shall issue a Hearing Notice clearly specifying/ analysing the inventive step as per aforesaid direction (i) hereinabove before granting a hearing(s) to the appellant; and

(iii) The controller is expected to make all endeavours for deciding the outcome thereof by rendering a final decision within a period of *four months* from the date of conclusion of the hearing(s).

19. The Registry is directed to supply a copy of this judgment to the office of the Controller General of Patents, Designs and Trademarks of India on

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email llc-ipo@gov.in for compliance of the directions in the judgment. Further, the learned CGSC shall also communicate the aforesaid directions as also forward a copy of the present order to the office of the Controller General of Patents, Designs and Trademarks of India.

SAURABH BANERJEE, J.

SEPTEMBER 20, 2024
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