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

% *Date of Decision: 19th May, 2026*

\+ C.A.(COMM.IPD-PAT) 47/2024

BIOTYX MEDICAL SHENZHEN CO., LTD .....Appellant

Through: Ms. Priyam Lizmary Cherian, Dr. Amitavo Mitra, Mr. Vivek Kumar and Mr. Saif Ansari, Advocates.

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGN .....Respondent

Through: Ms. Radhika Bishwajit Dubey, CGSC with Ms. Gurleen Kaur Waraich and Mr. Kritarth Upadhyay, Advocates with Mr. Shivam Verma, Assistant Controller.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J. (ORAL)

1. This appeal is filed on behalf of the Appellant under Section 117A of the Patents Act, 1970 ('1970 Act') challenging order dated 04.04.2024 passed by the Respondent rejecting grant of Indian Patent Application No. 201917030431 in respect of invention titled 'ABSORBABLE STENT'.

2. To the extent necessary, facts as pleaded in the appeal are that Appellant is a Chinese company providing minimally invasive medical devices for cardiovascular diseases and disorders. Appellant applied for grant of patent in relation to invention titled 'ABSORBABLE

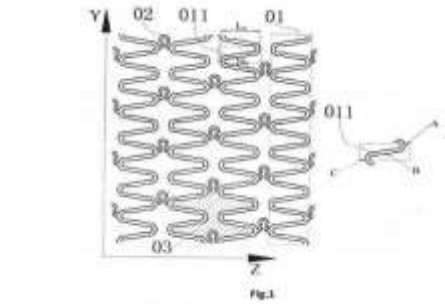
STENT' on 27.07.2019 and the bibliographic details of the patent application are as follows:-

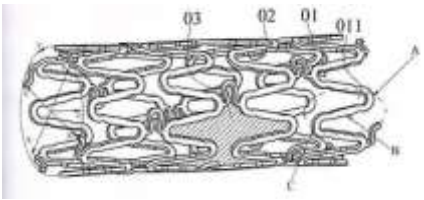
S.No.	Date	Event
1.	27.07.2019	Filing of national phase application 201917030431 titled 'Absorbable Stent'
2.	31.12.2016	Priority date of IN' 431
3.	27.07.2019	Request for examination date
4.	25.10.2019	Publication date
5.	18.03.2021	Issuance of FER date
6.	07.09.2021	Reply to FER date
7.	05.01.2024	Issuance of Hearing Notice date
8.	06.02.2024	Hearing date
9.	20.02.2024	Filing of post-hearing written submissions date
10.	04.04.2024	Refusal under Section 15

3. It is stated that Respondent has erroneously refused the application under Section 15 of the 1970 Act for lack of inventive step under Section 2(1)(ja) in light of prior arts D1 (US 9427344 B2) and D2 (US 2015/265438 Al). Relevant part of the order is as follows:-

> *"The invention presented here can be summarized as an absorbable stent, comprising: an absorbable matrix, the matrix comprising a plurality of wave-shaped rings (01) arrayed axially; two adjacent wave-shaped 5 rings (01) in the plurality of wave-shaped rings (01) are connected by a connection unit (02); each wave-shaped ring comprises a plurality of circumferentially arrayed waves (011); each wave (011) comprises a peak (A), a valley (C), and a supporting strut (B) connecting the peak (A) with the valley (C); two adjacent wave-shaped rings (01) in the plurality of wave-shaped rings (01) and the connection units (02) form a closed side*

branch unit (03); and the absorbable matrix volume per unit vascular area is [4,40] μm, wherein the matrix when expanded to a rated diameter, a section length (L) of each supporting strut is [0.4,9] mm and wherein the matrix is selected from the group consisting of magnesium-based alloy, iron-based alloy, and zinc-based alloy."





The cited documents D1: US9427344B2 and D2: US2015265438A1 describes similar stent devices.

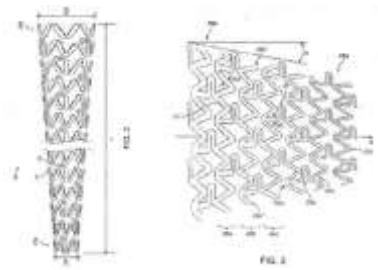
D1 discloses a tube or cylindrical shaped bioabsorbable stent made of polymer.

The applicant in his written submission states that the matrix of the stent of D1 will not be able to provide a balance between corrosion cycle and mechanical strength, let alone arrive at matrix volume per unit vascular area being in the range of 4-40μm, and section length of the supporting struts (B) being in the range of 0.4-9mm. Superior radial support strength, binding performance, and side branch passing performance will not be realized basis the teachings of D1. The Applicant also submits that the matrix features of the stent of D1 is entirely different than that of the present invention.

D2 discloses a stent device made comprising: frustum scaffold made from

a polymer, the frustum comprising: a network of rings interconnected by links, wherein a ring is formed by struts connected at crowns to form a zig-zag or undulating pattern of struts about a bore axis of the frustum, and wherein a link connects a ring to an adjacent ring at either a Y crown or a W crown.

It describes the similar scaffold structure as the claimed invention i.e. plurality of wave shaped rings in form of zig-zag comprising a plurality of circumferentially arrayed waves; each wave having a peak and valley and connected by a curved strut or a linking structure.



The applicant in his written submission states that the Learned Controller has identified D2 as the "closest" prior in view of the matrix of D2 which looks similar to that of the present invention. However, the Applicant submits that "mere similarity" in appearance is insufficient for a person skilled in the art to arrive at the present invention basis D2 for at least the following reasons.

> *I. Scaffold of D2 is made from a "'polymer" (see claim 1) and is not based on a metal. Therefore, for this reason alone, the corrosion and mechanical properties of such polymeric materials will be entirely different, and not comparable to that of the present invention.*
>
> *However D2 does mention usage of PLLA-co-PCL blended with PEO or PVP as scaffold material in claim 22, the description also discloses usage of bioerodible metals inkling metal alloys as magnesium, iron, zinc alloys (see paragraph 204), further the inventive feature of the current application lies in the specific design of the structure and not the material used. The current application provides little information regarding the material aspect and usage of general biodegradable metal alloys, polymers and ceramics are very well known in the art and are obvious to a person skilled in the art unless a new sort of material is claimed.*
>
> *II. There is no teaching or hint in D2 about any relationship between "matrix volume per unit vascular area" and "section length of supporting struts (B)", which could form a basis for balancing the requirements of shorter corrosion cycle and enhanced mechanical properties to meet clinical requirements.*

The matrix volume per unit vascular area and strut lengths are general principles of vascular stent designs and are fairly known in the art, the applicant has merely disclosing a dimension and mechanical property of the proposed device, these calculations are regularly used in designing stents and do not correspond to an inventive feature and therefore even if the cited art does not discloses the specific mechanical and structural values it is obvious to a person skilled in the art since all the vascular stents are of the similar dimensions and unless the inventive feature resides in these calculations , these mere values are non-inventive.

III. The scaffold of D2 has varying mechanical properties over its length, such as varying stiffness, porosity, and elastic modulus. As evident from representative Fig. 1 below, the strut and link widths change linearly from the distal to proximal ends. The varying thickness is also apparent from Fig. 4A and Fig. 4B below.

The scaffold as mentioned in D2 is in shape of a frustum and therefore the properties vary along its length unlike the proposed device in the current application which is in a cylindrical shape, however it is obvious to a person skilled in the art that if D2 disclosed a cylindrical shape instead of a frustum shaped stent then its properties would be same as the proposed device of the current application. Furthermore D2 does disclose the same structure of the scaffold matrix as the claimed invention which is also the inventive feature of the current application.

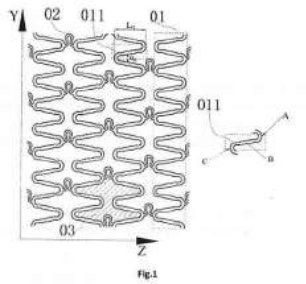
Thus there is enough motivation for a person skilled in the art to combine the teachings of D1 (tubular/cylindrical biodegradable vascular stent) and D2 (biodegradable stent of metal alloy with same matrix design) to arrive at the subject matter of the current application.

Therefore claims 1-15 of the current application do not satisfy the requirements of novelty and inventive step under section 2(1)(ja) of the Indian Patent Act 1970 (as amended).

5. After duly considering all documents on record, it was found that objections pertaining to section 2(1)(ja) of the Indian Patent Act, 1970 (as amended) still outstanding. In view of the above analysis and pending objections communicated in the hearing, the undersigned is satisfied that the patent application filed under the pursuance thereof does not comply with the requirements of the Patent Act. I, therefore conclude and hereby order that the grant of a patent for application no. 201917030431 is ***refused*** *under the provision of Section 15 of the Indian Patent Act 1970 (as amended).”*

4. Learned counsel for the Appellant submits that the claimed invention

relates to technical field of interventional medical devices, more particularly, an absorbable stent (Figure-1) having a relatively short corrosion and absorption cycle, while at the same time providing enhanced radial supporting strength to meet clinical applications and hence, claimed invention provides a solution to limitations of prolonged corrosion and absorption cycle of absorbable stents of the prior arts. The invention provides an absorbable stent comprising an absorbable matrix, which comprises multiple turns of wave-shaped rings (01) connected by connection units (02) and arrayed axially. Each wave-shaped ring includes multiple circumferentially arrayed waves (011) and includes a peak (A), a valley (C) and a supporting strut (B) connecting the peak with the valley. Two adjacent wave-shaped rings and the connection units form a closed side branch unit (03). Figure-1 is as follows:-



5. It is submitted that the inventive step of the present invention lies in the structural arrangement of the matrix of the stent for improved radial strength along with greater section length for supporting strut (B) and an open loop design which is favourable for better side branch capacity. Advantageously, as shown in embodiments 1-14 of the complete specification of the present invention, when the section length of the supporting struts (B) is in the range of 0.4-9 mm, superior radial support strength, binding performance and side branch passing performance are

obtained. Further, the absorbable stent of the present invention is composed of magnesium/iron/zinc alloy-based material which provides low corrosion and a shorter degradation and absorption cycle. The present invention provides a desirable balance between 'smaller matrix volume per unit area' and 'greater section length of support struts (B)', which forms a basis for balancing the requirements of shorter corrosion cycle and enhanced mechanical properties to meet clinical requirements of the stent by providing a matrix which has a smaller matrix volume per unit vascular area in the range of 4 - 40µm and improved radial supporting strength along with greater section length for supporting strut and an open loop design which is favourable for better side branch capacity.

6. It is submitted that the corrosion and absorption cycle of an absorbable stent and the radial supporting force within the early stages of implantation are two important performance indexes. While a shorter corrosion and absorption cycle is desirable, however, optimizing for this feature would result in reduction in radial supporting force of the absorbable stent, which is not desired. Therefore, there is a need to balance these two indices such that the absorbable stent satisfactorily meets the clinical requirements of both the performance indices. Corrosion and absorption cycle is related to the matrix volume per unit vascular area of the stent. If the matrix volume per unit vascular area of the stent is smaller the corrosion and absorption cycle is also shorter, however, a small matrix volume per unit vascular area generally indicates low radial supporting strength. The stent of claimed invention achieves a desired balance between the two indices by identifying the relationship between 'matrix volume per unit vascular area' of the stent and 'section length of each supporting strut' of the stent matrix,

where the matrix volume per unit vascular area is in the range of 4-40µm and section length of each supporting strut is in the range of 0.4-9mm. The stent thereby achieves a desirable balance between corrosion cycle and mechanical strength.

7. It is urged that Respondent has illegally and arbitrarily refused the application which involves a very useful invention and the impugned order deserves to be set aside *inter alia* on the following grounds:-

a) It is trite that while considering an invention for lack of inventive step, Respondent had to consider three elements: (i) invention disclosed in the prior arts; (ii) invention disclosed in the application under consideration; and (iii) manner in which subject invention would be obvious to person skilled in the art. The impugned order lacks any analysis on how prior art D1 is the relevant prior art for teaching the present invention and/or how it can be combined with D2 so as to lead a person skilled in the art to the present invention without expending any intellectual merit or creativity. There is no explanation why Appellant's submissions were found insufficient when Respondent took into consideration only limited submissions. Respondent has failed to apply correct test for obviousness in determining inventive step by failing to identify common and coherent thread linking claimed invention with prior arts. Reading of prior arts as a whole without benefit of hindsight knowledge of claimed invention clearly teaches away from the invention. While mosaicking of prior arts is allowed, when refusing a patent on ground of obviousness and lacking inventive step, the common thread linking prior art to claimed

invention must be traced and identified. To come to a conclusion that claimed invention lacks inventive step, order must disclose specifically the portions of each of the prior arts, which when mosaicked together will teach, suggest or motivate a person skilled in the art to take the disclosures of the prior arts to the claimed invention. Respondent has ignored all settled principles in the instant case and order does not indicate how the prior arts cited, either individually or in combination provide the starting point and/or any teaching which could identify and arrive at the invention;

b) Prior art D1 essentially teaches use of polymer-based stents with reduced immunogenicity to reduce risk of restenosis i.e., reduction in diameter of vessel lumen (wall) after angioplasty due to formation of scar tissue. Stent of D1 is of polymer material and particularly imparts polymers with additional molecular free volume to the base polymer to encourage sufficient molecular motion to allow for re-crystallization to occur in physiological conditions. In contrast, the stent of the present invention is metal-based, which clearly teaches away. D1 is silent on matrix volume per unit vascular area and section length supporting struts and has no indication on relationship between the two to achieve a desirable balance between corrosion cycle and mechanical strength of the stent and there is nothing in the impugned order which establishes that D1 would motivate a person skilled in the art to reach the invention. Respondent has replicated submissions of the Appellant from the post-hearing submissions but has failed to

analyse them;

c) Prior art D2 discloses a frustum-shaped stent with varied mechanical properties over its length which is different from claimed cylindrical strength with uniform properties. There is not a whisper in the order which shows how according to the Respondent, person skilled in the art would be motivated to deviate from D2 to arrive at the claimed invention. Respondent's reasoning is based on hindsight analysis relying on information revealed by present invention to hypothesize that if frustum-shaped stent of D2 was cylindrical, it would necessarily have the same properties as claimed invention. An order cannot be based on hypothesis and even otherwise this conclusion is wholly incorrect and is clearly based on the erroneous classification made by the Respondent, treating the design of the frustum and the matrix of the stent in present invention as identical, whereas there is a stark difference between the two;

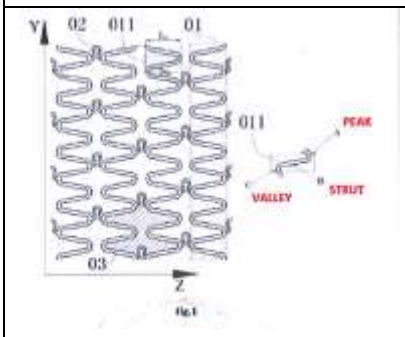
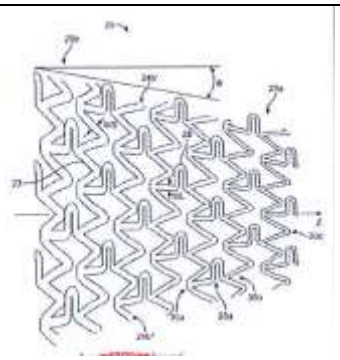
d) Respondent's conclusion that teaching of D1 combined with D2 renders the invention lacking inventive step, has its genesis in the tubular/cylindrical biodegradable vascular stent as taught by D1 without appreciating that the invention does not lie in the stent being tubular or cylindrical or that stent is made of biodegradable material. In fact, Appellant admits that tubular/cylindrical biodegradable stents are well known in the art but none of the cited prior arts relate to objective of achieving a balance between corrosion cycle while enhancing mechanical properties. Invention

of D1, even when considered as a whole is related to structural implementation of a stent and intends to solve the problem of flexibility by providing bioabsorbable stent having combination of mechanical properties, balancing elasticity, rigidity and flexibility which allow bending and crimping of the scaffold tube onto an expandable delivery system for vascular implantation and no person skilled in the art would contemplate absorbable stent of present invention from D1;

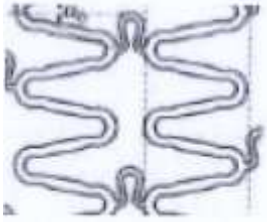
e) The reasons given by the Respondent to refuse the application are wholly incorrect. While 'matrix volume per unit vascular area' and 'strut length', are individually and separately known concepts, there is no prior art identified by Respondent, basis which one could come to the conclusion that there exists a relationship between the two such that requirements of shorter corrosion cycle and enhanced mechanical properties to meet clinical requirements of the stent, could be balanced. Respondent cannot trivialise the invention by an assertion that values are obvious to a person skilled in the art since all vascular stents are of similar dimensions. Broadly, all stents may appear similar, however, there exist many structural and other differences depending on requirements in the designs which is not even considered in the order;

f) In the written submissions, it was brought forth by the Appellant that scaffold of D2 has a shape of frustum having varying mechanical properties over its length, such as varying ring stiffness, porosity or elastic modulus. In the embodiment, the strut and link widths change linearly

from the distal to the proximal ends. These are essential features of the scaffold of D2. In contrast, the scaffold of the stent of the present invention is not shaped like a frustum and does not have varying mechanical properties over its length. There was no reason for the Respondent to believe that a stent with cylindrical shape will necessarily have properties uniform over its length let alone having properties similar to the invention. It is just as feasible that a cylindrical stent may be designed such that it has varying properties across its length. This hindsight approach is completely impermissible in determining inventive step under Section 2(1)(ja) of 1970 Act. Appellant completely refutes any assertion by the Respondent that matrix design of frustum of D2 is the same as that of the present invention and this is evident from a comparison of the matrix structure of the claimed invention and D2 as follows:-;

Present Invention	**D2**
	

g) In fact, a close look at the repeating units of the matrix of the present invention and D2 highlights the dissimilarities as follows; and

Present Invention	D2
	

h) It is well-known in patent jurisprudence that examples of drawings are only exemplary and not limiting in nature and therefore, a mere comparison of drawings without regard to the respective descriptions is an incorrect assessment, what is exactly what Respondent has done.

8. Ms. Radhika Bishwajit Dubey, learned CGSC appearing for the Respondent defends the impugned order and submits that it is a well-reasoned and speaking order and raises the following points:-

a) The claimed invention lacks inventive step inasmuch as cited prior arts D1 and D2 disclose similar stent devices. D1 discloses a tube or cylindrical shaped bioabsorbable stent made of polymer. D2 discloses a stent device made comprising: frustum scaffold made from a polymer comprising a network of rings interconnected by links, wherein a ring is formed by struts connected at crowns to form a zig-zag or undulating pattern of struts about a bore axis of the frustum wherein a link connects a ring to an adjacent ring at either the Y crown or the W crown.

D1 describes a similar scaffold structure as the claimed invention i.e., plurality of wave-shaped rings in the form of zig-zag comprising a plurality of circumferentially arrayed waves, each having a peak and valley and connected by a curved strut or linking structure;

b) Respondent correctly identified D2 as the closet prior art based on structural similarity of the matrix design and then assessed what additional features would be required to arrive at the claimed invention and found that the features were either disclosed in D1 or were obvious variations. Both D1 and D2 are linked by a common field of absorbable vascular stents and address the same technical problem. Person skilled in the art would naturally look to both D1 and D2 when designing an improved absorbable stent and there is no hindsight analysis or mosaicking;

c) D1 discloses an absorbable stent comprising an absorbable matrix with a plurality of wave-shaped rings arranged axially and connected by connection units. Each wave comprises a peak, a valley and a supporting strut. D1 further discloses that the absorbable matrix volume per unit vascular area is within the range of [4 - 40] μm and that when the matrix is expanded to a rated diameter, the section length (L) of each supporting strut is [0.4,9] mm. D1 teaches that a tubular/cylindrical biodegradable vascular stent along with D2 leads to claimed invention. The claimed inventiveness in balancing between corrosion cycle and mechanical strength is

misconceived. Matrix volume per unit vascular area and strut lengths are general design parameters in vascular stent technology and are well-established in the art.

d) D2 does mention usage of PLLA-co-PCL blended with PEO or PVP as scaffold material in claim 22 and also discloses usage of bio-erodible metals inkling metal alloys as magnesium, iron and zinc alloys. Furthermore, inventive feature of the present application lies in the specific design of the structure and not the material used and the application provides little information regarding material aspect and usage of general biodegradable metal alloys, polymers and ceramics;

e) Appellant repeatedly asserts that the scaffold disclosed in D2 exhibits varying mechanical properties along its length, thereby implying that its geometry is frustoconical rather than cylindrical. However, this contention is wholly untenable as the claims of the present application do not, at any point, incorporate or rely upon any such feature and thus, Appellant cannot import into the claimed invention characteristics that are neither claimed nor disclosed within the application itself;

f) Moreover, scaffold in D2 is in shape of a frustum and therefore the properties vary along its length unlike the proposed device in the present invention which is in a cylindrical shape. Therefore, there is enough motivation for person skilled in the art to combine teachings of D1 (tubular/cylindrical biodegradable vascular stent) and D2 (biodegradable stent of metal alloy with same matrix design) to

arrive at the claimed invention and hence, claims 1-15 do not satisfy the requirement of inventive step under Section 2(1)(ja) of 1970 Act; and

g) D1 discloses a cylindrical stent and considering that the purported inventive contribution of the present application resides in the specific matrix design of the stent, already disclosed in D2, it would be obvious to a person skilled in the art to combine the teachings of D2, disclosing the same matrix structure as claimed with those of D1, disclosing the cylindrical stent geometry and arrive at the present invention without exercising inventive skill. Respondent has meticulously examined the prior arts and the claimed invention as also the submissions made by the Appellant before reaching a conclusion that the claimed invention lacks inventive step.

9. Heard learned counsels for the parties and examined their submissions.

10. The subject application relates to invention titled ‘ABSORBABLE STENT’. To overcome the objections in FER relating to novelty and lack of inventive step, Appellant introduced limitation in characterising portion of claim reciting section length of supporting strut in the range of 0.4-9 mm. By the impugned order, Respondent has refused the application on lack of inventive step owing to prior arts D1 and D2. Appellant submits that the finding that the claimed invention lacks inventive step is completely erroneous for multiple reasons. In the field of implantable devices, particularly stent, where there is a need to limit prolonged corrosion and

absorbable cycle of the metal substrate, while at the same time enhancing the radial strength of the stent to meet clinical applications. Corrosion and absorbable cycle can be reduced by reducing the thickness of the metal substrate or using a metal which has high corrosion rate but this would negatively affect the mechanical properties of the stent. Conversely, a metal substrate of higher thickness or material which has low corrosion rate would have desirable mechanical strength but it would not corrode in a timely manner after clinical requirements are met. Present invention achieves a desirable balance between corrosion cycle and mechanical strength by providing a matrix which has a smaller matrix volume per unit vascular area in the range of 4 - 40μm and improved radial supporting strength along with greater section length for supporting strut and an open-loop design which is favorable for better side branch capacity. When the section length of the supporting struts is in the range of 0.4-9 mm, superior radial support strength, binding performance and side branch passing performance is realized.

11. It is asserted that in the present invention, the absorbable matrix includes multiple tune of wave shaped rings (01) connected by connection units (02) and arrayed axially. Each wave shaped ring includes multiple circumferentially arrayed waves (011) and includes peak (A), a valley (C) and a supporting strut (B) connecting the peak with the valley. Objective of D1 is to provide a lockable and expandable bioabsorbable scaffold having low immunogenicity, manufactured from a crystallized polymer blend and therefore the matrix of the stent of D1 will not able to provide a balance between corrosion cycle and mechanical strength, let alone arrive at matrix volume per unit vascular area being in the range of 4-40μm and section

length of the supporting struts (B) being in the range of 0.4-9 mm. Superior radial support strength, binding performance and side branch passing performance will not be realized basis the teachings of D1. This argument was brought forth before the Respondent in the written submissions by the Appellant as the record indicates. Appellant also brought forth that there was no teaching or hint in D1 of any relationship between matrix volume per unit vascular area and section length of supporting struts (B), which could form a basis for balancing the requirements of shorter corrosion cycle and enhanced mechanical properties to meet clinical requirements and that person skilled in the art basis the teachings of D1 will not find any actionable teaching or motivation to arrive at characteristic features of claimed invention. Strangely, while these submissions on D1 are taken note of, but Respondent does not deal with them in the "Reasons for decision" and proceeds to deal with submissions with respect to D2 and this, in my view, is a glaring error and violation of principles of natural justice.

12. Appellant also brought forth that D2 identified as closet prior art in view of its matrix, was not sufficient for person skilled in the art to arrive at the claimed invention only because of their similarity for two reasons: firstly, scaffold of D2 is made of polymer and not metal and hence, corrosion and mechanical properties of polymeric material will be entirely different; and secondly, D2 has no teachings on relationship between matrix volume per unit vascular area and section length, which could balance the requirement of shorter corrosion cycle and enhanced mechanical properties to meet clinical requirements. Scaffold of D2 has varying mechanical properties over its length such as stiffness, porosity and elastic modulus and person skilled in the art will find no motivation to deviate from these

structural features of the scaffold to come to present invention which is entirely different. Respondent has negated all the three grounds raised by the Appellant i.e., scaffold of D2, which is the closed prior art is made from polymer and not metal; D2 does not teach any relationship between matrix volume per unit vascular area and section length of supporting struts, which could balance requirement of shorter corrosion cycle and enhanced mechanical properties for meeting clinical requirements; and scaffold of D2 has varying mechanical properties and person skilled in the art will not be motivated to move from the structural features to the claimed invention.

13. In response to the first objection pertaining to the difference in the scaffold, Appellant has brought forth that Respondent's finding is incorrect and is based solely on para [0204] of D2, which discloses that medical devices may include bio-erodible metals or metal alloys. However, Respondent failed to appreciate that both i.e., the filed claim 1 and the granted claim 1 of D2 have an essential limitation that frustum scaffold of D2 is made from a polymer. In fact, D2 clearly teaches/motivates using polymeric material for the scaffold and nowhere elucidates that scaffold is made of metal alone or in combination with polymer. Usage of PLLA-co-PCL blended with PEO or PVP as scaffold material is an essential aspect of the scaffold of D2. A wholesome reading of D2 establishes that para [0204] is a mere generic disclosure. The fact that independent claim 1 of D2 is limited to polymer material for scaffold is sufficiently indicative as to where the invention in D2 lies and clearly, a person skilled in the art, without knowledge of present invention and only on reading D2 will find no reason to select teaching of para [0204] and disregard the fact that polymer material is an essential and preferred material for the substrate. In contrast, the matrix

material in the stent of the present invention is metal based. This point has not been dealt with in the impugned order, as rightly pointed out by the Appellant, which if considered, would have had a material bearing on the final decision. This Court in ***Agriboard International LLC v. Deputy Controller of Patents and Designs, 2022 SCC OnLine Del 940*** held that the Controller has to analyse as to what is the existing knowledge and how the person skilled in the art would move from the existing knowledge to the subject invention and when such analysis is not done, rejection of application on the ground of lack of inventive step will be contrary to Section 2(1)(ja) itself. In the judgement relied upon by the Court, the Supreme Court held that application of mind at the time of passing an order is a facet of principles of natural justice. Relevant paragraphs are as follows:-

> *"22. The Supreme Court in Assistant Commissioner v. Shukla and Brothers (supra), has categorically held that passing of a reasoned and a speaking order is an integral part of the principle of audi alteram partem. The relevant paragraph reads as under:*
>
> > *"9. The increasing institution of cases in all Courts in India and its resultant burden upon the Courts has invited attention of all concerned in the justice administration system. Despite heavy quantum of cases in Courts, in our view, it would neither be permissible nor possible to state as a principle of law, that while exercising power of judicial review on administrative action and more particularly judgment of courts in appeal before the higher Court, providing of reasons can never be dispensed with. The doctrine of audi alteram partem has three basic essentials. Firstly, a person against whom an order is required to be passed or whose rights are likely to be affected adversely must be granted an opportunity of being heard. Secondly, the concerned authority should provide a fair and transparent procedure and* ***lastly, the authority concerned must apply its mind and dispose of the matter by a reasoned or speaking order.*** *This has been uniformly applied by courts in India and abroad."*
>
> *23. The said reasoning has been reiterated by the Supreme Court in*

Manohar v. State of Maharashtra, (2012) 13 SCC 14 : AIR 2013 SC 681 wherein it has been categorically observed that application of mind and recording of reasoned decision are the basic elements of natural justice. There can be no doubt that scrupulous adherence to these principles would be required while rejecting patent applications.

24. In the opinion of this Court, while rejecting an invention for lack of inventive step, the Controller has to consider three elements-

- *the invention disclosed in the prior art,*
- *the invention disclosed in the application under consideration, and*
- *the manner in which subject invention would be obvious to a person skilled in the art.*

25. Without a discussion on these three elements, arriving at a bare conclusion that the subject invention is lacking inventive step would not be permissible, unless it is a case where the same is absolutely clear. Section 2(1)(ja) of the Act defines 'inventive step' as under:

> *(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 person skilled in the art.*

26. Thus, the Controller has to analyse as to what is the existing knowledge and how the person skilled in the art would move from the existing knowledge to the subject invention, captured in the application under consideration. Without such an analysis, the rejection of the patent application under Section 2(1)(ja) of the Act would be contrary to the provision itself. The remaining prior arts which are cited by ld. Counsel having not been considered in the impugned order, the Court does not wish to render any opinion in this regard."

14. The second ground taken by the Appellant has been negated by the Respondent holding that matrix volume per unit vascular area and strut lengths are general principles of vascular stent designs and fairly known in the art and Appellant has merely disclosed a dimension and mechanical property of the proposed device, which calculations are regularly used in designing stents and do not constitute an inventive feature. Appellant brings forth that Respondent has failed to identify any teaching of D2, which would identify these features and has also failed to bring forth any nexus between

the two to render the claimed relationship obvious. The error committed by the Respondent is that he has failed to appreciate that while matrix volume per unit vascular area and strut length may be individually and separately known concepts but there is no teaching in the prior art identified by the Respondent, basis which it can be said that there exists a relationship between the two concepts and basis which the requirement of shorter corrosion cycle and enhanced mechanical properties can be balanced. In fact, a smaller matrix volume per unit vascular area is generally indicative of shorter corrosion and absorption cycle of the stent, however, such stents have low radial supporting strength. Therefore, person skilled in the art will not look into the relationship between the two parameters to achieve the required balance. Impugned order does not even consider this crucial aspect and there is no reasoning as to why a person skilled in the art basis D2 will be motivated to pursue an unconventional course of action. Historically, Courts have elucidated fundamental principles for determining inventive step or lack thereof. Patent Office has also laid down guidelines from time to time and in order to avoid prolixity, I may allude to the judgement of this Court in ***Avery Dennison Corporation v. Controller of Patents and Designs, 2022 SCC OnLine Del 3659,*** which captures the judicial precedents on the subject and holds as follows:-

> *"**10.** In order to decide this issue, some of the fundamental principles for determining the existence of an inventive step and the lack of obviousness need to be emphasised.*
>
> ***11.** For determining inventive step or lack thereof, various approaches and tests have emerged over the years from decisions of courts/authorities as also from examination guidelines of patent offices from different jurisdictions. The same include:*
>
> *i. Obvious to try approach:*

• *This approach involves an analysis of whether in view of the teachings/solutions proposed in the prior art, it was obvious to try and arrive at the subject invention.*

ii. Problem/solution approach:

• *This approach considers whether in the light of the closest prior art and the objective technical problem, the solution claimed in the invention would be obvious to the skilled person. If the skilled person can decipher the solution being claimed, then the subject matter is held to be obvious.*

• *This test has been discussed by the Division Bench in F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2016) 65 PTC 1 (Del).*

iii. Could-Would Approach

• *In this approach the question that is raised is whether there is any teaching in the prior art as a whole that would and not simply could have prompted a skilled person, with the knowledge of the objective technical problem, to either modify or adapt the closest prior art to arrive at the subject matter of the claims.*

iv. Teaching Suggestion Motivation (TSM test)

• *This test originated in the USA as per which, if by the Teaching, Suggestion or Motivation from the prior art, an ordinary skilled person can modify the prior art reference or combine prior art references to arrive at the claimed invention, then the subject matter being claimed is obvious.*

• *However, the application of this test ought not to be done in a narrow manner as held by the US Supreme Court in the case of KSR International v. Teleflex, 550 US 398 (2007).*

12. *The above mentioned approaches to determining inventive step have been discussed and debated in various jurisdictions, including the UK, EPO, USA etc. These approaches have also been applied, even with modifications, in order to suit the facts and circumstances of each case by Courts. Some of these approaches to determine lack of obviousness also find a mention in the Guidelines for Examination published by the European Patent Office.*

13. *One of the seminal tests for determining inventive step and lack of obviousness was first laid down by the House of Lords in Windsurfing International Inc. v. Tabur Marine Ltd., [1985] RPC 59.*

14. *In Windsurfing (supra) the Court laid down a four-step test to determine whether a patent satisfied the requirement of inventive step and lack of obviousness. The said steps are as under:*

> *"1. Identifying the inventive concept embodied in the patent;*
>
> *2. Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;*
>
> *3. Identifying the differences if any between the matter cited and the alleged invention; and*
>
> *4. Deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps that would have been obvious to the skilled man or whether they required any degree of invention."*

15. *The tests laid down in Windsurfing (supra) were again considered by the England and Wales Court of Appeals in Pozzoli Spa v. BDMO SA, [2006] EWHC 1398 (Ch) and modified by Jacob LJ as under:*

> *"1. (a) Identify the notional "person skilled in the art"*
>
> *(b) Identify the relevant common general knowledge of that person;*
>
> *2. Identify the inventive concept of the claim in question or if that cannot readily done, construe it;*
>
> *3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;*
>
> *4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"*

16. *The ld. Division Bench of this Court in F. Hoffmann-La Roche Ltd. (Supra) added a further step as elaborated below:*

> *"Step No. 1 To identify an ordinary person skilled in the art,*
>
> *Step No. 2 To identify the inventive concept embodied in the patent,*
>
> *Step No. 3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.*

Step No. 4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,

Step No. 5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and ***rule out a hindside approach****"*

17. *Further, this Court in Bristol-Myers Squibb Holdings (supra) has summarised some of the principles which can be used determine whether an invention is obvious or not. The said principles are:*

"(i) ***A hindsight reconstruction by using the patent in question as a guide through the maze of prior art references in the right way so as to achieve the result of the claim in the suit, is required to be avoided.***

(ii) The patent challenger must demonstrate the selection of a lead compound based on its promising useful properties and not a hindsight driven search for structurally similar compounds.

(iii) There should be no teachings away from the patent in question in the prior art.

(iv) Mere structural similarity cannot form the basis of selection of lead compound in a prior art and the structural similarity in the prior art document must give reason or motivation to make the claim composition.

(v) Though mosaic of prior art documents may be done in order to claim obviousness, however, in doing so, the party claiming obviousness must be able to demonstrate not only the prior art exists but how the person of ordinary skill in the art would have been led to combine the relevant components from the mosaic of prior art.

(vi) It has to be borne in mind, small changes in structures can have unpredictable pharmacological effects and thus, structural similarity alone is not sufficient to motivate to selection of the lead compound.

(vii) Though ***it would be tempting to put together a combination of prior arts but this requires a significant degree of hindsight,*** *both in selection of relevant disclosures from these documents and also in disregarding the irrelevant or unhelpful teachings in them."*

18. *The above approaches, tests and steps laid down by various courts and authorities - all seek to formulate the manner in which prior arts are to be analysed and a patent application is to be tested on the anvil of inventive step. None of the above approaches and tests are to be adopted in a straightjacketed manner. Each patent application, depending on the field of technology and the nature of the prior arts may require different approaches or tests to be followed or applied. In some situations, the Court may even adopt an approach of combining more than one test as was done by the UK Supreme Court in Actavis v. ICOS, [2019] UKSC 15. In the ultimate analysis, the examiner in the patent office or the Court adjudicating the issue would need to identify the elements in the prior art and compare the same with the claims in question from the point of view of a person skilled in the art, as was done by the ld. Division Bench of this Court in 3M Innovative Properties Ltd. If the same demonstrates a technical advancement over the prior art on the priority date of the application, then the patent would be liable to be granted. Unlike the test of novelty or anticipation which is easier to determine by a straight comparison with the prior art, in the case of obviousness, the attempt of the Court is conjectural - making it a rather difficult exercise.*

19. *The decision of the UK Supreme Court in Actavis (supra) identified the ten relevant considerations to be made while assessing obviousness. The Court mentioned that the factors identified in the list are not exhaustive. The relevant considerations are:*

> *"(1) First, it is relevant to consider whether* ***something was "obvious to try" at the priority date****, in other words, whether it is* ***obvious to undertake a specific piece of research which had a reasonable or fair prospect of success*** *...;*
>
> *(2) Secondly, it* ***follows the routine nature of the research*** *and whether there is an established practice of following the research through to a particular point may be a relevant consideration which is weighed against the consideration that the claimed process or product was not obvious to try at the outset of a research programme. ...*
>
> *(3) Thirdly, the* ***burden and cost of the research programme is relevant****. But the weight to be attached to this factor will vary depending on the particular circumstances....*
>
> *(4) Fourthly, the* ***necessity for and the nature of the value judgments*** *which the* ***skilled team would have in the course of a testing programme*** *are relevant considerations ....*
>
> *(5) Fifthly, the* ***existence of alternative or multiple paths of research will often be an indicator that the invention contained in the claim***

or claims was not obvious. *If the notional skilled person is faced with only one avenue of research, a "one way street", it is more likely that the result of his or her research is obvious than if he or she were faced with a multiplicity of different avenues. But it is necessary to bear in mind the possibility that more than one avenue of research may be obvious ...*

(6) Sixthly, the ***motive of the skilled person is a relevant consideration***. *The notional skilled person is not assumed to undertake technical trials for the sake of doing so but rather because he or she has some end in mind. It is not sufficient that a skilled person could undertake a particular trial; one may wish to ask whether in the circumstances he or she would be motivated to do so. The* ***absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult*** *...*

(7) Seventhly, the fact that the ***results of research which the inventor actually carried out are unexpected or surprising is a relevant consideration*** *as it may point to an inventive step ...*

(8) Eighthly, the courts have repeatedly emphasised that ***one must not use hindsight***, *which includes knowledge of the invention, in addressing the statutory question of obviousness. That is expressly stated in the fourth of the Windsurfing/Pozzoli questions ...*

(9) Ninthly, it is necessary to consider whether a feature of a claimed invention is ***an added benefit in a context in which the claimed innovation is obvious for another purpose*** *..."*

15. The same view was taken in ***Gogoro Inc v. Controller of Patents and Designs and Another, 2022 SCC OnLine Del 2577,*** as follows:-

*"**8.** This Court in the case of Agriboard International LLC. v. Deputy Controller of Patents & Designs [C.A.(COMM. IPD-PAT) 4/2022 dated 31st March, 2022] has held that while rejecting an application for lack of inventive step, discussion on prior art, the subject invention and manner in which the subject invention would be obvious to a person skilled in the art is mandatory. Merely arriving at a bare conclusion that the subject invention lacks inventive step would be contrary to Section 2(1)(ja) of the Act itself. The relevant portion of the judgment reads as under:*

24. In the opinion of this Court, while rejecting an invention for lack of inventive step, the Controller has to consider three elements-

- *the invention disclosed in the prior art,*
- *the invention disclosed in the application under consideration, and*

> *• the manner in which subject invention would be obvious to a person skilled in the art.*
>
> *25. Without a discussion on these three elements, arriving at a bare conclusion that the subject invention is lacking inventive step would not be permissible, unless it is a case where the same is absolutely clear. Section 2(1)(ja) of the Act defines 'inventive step' as under:*
>
> *(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 person skilled in the art.*
>
> *26.* ***Thus, the Controller has to analyse as to what is the existing knowledge and how the person skilled in the art would move from the existing knowledge to the subject invention, captured in the application under consideration. Without such an analysis, the rejection of the patent application under Section 2(1)(ja) of the Act would be contrary to the provision itself.*** *The remaining prior arts which are cited by ld. Counsel having not been considered in the impugned order, the Court does not wish to render any opinion in this regard.*
>
> ***9.*** *In view of the above judgment, completely unreasoned nature of the impugned order passed by the ld. Asst. Controller and the fact that there is no discussion as to why the application is being held to be lacking inventive step in view of the prior arts D1, D2 and D3, the impugned order is liable to be set aside and the application is restored to its original position."*

16. None of the aforestated principles have been followed by the Respondent. On the third aspect of varying mechanical properties of scaffold of D2, Respondent has held that the scaffold in D2 is in shape of a frustum and properties vary along its length unlike the proposed device in the claimed invention which has a cylindrical shape. Nonetheless, it will be obvious to a person skilled in the art that if D2 disclosed a cylindrical shape, then its properties will be the same as the proposed device. This according to the Appellant is a completely misconceived finding and rightly so, as the approach is completely hypothetical. In its zeal to build a connection with prior art D2, Respondent has conjectured into presuming that if D2 disclosed a cylindrical shape, its properties will be the same as of the proposed device

of the claimed invention. There is no reasoning to arrive at this presumptive conclusion and secondly, it was not open to the Respondent to refuse the application on mere hypothesis. Thirdly and more importantly, hypothesis is based on a hindsight approach, which is impermissible in law. Appellant submits that given the mechanical properties of frustum varying over its length, it is only an improbable mathematical possibility that a particular cross section of the frustum along its length, randomly selected without D2 would have same properties as of the claimed device and a person skilled in the art cannot have a divine foresight to identify the properties in the claimed invention in D2 basis their shapes.

17. On an overall analysis of the impugned order and the documents filed by the Appellant including response to FER and written submissions, this Court agrees with the Appellant that the application deserves to be reconsidered. The impugned order is based on hindsight analysis and more importantly, most of the crucial submissions of the Appellant have not been considered. D1, which forms large part of the impugned order does not even figure in the reasoning part. It is trite that while adjudicating an application for lack of inventive step, Respondent was required to identify the person skilled in the art and consider three elements viz., invention disclosed in the prior art, invention disclosed in the subject application and the manner in which the subject invention will be obvious to the person skilled in the art, to determine the inventive step or lack thereof. This exercise has been undertaken more in violation of law than in compliance.

18. Accordingly, impugned order dated 04.04.2024 is quashed and set aside remanding the matter back to the Respondent for considering the Indian Patent Application No. 201917030431 afresh in respect of the

objection of lack of inventive step. Needless to state that Respondent shall grant an opportunity of hearing to the Appellant and take into consideration the detailed response to FER and written submissions. The decision shall be taken with an outer limit of four months from today. It is made clear that this Court has not expressed any opinion on the merits of the case.

19. Appeal is disposed of in the aforesaid terms.

JYOTI SINGH, J.

MAY 19, 2026
S.Sharma