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

Reserved on: 20 December 2025
Pronounced on: 12 January 2026

\+ FAO(OS) (COMM) 120/2025, CM APPL. 44383/2025, CM APPL. 44386/2025 & CM APPL. 44388/2025

ZYDUS LIFESCIENCES LIMITED .....Appellant

Through: Dr. Abhishek Manu Singhvi and Mr. Dayan Krishnan, Sr Advs. with Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms Vrinda Pathak, Mr. P.S. Manjunathan, Mr Rajnish Kumar, Ms. Aakashi Lodha, Mr. Shreedhar Kale, Mr. Parth Singh, Mr. Chanan Parwani and Mr. Rishi Agrawala, Advs.

versus

E. R. SQUIBB AND SONS, LLC & ORS. .....Respondents

Through: Mr. Sandeep Sethi, Sr. Adv., Mr. Pravin Anand, Ms. Archana Shanker, Ms. Prachi Agarwal, Mr. Devinder Singh Rawat, Ms. Elisha Sinha, Mr. Manan Mondal, Mr. Krisna Gambhir, Ms. Shreya Sethi, Advs.

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR
HON'BLE MR. JUSTICE OM PRAKASH SHUKLA

JUDGMENT

% 12.01.2026

C. HARI SHANKAR, J.

A Prefatory Note summarizing the judgment in conspectus

1. This appeal throws up issues, for consideration, which are of fundamental importance, not merely as legal principles relating to the patent regime, but also vitally of public interest.

2. The impugned order restrains the appellant from manufacturing or releasing, in the market, its product ZRC 3276, which is an anti-cancer drug and is essential for treatment of a wide variety of life-threating carcinomas, on the premise that the product infringes the respondent's patent. According to the appellant, treatment, using the appellant's product, would be 70% cheaper than treatment using the respondent's patented drug 5C4.

3. The Supreme Court has, in its decisions in ***Ramnik Lal Bhutta v. State of Maharashtra***[1] and ***Raunaq International v. I.V.R. Construction Ltd***[2], held that, while considering pleas for injunction or stay, public interest is also a consideration to be borne in mind, apart from the classical *troika* of a *prima facie* case, balance of convenience and irreparable loss.

4. That said, we have no doubt about the fact that the mere fact that the injuncted product is a life saving drug is no absolute armour against injunction. Products which infringe patents of others cannot be permitted to circulate in the market. Intellectual property rights are entitled to protection.

[1] **(1997) 1 SCC 134**
[2] **(1999) 1 SCC 492**

5. This case, however, is peculiar, as *there is admittedly no mapping of the appellant's product ZRC 3276 onto the claims in the respondent's suit patent at any stage. Injunction has, therefore, been granted without any product-to-claim mapping.*

6. The impugned order seeks to justify this course of action on the ground that the suit is a *quia timet* action, instituted in anticipation of future infringement and that, therefore, as the appellant's product is not commercially available, no product-to-claim mapping is possible.

7. Rule 3(A)(ix)[3] of the High Court of Delhi Rules Governing Patent Suits, 2022[4] specifically requires product-to-claim mapping as one of the necessary ingredients of a patent infringement suit. However, the impugned judgment holds that the words "to the extent possible", in Rule 3A may, in a *quia timet* action, justify doing away with the requirement of product-to-claim mapping altogether.

8. This is of vital importance, as Section 48[5] of the Patents Act, 1970 confers, on the holder of a registered patent, the exclusive right to prevent third parties from using, offering, selling or importing *that*

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[3] **A. Plaint:**
The Plaint in an infringement action shall, to the extent possible, *inter alia*, contain a description of the following:
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(ix) Precise claims versus product (or process) chart mapping including claim chart mapping through standards;

[4] "the DHC Patent Suits Rules" hereinafter

[5] **48. Rights of patentees**.—Subject to the other provisions contained in this Act and the conditions specified in Section 47, a patent granted under this Act shall confer upon the patentee—
(*a*) where the subject-matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
(*b*) where the subject-matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:

product in India, without consent of the patentee. The issue of whether, in the absence of any mapping of the defendant's product to the plaintiff's granted claim in the suit patent, the defendant's product can be said to be *that product*, therefore, requires serious consideration. Especially so as the product is a life-saving drug needed for cancer therapy.

9. The learned Single Judge holds that, even in the absence of product-to-claim mapping, the fact that the appellant's product is in fact the product claimed in the suit patent stands *prima facie* established through other material.

10. Pared down to essentials, the suit patent claims an isolated monoclonal antibody, through two indicia, which are that (i) the antibody "*binds specifically to* human Programmed Death (PD-1)", and (ii) the antibody comprises chains consisting of amino acids in specified sequences.

11. PD-1 is a protein found in the human body, of the CD 28 family. Antibodies are also proteins. Every protein consists of amino acids in a particular unique sequences.

12. *There is no dispute that the appellant's product binds not only to PD-1, but also to other proteins of the CD 28 family*. The learned Single Judge holds that the word "specifically" does not mean "exclusively", and that binding with other proteins of the CD 28 family is not, therefore, a factor which would take the appellant's product ZRC 3276 outside the scope of the suit patent.

13. We are unable, for reasons which this judgment would disclose in detail, to agree with this finding, on facts or in law. The respondent has *itself*, while responding to pre-grant objections, explained the expression "specifically" as meaning that there should be *no statistically significant* binding with other proteins of the CD 28 family. Statistically significant binding, as per the respondent itself in the said response, is binding with a 'p' factor of less than 0.05. The 'p' binding factor of the appellant's ZRC 3276 is of the range of 0.0001. *Given the standards suggested in this regard by the respondent itself, we find that ZRC 3276, in fact, did have statistically significant binding with other CD 28 family proteins.*

14. The impugned judgment, however, does not advert to this aspect at all, despite noting the appellant's contention in that regard.

15. Impugned judgment proceeds on the basis of product-to-product mapping

15.1 In fact, submitted the appellant, the respondent's 5C4 product itself did not conform to the granted claim in the suit patent, as it, too, had a 'p' binding factor of much less than 0.05. The learned Single Judge has held that, as ZRC 3276 and 5C4 were both revealed, on testing, to bind comparably to CD 28 proteins other than PD-1, ZRC 3276 mapped onto the suit patent.

15.2 This is, to our mind, fundamentally flawed, as it would envisage a product-to-product mapping, whereas patent infringement is to be

assessed on the basis of a product-to-claim mapping. In fact, the position would be that neither ZRC 3276, nor 5C4, would actually map onto the granted claim in the suit patent.

16. On the second aspect of the claim in the suit patent, of amino-acid sequencing, the learned Single Judge observes that (i) the appellant had sought exemption from detailed drug control research on the ground that ZRC 3276 is a biosimilar of Nivolumab which was, therefore, the "reference biologic" of ZRC 3276, (ii) 5C4, which was the claimed antibody in the suit patent, had the same amino acid sequencing as in Nivolumab and (iii) biosimilars had necessarily to have the same amino acid sequencing. Once, therefore, as its biosimilar, ZRC 3276 had the same amino acid sequencing as Nivolumab, and 5C4 also had the same amino acid sequencing as Nivolumab, the corollary would be that ZRC 3276 and 5C4 have the same amino acid sequences. If a equals b, and c equals b, holds the learned Single Judge, a must necessarily equal c.

17. It is in premise (iii) of this reasoning that, to our mind, the learned Single Judge has erred. There is nothing, in the impugned judgment, to indicate, as an inflexible principle, that biosimilars have the same amino acid sequencing.

18. Apart from this "biosimilar analysis", there is nothing, in the impugned judgment, to sustain the *prima facie* finding that ZRC 3276 has the same amino acid sequences as 5C4. Indeed, there could be none, as there has never been, at any stage, mapping of the appellant's ZRC 3276 product to the respondent's granted claim in the suit patent.

19. To our mind, while precise product-to-claim mapping, as envisaged by Rule 3(A)(ix) of the DHC Patent Suit Rules may, in a given case, suffice to establish a *prima facie* case of infringement, the collateral material, on the basis of which the learned Single Judge has proceeded, in the absence of any product-to-claim mapping, raise, at the best, issues which are highly arguable, and would require expert evidence. We are, therefore, unable to satisfy ourselves that, on this material, the learned Single Judge was justified in entirely injuncting the appellant from releasing its product in the market.

20. Rather, given the fact that the product is a life saving drug needed for cancer therapy, and keeping in mind the pre-eminent consideration of public interest, we are of the opinion that the interests of justice would adequately have been subserved if the appellant were to be directed to maintain and file, with this Court, periodical accounts of the amounts earned through sale of the appellant's product, so as to secure the respondent in the event of its succeeding in the suit.

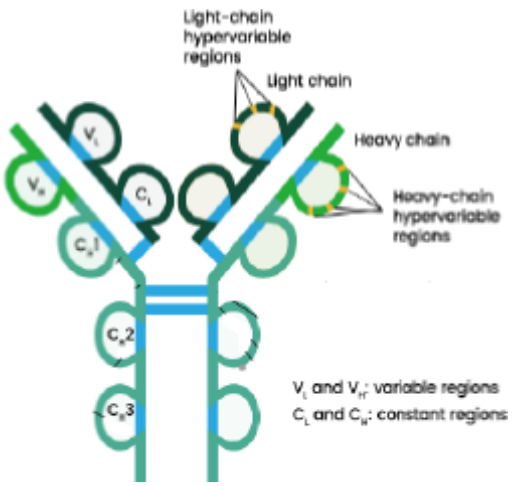
21. Besides, the suit patent expires on 2 May 2026. Thereafter, there can be no embargo on anyone marketing the patented drug. The only issue is, therefore, whether the appellant's product should be made available to the public for the next four months. Given the nature of the product, and applying the principle of balance of convenience, too, the interests of justice would require the appellant to be bound down to maintain accounts of the realizations from the sale of its product till the expiry of the suit patent, rather than depriving the ailing public of access to the product.

Facts

22. With that prefatory note, we proceed to the facts.

23. The rival products are proteins. Proteins consist of amino acid sequences. Paras 23 to 31 of the impugned judgment set out, with lucid clarity, the science of the suit patent, and we can do no better than to reproduce the said paragraphs, verbatim:

> "23. The white blood cells ("WBCs") in our blood are divided into five types, one of them being, lymphocytes. Lymphocytes are immune cells which are prepared in our bone marrow, and are found in the blood and lymph tissue. Lymphocytes further consist of B-lymphocytes (B-cells) and T-lymphocytes (T-cells).
>
> 24. B-cells are the ones responsible for producing antibodies. Antibodies are Y-shaped proteins that protect us when an unwanted foreign substance enters our body. They are produced by our immune systems to neutralise pathogens such as bacteria, virus, etc. In the event that such a pathogen enters our body, it stimulates our immune system to produce antibodies that bind with a unique molecule of the pathogen, called an antigen.
>
> 25. The 'Y'-shaped structure of an antibody contains two 'Heavy' and two 'Light' chains. The variable region in each heavy and light chain, responsible for generating antigen-binding site of the antibody, are termed Complementarity Determining Regions - CDRs, which are immunoglobulin (Ig) hypervariable domains. Thus, the CDRs are responsible for binding to the target antigen. The variable regions of both the heavy chain and the light chain have three CDRs each and these CDRs are specific to an antibody for binding to an antigen. General structure of an antibody, is represented in the following manner:



26. The antibodies present in our body are basically proteins. Proteins in turn are made up of amino acids which are small molecules that are the building blocks of proteins. There are 20 amino acids commonly found in the protein present in our body. The amino acids present in our body are represented by standard codes. The unique arrangement of amino acids is called an amino acid sequence.

27. Further, the T-cells in our WBCs are responsible for the identification and destruction of abnormal/infected cells. They have CD-28 proteins, which signal the immune system if a cell is normal or abnormal. When T-cells receive this signal, the immune system attacks the abnormal cells. One important CD-28 protein on T-cells is called Programmed Death 1, i.e., PD-1, which helps in identification of abnormal cells.

28. PD-1 has two ligands, i.e., PD-L1 (Programmed Death-Ligand 1) and PD-L2 (Programmed Death-Ligand 2). PD-L1 and PD-L2 are proteins which are located on the surface of normal cells. In a healthy human body, once PD-1 binds with either of its ligands, it essentially signals to the T-cell to tolerate those normal cells, and not attack them. Thus, engagement of PD-1 with either of its two ligands suppresses immune system responses in case of healthy normal cells.

29. However, cancer cells also have PD-L1 on their surface and have the potential to impair PD-1's ability to send signals to the T-cell. Therefore, when PD-1 on our T-cell binds to the PD-L1 ligand on a cancerous cell, it deactivates the PD-1 on the T-cell. When PD-1 is inactive, T-cells do not attack the cancer cells.

30. Thus, to prevent this binding between PD-1 and PD-L1 on a cancer cell, monoclonal antibodies have been developed in order to allow the immune system to recognise and destroy cancer cells.

> Monoclonal antibodies are man-made antibodies which are created artificially in laboratories and are designed to act like human antibodies for specific purposes. As the name suggests, they are a single kind of antibody that bind to a single target receptor/antigen or ligand.
>
> 31. The suit patent, i.e., Nivolumab, is one such monoclonal antibody, which is an anti-PD-1 antibody, also called '5C4' antibody. In other words, Nivolumab binds with the PD-1 protein on our T-cell, which prevents PD-1 from binding itself with PD-L1 ligand on a cancer cell. This ensures that our T-cells are not rendered inactive and the immune system is able to identify the cancer cell and act accordingly."

24. <u>The suit patent</u>

24.1 The respondent is the holder of Indian Patent No. IN 340060[6], titled "Human Monoclonal Antibodies to Programmed Death 1 (PD-1) for use in treating Cancer". Claims 1, 3 and 7 in the suit patent read thus:

> "1. An isolated monoclonal antibody or an antigen-binding portion thereof that binds specifically to human Programmed Death (PD-1), comprising:
>
> a) a heavy chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 18;
>
> b) a heavy chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 25;
>
> c) a heavy chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 32;
>
> d) a light chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 39;
>
> e) a light chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 46; and
>
> f) a light chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 53.

[6] "IN'060", also referred to as "the suit patent" hereinafter

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3. The monoclonal antibody or antigen-binding portion thereof, as claimed in claim 1, which comprises:

a) a heavy chain variable region comprising the amino acid sequence set forth in SEQ ID NO: 4; and

b) a light chain variable region comprising the amino acid sequence set forth in SEQ ID NO: 11.

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7. A composition comprising the monoclonal antibody or antigen-binding portion thereof as claimed in any one claims 1-6 and a pharmaceutically acceptable carrier."

24.2 Clearly, therefore, the claims in the suit patent consists of two main features; firstly, the fact that it "binds *specifically* to PD-1" and, secondly, that it consists of the specified amino acid sequences.

24.3 The antibody 5C4, or Nivolumab, is marked by the respondent outside India as Opdivo®, and in India as Opdyta®.

25. Concept of infringement in the Patents Act

25.1 The Patents Act is a peculiar statute, in the intellectual property firmament. Unlike other intellectual property statutes, it does not define "infringement", though it refers to it. Section 48, however, refers to the rights of patentees, and, for want of any other definition, one presumes that infraction of those rights amounts to infringement. Particularly so, as Section 49, which follows, sets out circumstances which *do not* amount to infringement.

25.2 In the case of a product patent, therefore, Section 48 confers, on the patentee, exclusive right to prevent third parties from making, using, offering, selling or importing *that product* in India, without consent of the patentee. "That product", obviously, refers to the product which is subject matter of the patent. It is for this reason that mapping of the product to the granted claim in the patent becomes indispensable, for it is only then that it can be said that the product in which the defendant is dealing is the product which is subject matter of the plaintiff's patent.

25.3 That said, "mapping" is not a word of art; it merely implies identification of the product in which the defendant is dealing as the product of which the plaintiff holds the patent, and nothing else. Any method by which this can be established would suffice, to constitute "mapping".

25.4 What is of the essence, however, is that the essential features of the patented claim must be found to exist in the infringing product. Minor "workshop improvisations" cannot mitigate infringement. It is for this reason that the doctrine of equivalents has been formulated. The extent to which this doctrine would apply in the case of chemical or pharmaceutical patents is, however, to our mind, seriously disputable. Ultimately, the outcome of the *lis* would turn on whether the product of the defendant is the product claimed in the plaintiff's patent.

26. <u>The impugned judgment</u>

26.1 We are restricting our observations and findings, qua the impugned judgment, to the issues on which we feel that a case for interference, even within the limited parameters of para 14 of ***Wander Ltd v. Antox India (P) Ltd***[7], is made out. On other issues, though contentions were advanced by both sides, we are of the view that any interference by us would amount to our substituting our view for the view of the learned Single Judge, which ***Wander*** does not permit.

26.2 <u>On infringement – The "biosimilar" approach</u>

26.2.1 The impugned order, admittedly, does not proceed on the basis of any mapping of the appellant's product to the Claims in the suit patent. The learned Single Judge holds that, as the suit was in the nature of a *quia timet* action, and commercial release of the appellant's product in the market had been injuncted by order dated 8 May 2024, no product, which could be mapped on to the suit patent, was available. The impugned order proceeds, therefore, on the basis of an "indirect mapping" basis, through the following steps:

(i) The amino acid sequence of the respondents' 5C4 antibody mapped onto the amino acid sequence of INN Nivolumab.

(ii) The appellant's ZRC 3276 claimed to be a biosimilar of INN Nivolumab.

[7] **1990 Supp SCC 727**

(iii) Biosimilars necessarily had to have the same amino acid sequence.

(iv) Ergo, the amino acid sequence of ZRC 3276 and 5C4 was necessarily the same.

26.2.2 There are, in our view, clear logistical difficulties in accepting this method of mapping.

26.2.3 Qua Step (i)

26.2.3.1 We may commence our analysis from step (i), i.e. the "mapping" of 5C4 onto INN Nivolumab. In this regard, Para 93 of the impugned judgment reads thus:

> "93. Further, the plaintiffs have done complete mapping of the suit patent with Nivolumab as contained in INN, which is reproduced as under:

Claims 1 and 3 of IN '060	Sequence ID	Nivolumab INN
Claim 1 1. An isolated monoclonal antibody or an antigen-binding portion thereof that binds specifically to human Programmed Death (PD-1), comprising: a) a heavy chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 18; b) a heavy chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 25; c) a heavy chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 32;	SEQ ID NO:18 as per sequence listing and read with fig 8 Asn Ser Gly Met His N S G M H SEQ ID NO:25 as per sequence listing and read with fig 8 Val Ile Trp Tyr Asp Gly Ser Lys Arg Tyr Tyr Ala Asp Ser Val Lys Gly V I W Y D G S K R Y Y A D S V K G SEQ ID NO:32 as per sequence listing and read fig 8 Asn Asp Asp Tyr N D D Y	**Heavy chain** QVQLVESGGG VVQPGRSLRL DCKASGITFS NSGMHWVRQA PGKGLEWVAV 50 IWYDGSKRYY ADSVKGRFTI SRDNSKNTLF LQMNSLRAED TAVYYCATND 100 DYWGQGTLVT VSSASTKGPS VFPLAPCSRS TSESTAALGC LVKDYFPEPV 150 TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG TKTYTCNVDH 200 KPSNTKVDKR VESKYGPPCP PCPAPEFLGG PSVFLFPPKP KDTLMISRTP 250 EVTCVVVDVS QEDPEVQFNW YVDGVEVHNA KTKPREEQFN STYRVVSVLT 300 VLHQDWLNGK EYKCKVSNKG LPSSIEKTIS KAKGQPREPQ VYTLPPSQEE 350 MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV LDSDGSFFLY 400

d) a light chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 39;

SEQ ID NO:39 as per sequence listing and read with fig 9

Arg	Ala	Ser	Gln	Ser	Val	Ser	Ser	Tyr	Leu	Ala
R	A	S	Q	S	V	S	S	Y	L	A

e) a light chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 46; and

SEQ ID NO:46 as per sequence listing and read fig 9

Asp	Ala	Ser	Asn	Arg	Ala	Thr
D	A	S	N	R	A	T

f) a light chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 53.

SEQ ID NO:53 as per sequence listing and read with fig 9

Gln	Gln	**Ser**	Ser	Asn	Trp	Pro	**Arg**	Thr
Q	Q	**S**	S	N	W	P	**R**	T

SRLTVDKSRW QEGNVFSCSV MHEALHNHYT QKSLSLSLGK 440

Light chain

EIVLTQSPAT LSLSPGERAT LSCRASQSVS SYLAWYQQKP GQAPRLLIYD 50

ASNRATGIPA RFSGSGSGTD FTLTISSLEP EDFAVYYCQQSSNWPRTFGQ 100

GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150

DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200

LSSPVTKSFN RGEC 214

Claim 3

3. The monoclonal antibody or antigen-binding portion thereof, as claimed in claim 1, which comprises:

a) a heavy chain variable region comprising the amino acid sequence set forth in SEQ ID NO: 4; and

SEQ ID NO:4 as per sequence listing

Gln	Val	Gln	Leu	Val	Glu	Ser	Gly	Gly	Gly
Q	V	Q	L	V	E	S	G	G	G

Val	Val	Gln	Pro	Gly	Arg	Ser	Leu	Arg	Leu

V	V	Q	P	G	R	S	L	R	L

Asp	Cys	Lys	Ala	Ser	Gly	Ile	Thr	Phe	Ser
D	C	**K**	A	S	G	**I**	T	F	S

Asn	Ser	Gly	Met	His	Trp	Val	Arg	Gln	Ala
N	**S**	G	M	H	W	V	R	Q	A

Pro	Gly	Lys	Gly	Leu	Glu	Trp	Val	Ala	Val
P	G	K	G	L	E	W	V	A	V

Ile	Trp	Tyr	Asp	Gly	Ser	Lys	Arg	Tyr	Tyr
I	W	Y	D	G	S	**K**	**R**	Y	Y

Ala	Asp	Ser	Val	Lys	Gly	Arg	Phe	Thr	Ile
A	D	S	V	K	G	R	F	T	I

Ser	Arg	Asp	Asn	Ser	Lys	Asn	Thr	Leu	Phe
S	R	D	N	S	K	N	T	L	**F**

Leu	Gln	Met	Asn	Ser	Leu	Arg	Ala	Glu	Asp
L	Q	M	N	S	L	R	A	E	D

Thr	Ala	Val	Tyr	Tyr	Cys	Ala	Thr	Asn	Asp

DYWGQGTLVT VSSASTKGPS VFPLAPCSRS TSESTAALGC LVKDYFPEPV 150

TVSWNSGALT SGVHTFPAVL QSSGLYSLSS VVTVPSSSLG TKTYTCNVDH 200

KPSNTKVDKR VESKYGPPCP PCPAPEFLGG PSVFLFPPKP KDTLMISRTP 250

EVTCVVVDVS QEDPEVQFNW YVDGVEVHNA KTKPREEQFN STYRVVSVLT 300

VLHQDWLNGK EYKCKVSNKG LPSSIEKTIS KAKGQPREPQ VYTLPPSQEE 350

MTKNQVSLTC LVKGFYPSDI AVEWESNGQP ENNYKTTPPV LDSDGSFFLY 400

SRLTVDKSRW QEGNVFSCSV MHEALHNHYT QKSLSLSLSLOK 440

T	A	V	Y	Y	C	A	**T**	**N**	**D**

Asp	Tyr	Trp	Gly	Gln	Gly	Thr	Leu	Val	Thr
D	Y	W	G	Q	G	T	L	V	T

Val	Ser	Ser
V	S	S

b) a light chain variable region comprising the amino acid sequence set forth in SEQ ID NO: 11.

SEQ ID NO:11 as per sequence listing and fig 9

Glu	Ile	Val	Leu	Thr	Gln	Ser	Pro	Ala	Thr
E	I	V	L	T	Q	S	P	A	T

Leu	Ser	Leu	Ser	Pro	Gly	Glu	Arg	Ala	Thr
L	S	L	S	P	G	E	R	A	T

Leu	Ser	Cys	Arg	Ala	Ser	Gln	Ser	Val	Ser
L	S	C	R	A	S	Q	S	V	S

Ser	Tyr	Leu	Ala	Trp	Tyr	Gln	Gln	Lys	Pro
S	Y	L	A	W	Y	Q	Q	K	P

Gly	Gln	Ala	Pro	Arg	Leu	Leu	Ile	Tyr	Asp
G	Q	A	P	R	L	L	I	Y	D

Light chain

EIVLTQSPAT LSLSPGERAT LSCRASQSVS SYLAWYQQKP GQAPRLLIYD 50

ASNRATGIPA RFSGSGSGTD FTLTISSLEP EDFAVYYCQQ SSNWPRTFGQ 100

GTKVEIKRTV AAPSVFIFPP SDEQLKSGTA SVVCLLNNFY PREAKVQWKV 150

DNALQSGNSQ ESVTEQDSKD STYSLSSTLT LSKADYEKHK VYACEVTHQG 200

LSSPVTKSFN RGEC 214

Ala	Ser	Asn	Arg	Ala	Thr	Gly	Ile	Pro	Ala
A	S	N	R	A	T	G	I	P	A

Arg	Phe	Ser	Gly	Ser	Gly	Ser	Gly	Thr	Asp
R	F	S	G	S	G	S	G	T	D

Phe	Thr	Leu	Thr	Ile	Ser	Ser	Leu	Glu	Pro
F	T	L	T	I	S	S	L	E	P

Glu	Asp	Phe	Ala	Val	Tyr	Tyr	Cys	Gln	Gln
E	D	F	A	V	Y	Y	C	Q	Q

Ser	Ser	Asn	Trp	Pro	**Arg**	Thr	Phe	Gly	Gln
S	S	N	W	P	**R**	T	F	G	Q

Gly	Thr	Lys	Val	Glu	Ile	Lys
G	T	K	V	E	I	K

26.2.3.2 The learned Single Judge holds that the respondents did "complete mapping" of the suit patent with Nivolumab as given in INN. Inasmuch as Nivolumab is the INN assigned name to one of the exemplified products in the suit patent itself, we fail to understand the concept of "mapping" of the suit patent onto INN Nivolumab. True, Claim 1 in the suit patent could cover a wide variety of proteins, containing the amino acid sequences indicated therein, depending on the other amino acids contained in the entire protein chain. Each, however, is an exemplified product in the suit patent, which includes Nivolumab. The claims in the suit patent were, therefore, *bound* to map onto INN Nivolumab.

26.2.3.3 In this context, before proceeding to other aspects of indirect mapping, we may reproduce paras 42 to 44 of the impugned judgment, thus:

> "42. As noted above, antibodies are proteins that protect us when an unwanted substance enters the body. All antibodies are constructed in the same way. As per the suit patent, Nivolumab is a PD-1 blocking antibody for treatment of cancer. It has specific amino acid sequences of heavy and light chains of an antibody termed as the '5C4 antibody', which contains six CDRs. Changes have been made in the amino acid sequencing, which has resulted in creation of the suit patent, Nivolumab, i.e., monoclonal anti-PD-1 antibody for treatment of cancer. Three changes have been made in the sequencing of amino acid in the heavy chain variable and three changes have been made in the sequencing of amino acid in the light chain variable, totalling to six changes.
>
> 43. The changes, as made by the plaintiffs, in the amino acid sequencing in the heavy chain variable region and light chain variable region, which is reflected in red colour, is reproduced as under:

Amino acid	Gln	Val	Gln	Leu	Val	Glu	Ser	Gly	Gly	Gly	Val	Val	Gln	Pro	Gly	Arg
Amino acid code	Q	V	Q	L	V	E	S	G	G	G	V	V	Q	P	G	R
Amino acid	Ser	Leu	Arg	Leu	Asp	Cys	Lys	Ala	Ser	Gly	Ile	Thr	Phe	Ser	Asn	Ser
Amino acid code	S	L	R	L	D	C	K	A	S	G	I	T	F	S	N	S
Amino acid	Gly	Met	His	Trp	Val	Arg	Gln	Ala	Pro	Gly	Lys	Gly	Leu	Glu	Trp	Val
Amino acid code	G	M	H	W	V	R	Q	A	P	G	K	G	L	E	W	V
Amino acid	Ala	Val	Ile	Trp	Tyr	Asp	Gly	Ser	Lys	Arg	Tyr	Tyr	Ala	Asp	Ser	Val
Amino acid code	A	V	I	W	Y	D	G	S	K	R	Y	Y	A	D	S	V
Amino acid	Lys	Gly	Arg	Phe	Thr	Ile	Ser	Arg	Asp	Asn	Ser	Lys	Asn	Thr	Leu	Phe
Amino acid code	K	G	R	F	T	I	S	R	D	N	S	K	N	T	L	F
Amino acid	Leu	Gln	Met	Asn	Ser	Leu	Arg	Ala	Glu	Asp	Thr	Ala	Val	Tyr	Tyr	Cys
Amino acid code	L	Q	M	N	S	L	R	A	E	D	T	A	V	Y	Y	C
Amino acid	Ala	Thr	Asn	Asp	Asp	Tyr	Trp	Gly	Gln	Gly	Thr	Leu	Val	Thr	Val	Ser
Amino acid code	A	T	N	D	D	Y	W	G	Q	G	T	L	V	T	V	S
Amino acid	Ser															
Amino acid code	S															

b. SEQ ID No. 11 (light chain variable region)

Amino acid	Glu	Ile	Val	Leu	Thr	Gln	Ser	Pro	Ala	Thr	Leu	Ser	Leu	Ser	Pro	Gly
Amino acid code	E	I	V	L	T	Q	S	P	A	T	L	S	L	S	P	G
Amino acid	Glu	Arg	Ala	Thr	Leu	Ser	Cys	Arg	Ala	Ser	Gln	Ser	Val	Ser	Ser	Tyr
Amino acid code	E	R	A	T	L	S	C	R	A	S	Q	S	V	S	S	Y
Amino acid	Leu	Ala	Trp	Tyr	Gln	Gln	Lys	Pro	Gly	Gln	Ala	Pro	Arg	Leu	Leu	Ile
Amino acid code	L	A	W	Y	Q	Q	K	P	G	Q	A	P	R	L	L	I
Amino acid	Tyr	Asp	Ala	Ser	Asn	Arg	Ala	Thr	Gly	Ile	Pro	Ala	Arg	Phe	Ser	Gly
Amino acid code	Y	D	A	S	N	R	A	T	G	I	P	A	R	F	S	G
Amino acid	Ser	Gly	Ser	Gly	Thr	Asp	Phe	Thr	Leu	Thr	Ile	Ser	Ser	Leu	Glu	Pro
Amino acid code	S	G	S	G	T	D	F	T	L	T	I	S	S	L	E	P
Amino acid	Glu	Asp	Phe	Ala	Val	Tyr	Tyr	Cys	Gln	Gln	Ser	Ser	Asn	Trp	Pro	Arg
Amino acid code	E	D	F	A	V	Y	Y	C	Q	Q	S	S	N	W	P	R
Amino acid	Thr	Phe	Gly	Gln	Gly	Thr	Lys	Val	Glu	Ile	Lys					
Amino acid code	T	F	G	Q	G	T	K	V	E	I	K					

44. The six separate changes in the amino acid sequencing, as done by the plaintiffs, are reproduced as under:

"27. ……

a. SEQ ID No. 18 (heavy chain CDR 1)

Amino acid	Asn	Ser	Gly	Met	His
Amino acid code	N	S	G	M	H

b. SEQ ID No. 32 (heavy chain CDR 2)

Amino acid	Val	Ile	Trp	Tyr	Asp	Gly	Ser	Lys	Arg	Tyr	Tyr	Ala	Asp	Ser	Val	Lys	Gly
Amino acid code	V	I	W	Y	D	G	S	K	R	Y	Y	A	D	S	V	K	G

c. SEQ ID No. 32 (heavy chain CDR 3)

Amino acid	Asn	Asp	Asp	Tyr
Amino acid code	N	D	D	Y

d. SEQ ID No. 39 (light chain CDR 1)

Amino Acid	Arg	Ala	Ser	Gln	Ser	Val	Ser	Ser	Tyr	Leu	Ala
Amino acid code	R	A	S	Q	S	V	S	S	Y	L	A

e. SEQ ID No. 46 (light chain CDR 2)

Amino Acid	Asp	Ala	Ser	Asn	Arg	Ala	Thr
Amino acid code	D	A	S	N	R	A	T

f. SEQ ID No. 53 (light chain CDR 3)

Amino Acid	Gln	Gln	Ser	Ser	Asn	Trp	Pro	Arg	Thr
Amino acid code	Q	Q	S	S	N	W	P	R	T

26.2.3.4 We have gone through the pleadings in detail, but find no reference to any "changes" made by the respondent in amino acid sequencing. The learned Single Judge, therefore, appears to have proceeded on the premise that the respondent had carried out changes

in the amino acid sequencing, which does not appear to be correct. Indeed, if there were in fact changes in the amino acid sequencing, there would have had to be an "unchanged" amino acid sequence. There is none.

26.2.3.5 What the respondents appear, instead, to have claimed, in the suit patent, is any isolated monoclonal antibody which has, in the various heavy chain and light chain CDRs, amino acids in the claimed sequences at any point, and which bind specifically to PD-1.

26.2.3.6 Once this is understood, the principle of "mapping" of the 5C4 antibody onto INN Nivolumab becomes meaningless, as it is no more, and no less, than mapping onto oneself. Nivolumab is, even as per the respondent, the INN nomenclature of the 5C4 antibody, containing the amino acid sequences claimed in Claims 1 (a) to (f). It is not as though there was any pre-existing INN Nivolumab onto which 5C4 mapped; indeed, had there been, the suit patent would itself become vulnerable to invalidity for lack of inventiveness.

26.2.3.7 The first step of the "indirect mapping" analysis of the learned Single Judge, therefore, really does not advance the discussion to any meaningful extent.

26.2.4 Qua step (ii)

26.2.4.1 On this, there can be no cavil, as the appellants, in fact, claimed ZRC 3276 to be a biosimilar of Nivolumab.

26.2.4.2 But what follows?

26.2.5 Qua step (iii)

26.2.5.1 The learned Single Judge, thereafter, proceeds on a premise that all biosimilars would have identical amino acid sequences. The impugned judgment, to our mind, does not support such a finding.

26.2.5.2 As this is the very basis of the "indirect mapping", following which the learned Single Judge has returned a finding of infringement, it assumes stellar importance.

26.2.5.3 The issue of whether a biosimilar product can, on that basis alone, be said to be infringing of the reference biologic, appears to us to be extremely thorny. If the impugned judgment is accepted, every biosimilar product would, on that basis alone, infringe the patent claimed by the reference biologic.

26.2.5.4 As we have already noted, the Claims in the suit patent, which are alleged to be infringed, have, as their distinguishing features, their "specific" binding to the PD-1, and the amino acid sequencing in their chains. The learned Single Judge holds that, having claimed itself to be biosimilar to INN Nivolumab, the amino acid sequences of ZRC 3276 and Nivolumab were necessarily identical.

26.2.5.5 There is, however, in the impugned judgment, no material on the basis of which such a finding could be arrived at. In para 81, the learned Single Judge has quoted the following definition of "Similar Biologic Product" in the Similar Biologic Guidelines issued by the Department of Biotechnology, Government of India:

> "A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability."

Thus, biologics are similar only in *quality, safety and efficacy*. The definition in the Similar Biologic Guidelines does not state that they have identical amino acid sequencing, or are similar in other respects.

26.2.5.6 The learned Single Judge also refers to para 6.3.2 (i) of the Similar Biologic Guidelines under the head "Product Characterization", which reads:

> "6.3.2 **Product Characterization**
>
> *****
>
> **i. Structural and Physicochemical Properties:** The analysis of physicochemical characteristic should include determination of primary and higher order structure of the drug substance and the product along with other significant physicochemical properties. The target amino acid sequence of the Similar Biologic should be confirmed and *is expected to be the same* as for the Reference Biologic. Analytical methods that are used (including Biological and functional assays) should have acceptable precision and accuracy. In cases, where post translational modifications are taking place, these modifications need to be identified and quantified. In case any significant differences are found, these should be scientifically justified and critically examined in preclinical studies and clinical trials."
>
> (Emphasis supplied)

26.2.5.7 Immediately following the reproduction of this extract, the impugned judgment observes:

> "84. Thus, in bio-similar drugs, the efficacy and amino acid sequencing, is also similar, *however, chemically, the said drugs would be different*."
>
> (Emphasis supplied)

This observation, even by itself, throws the entire reliance, by the learned Single Judge, on the "biosimilarity" between ZRC 3276 and Nivolumab, as a basis to arrive at a finding of infringement, seriously disputable.

26.2.5.8 In the first place, what is needed is not *similarity* of amino acid sequencing, but *identity*. Else, the Court would have to assess the degree of dissimilarity and hold that, despite there being dissimilarity, ZRC 3276 infringes the suit patent.

26.2.5.9 Secondly, if the amino acid sequencing is identical, it is not possible to understand how chemically the products would be different, as the impugned judgment itself holds that each amino acid sequence is unique to a particular protein.

26.2.5.10 Thirdly, if the products are chemically different, it is again highly arguable as to whether they can be said to map on to one another. Or as to whether, if Nivolumab maps on to the claims in the suit patent, ZRC 3276 can also be said to do so. In any case, once the impugned judgment that biosimilar products can be chemically different – in fact, it asserts that they *would be* chemically different –

it is impossible to understand how Section 48(1) of the Patents Act would at all apply, as it employs the expression "*that product*".

26.2.5.11 The learned Single Judge proceeds to presume that para 12 of the Note submitted by the appellant sufficed to *prima facie* establish the similarity in the amino acid sequencing of ZRC 3276 and Nivolumab. Para 12 read thus:

> "12. *The Defendant's product can certainly be called a biosimilar of "Nivolumab". A product can be called Nivolumab so long as it comprises the specific sequence of amino acids mentioned in the "WHO Drug Information" document.* However, claim 1 of the suit patent has an added limitation over and above such sequences, i.e., the product having such sequences must be isolated and bind specifically to PD-1. Defendant's product does not fulfil this additional requirement of claim 1 of the suit patent."

The learned Single Judge regards the italicized sentences in the above extracted para 12 as establishing, *prima facie*, similarity in the amino acid sequencing of Nivolumab and ZRC 3276.

26.2.5.12 There is, to our mind, no such premise, which can legitimately be drawn. Para 12, to the extent emphasized, merely states that (i) ZRC 3276 is a biosimilar of Nivolumab (which cannot be, and is not, in dispute) and (ii) a product *can be called Nivolumab* if it comprises the specific sequence of amino acids mentioned in the WHO Drug Information document. There is, therefore, no admission that the amino acid sequence in ZRC 3276 is the same as that in the suit patent.

26.2.5.13 It cannot, therefore, to our mind, be regarded, merely on the basis of the fact that the respondent had claimed its product to be biosimilar to Nivolumab, that it mapped onto the suit patent.

26.3 Extending the mapping controversy

26.3.1 We are also of the view that the impugned judgment does not entirely appreciate, or address, the issue raised by the appellants, in their written statement, on the aspect of erroneous or incomplete mapping.

26.3.2 The written statement averred, *inter alia*, as under:

> "12. The underlying suit has been filed by the Respondents alleging that the Appellant's similar biologic/biosimilar of NIVOLUMAB infringes the patent IN 340060 (IN'060). *The Respondents' case is based inter alia on the premise that NIVOLUMAB is covered in the scope of the suit patent IN 060, and that the mere fact of applying for a similar biologic of the said drug by the Appellant would amount to an admission of infringement.* The Respondents have produced a 'claim mapping' with the present suit, which allegedly maps the claims of the suit patent with the INN of Nivolumab as given by the WHO, however what has been mapped is only the 6 CDR sequences, *while the rest of the claim is ignored*. For ease of reference, the claim 1 of the suit patent is reproduced below:
>
> Claim 1:
>
> 1. An isolated monoclonal antibody or an antigen-binding portion thereof that binds specifically to human Programmed Death (PD-1), comprising:
>
> a) a heavy chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 18.
>
> b) a heavy chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 25.

c) a heavy chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 32,

d) a light chain CDR1 consisting of the amino acid sequence set forth in SEQ ID NO: 39,

e) a light chain CDR2 consisting of the amino acid sequence set forth in SEQ ID NO: 46, and

f) a light chain CDR3 consisting of the amino acid sequence set forth in SEQ ID NO: 53.

*****

15. The Appellants have argued that *the mere manufacture of a bio-similar of Nivolumab can never amount to patent infringement or an admission thereof, since the test for patent infringement is claim-to-product comparison, while the test for assessment of bio-similar is based on a product-to-product comparison*. Further there is no justification about the grounds that led the Respondents to believe that the biosimilar employed by the Appellant is the same as the suit patent, since *the suit patent is not for NIVOLUMAB but for an 'isolated monoclonal antibody that 'binds specifically to PD-1'.* In the claim mapping done by the Respondents, the 6 CDR sequences have been mapped with the INN of Nivolumab, *however, the features of 'isolated' and 'binding specifically to PD-1' have not been mapped*. This incomplete mapping is a glaring error *since the Appellant's case of noninfringement is premised on the fact that Appellant's bio-similar is not 'isolated' and 'does not bind specifically to PD-1' but also to other members of the CD-28 family.*

16. It is further relevant to note that the 'Similar Biologics' guidelines 2016 gauges 'similarity' in terms of 'safety, efficacy and quality' and makes no reference to patent infringement. In fact, the guidelines provide a caveat that they are not meant to substitute or rephrase the Drugs and Cosmetics Act, 1940 or rules thereunder. It is a settled law that there is no patent linkage in India, and therefore, the mere fact of applying for a similar biologic cannot lead to a finding of patent infringement. *The Appellant had placed on record experimental data to show that the Respondents' own product was not isolated and displayed binding to other members of the CD-28 family, thereby confirming that the Appellant's product is a bio-similar of the Respondents product, but is not infringing the claims of the suit patent."*

(emphasis supplied)

26.3.3 Following this, it was pointed out, in the written statement, that, even in the submissions made by the respondent during prosecution proceedings preceding registration of IN'060, the respondent had sought to distinguish the prior art antibodies on the ground that as the 'p'[8] value in the test antibody wells, for binding with CD 28 protein family members, was less than 0.05, it was statistically significant. The relevant paragraphs from the respondent's submissions read thus:

> "c. Dr. Madamwar's arguments do not refute conclusions regarding cross-reactivity. Rather than discussing the actual results, Dr. Madamwar focuses on the scale of absorbance as depicted in graphs of the different antibody-binding (i.e., a y-axis with a maximum value of 0.15 or 0.08) that is lower than the scale depicted for the PD-1 binding experiment (i.e., a y-axis with a maximum value of 2.0).
>
> d. But the scale of each graph is irrelevant in view of the fact that each of those experiments showed statistically significant binding by the test prior art antibodies to members of the CD28 family of proteins relative to a control antibody. The absorbance levels charted are the raw output from the assays, and the bars represent the average of three individual measurements with the standard deviation shown by the error bars. Statistical analysis of those results with the Student's T Test indicated that in each case, the value in the test antibody wells was significantly higher than the IgG isotype control ($p < 0.05$). And thus there was significant specific binding by each prior art antibody to each CD28 family member tested."

26.3.4 The appellant pointed out, in its written statement, that independent third party studies by the Sardar Patel University revealed that the 'p' value, qua binding with members of the CD 28 family other than PD-1, was less than 0.0001, which was statistically significant, both in the case of ZRC 3276 as well as in the case of 5C4. This, it was submitted, clearly indicated that ZRC 3276 did not

[8] probability

map onto the claims in the suit patent. Para 18 of the appeal memorandum reads thus:

> "18. In view of the above, the Appellant conducted experiments in-house and also engaged an independent third party, i.e. Sardar Patel University, to show that the antibody of the Appellants' bio-similar shows statistically significant binding to other members of the CD-28 family. As per the experiment reports, "p" value of the Appellants antibody was <0.0001, which is "statistically significant" by Respondents' own admission. Further, to clarify that the product of the Appellant can be a bio-similar of the Respondents' product, while falling outside the scope of the suit patent, the Appellant also conducted the same tests on the Respondents' product, which resulted in the conclusion that the Respondent's product also displayed statistically significant binding to other members of the CD-28 family. In view of the test reports, it was pleaded that since the Appellants product binds to other members of the CD-28 family, the said product is non-infringing, and is in fact following the prior art. Further, since the Respondents' product also binds to other members of the CD-28 family, the product of the Appellant and the Respondent are bio-similars."

26.3.5 This submission of the appellant is also specifically noted in para 16.3 of the impugned judgment, thus, albeit without reference to the 'p' numbers:

> "16.3 It is the plaintiffs' case that the claim scope of the suit patent is limited to only those antibodies which bind to PD-1 with no binding or statistically insignificant binding with other receptors in the CD-28 family. The defendant's product does not fulfil this limitation and thus, is not infringing the suit patent. Further, in the defendant's product there is statistically significant binding, therefore, the defendant is following the prior art."

What was taken was, therefore, a Gillette defence, pleading that antibodies with statistically insignificant binding to non-PD-1 antibodies were known in the prior art and that, therefore, ZRC 3276 merely followed prior art, and did not infringe the suit patent.

26.3.6 There is, however, no finding, in the impugned judgment, on this argument of the appellant.

26.3.7 In fact, the impugned judgment overlooks this aspect of the matter altogether, as it merely concentrates on the *higher* binding specificity of the antibodies with the PD-1 ligand, as compared to binding with other proteins of the CD-28 family. The charts on which the impugned judgment itself relies, in para 101 to 105, clearly indicate considerable binding of the antibodies with other proteins of the CD-28 family which cannot, viewed any which way, be regarded as "statistically insignificant".

26.3.8 The fact that the respondent had obtained registration of the suit patent by pleading novelty, originality, and lack of anticipation vis-à-vis prior art on the ground that there was no statistically significant binding vis-à-vis non-PD-1 proteins, and had set a 'p' value of less than 0.05 as demonstrating statistically significant binding, has been totally overlooked by the learned Single Judge. Having obtained registration of the suit patent on this representation, the respondents were bound thereby.

26.3.9 Claim 1 in the suit patent professes, as it most particular feature, "(binding) *specifically* to human PD-1". "Specifically", plainly etymologically understood, would imply exclusivity. Even if one were to regard the interpretation, by the impugned judgment, of the expression "specifically" as not being amenable to interference in appeal given the ***Wander*** principles, the understanding of the expression in the pre-grant proceedings, and the explanation tendered

by the respondent in that regard, could not have been ignored, especially as prior art patents, which also claimed anti-PD-1 antibodies, were set up against the claim of the respondent, and the respondent bypassed the challenge by adopting a stand that there was no "statistically significant" binding, in the claim in the suit patent, with non-PD-1 antibodies of the CD 28 family. Once, therefore, the litmus test to determine statistical significance had been cited, by the respondent itself, before the Registrar, as a 'p' value of less than 0.05, the *prima facie* inexorable sequitur would be that antibodies with 'p' values of 0.05 would *not map onto the claims in the suit patent.*

26.3.10 Had this aspect been addressed by the learned Single Judge, and a plausible view taken thereon, we would have had to test the amenability of the view to interference on the ***Wander*** touchstone. However, the complete want of consideration, by the learned Single Judge, of this aspect, is, to our view, fatal to the impugned order.

26.4 Impugned judgment proceeds on product-to-product mapping

26.4.1 Instead of proceeding on the basis of the admitted standard of statistical significance [of a 'p' factor being less than 0.05], the impugned judgment returns a finding of infringement *on the basis of a product-to-product mapping*, which is *ex facie* unacceptable in law as a basis to determine patent infringement. This is clear from para 106 of the judgment, which reads thus:

> 106. The aforesaid test results to determine the binding specificity of Opdivo®, the product of the plaintiffs, and ZRC-3276, the product of the defendant, clearly demonstrate that both

> Opdivo® and ZRC-3276, are anti-PD-1 antibodies, that bind with PD-1 with high specificity than the other CD-28 family receptors, and do not bind substantially with human CD-28/CTLA4 or ICOS receptors."

26.4.2 The error into which the impugned judgment is apparent from the opening sentence in the next paragraph (para 107), which reads:

> "107. Considering the aforesaid test results filed by the defendant, it is apparent that both the products, i.e., Opdivo® of the plaintiffs and ZRC-3276 of the defendant, fall within the scope of the claims of the suit patent."

In arriving at this conclusion, we are of the respectful view that the learned Single Judge erred. The highest that the test results would reveal is that the respondent's 5C4 and the appellants' ZRC 3276 *mapped onto each other* – which, too, may be disputable. They cannot, in any case, make out a case of mapping onto the suit patent, which, in fact, they do not, as the 'p' factor was less than 0.0001 in both cases.

26.5 Absence of product-to-claim mapping – The duty of the Court

26.5.1 In a case as involved as this, we are of the opinion that it would be erroneous to injunct the appellant from releasing its product in the market without any product-to-claim mapping with the suit patent. While product-to-claim mapping may not be a cast-in-iron imperative in every case, in its absence, there must be overwhelming circumstantial material to indicate that the defendant's product maps onto the suit patent. There must be, in a manner of speaking, a

continuous and unbroken chain of circumstances to that effect. There is no room for assumption and presumption.

26.5.2 This would be additionally so in a case such as the present, when the injunction that is sought is against the release, in the market, of a life giving therapeutic preparation, especially where it is to treat an ailment such as cancer. Courts owe a debt to society. Public interest is, as held in ***Ramnik Lal Bhutta*** and ***Raunaq International***, also a pre-eminent consideration while deciding whether to grant, or not to grant, an absolute interlocutory injunction.

26.5.3 Courts have to be acutely conscious of their duties in such matters. The tightrope is shaky, and walking it is not always an enviable enterprise. Our oath of office, however, obligates us to do so and, while doing so, we have to bear in mind our duty to the teeming citizenry of this country who may be in dire need of the therapy, the release of which a plaintiff seeks to injunct.

26.5.4 There is, at the same time, also a pre-eminent element of public interest in ensuring protection of valuable patents, which not be forgotten. If Courts are to swing to the other extreme, and openly allow circulation, in the market, of drugs which infringe valuable pharmaceutical patents, the incentive to invent would be altogether lost, which might result in ebbing the stream at the source. There would be no incentive to expend valuable time, energy and often cripplingly huge financial resources in inventing a new and more efficacious drug, if one is not ensured of patent protection as available in law.

26.5.5 As we said, the tightrope is shaky, and walking it often an ordeal. Perhaps, the Court can hardly ever rest content in the conviction that it has fulfilled its task appropriately, much less adequately.

26.5.6 Where, however, a clear cut case of patent infringement, within the meaning of Section 48, is made out, *on the basis of product-to-claim mapping*, and there is no credible challenge made out to the validity of the asserted suit patent, the Court has to protect the patentee from infringement. On that, to our mind, there can be no compromise.

26.5.7 Where, however, no product-to-claim mapping has been attempted, and the Court is relying on other collateral material, that material, to our mind, has to be so conclusive, even at the *prima facie* stage, as to indicate that the defendant's product is *that product* of which the plaintiff holds the patent, before its dissemination to the public can be restrained.

26.5.8 Where the issue is triable, or involves complicated technical issues which would appropriately need a trial, then, in our opinion, where the product in question is a life-saving drug, the Court has to err in favour of public interest, and ensure securing of the plaintiff's interest by alternate methods, short of making the drug unavailable to the public during the entire period for which the suit would remain pending. *Withholding* such therapy from the public can cause untold and irreparable prejudice to lakhs of lives, and it is,

therefore, only where the Court is in possession of irrefutable material to indicate that a patented product is being released in the market without permission of the patentee, in breach of Section 48, that an injunction can issue.

26.5.9 Tested on this crucible, we are of the opinion that, in the present case, the issues which have persuaded the learned Single Judge to restrain the appellant from manufacturing or releasing ZRC 3276 in the market do not make out such a clear *prima facie* case as would justify the injunction. The issues are extremely technical, and would clearly require expert technical evidence to be led before even a *prima facie* view can be taken.

26.5.10 We are additionally persuaded in the view we take as the suit patent, in any event, expires on 2 May 2026, after which the respondent cannot, in any case, injunct the appellant from releasing its product in the market.

Conclusion

27. In these circumstances, we are of the opinion that the interests of justice would be adequately subserved if the impugned judgment is modified by vacating the injunction granted by the impugned judgment and requiring the appellant, instead, to file, with the Registry of this Court and an advance copy to the respondent, audited accounts of the amounts earned by the appellant by sale of the allegedly infringing product, till the expiry of the suit patent. As a period of hardly four months remains till the suit patent expires, this

arrangement would, to our mind, protect the interests of both sides and would also ensure that the availability of the appellant's product to the public, who may be in need of it, is not restrained any further.

28. The impugned judgment stands modified accordingly.

29. The appeal is allowed to the aforesaid extent with no orders as to costs.

C. HARI SHANKAR, J.

OM PRAKASH SHUKLA, J.

JANUARY 12, 2026