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

% *Judgment delivered on: 24.12.2025*

\+ **C.A.(COMM.IPD-PAT) 390/2022**

OSAKA UNIVERSITY .....Appellant

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS .....Respondent

Advocates who appeared in this case

For the Appellant : Mr. Sanjeev Kumar Tiwari, Mr. Shatadal Ghosh and Mr. Abhishek Jan, Advocates.

For the Respondent : Mr. Sumit Nagpal, SPC.

CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA

JUDGMENT

TEJAS KARIA, J

INTRODUCTION

1. The present Appeal is filed against the order dated 29.08.2020, ("**Impugned Order**") passed by the Assistant Controller of Patents and Designs ("**Respondent / Controller**"). The Respondent *vide* the Impugned Order refused to grant the patent in respect of Patent Application No. 3495/DELNP/2012 ("**Subject Application**"). The Respondent held that the

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claims are not inventive under Section 2(1)(j) of the Patents Act, 1970 ("**Act**"), and also objectionable under Section 3(d) of the Act.

FACTUAL MATRIX

2. The Appellant filed an application being the Subject Application for grant of patent titled '*BRIDGED ARTIFICIAL NUCLEOSIDE AND NUCLEOTIDE*' on 23.04.2012.

3. The Appellant had filed voluntary amended of the claims *via* Form 13 dated 14.04.2014. A request for examination of the Subject Application was filed on 21.08.2013. The Subject Application was examined, and First Examination Report was issued on 19.02.2018 ("**FER**"). The Appellant filed a detailed response to the FER on 16.08.2018 along with amended claims.

4. The Respondent issued a notice of hearing dated 16.10.2019 ("**Hearing Notice**") maintaining certain objections raised in the FER as regards to lack of inventive step under Sections 2(1)(j) and 3(d) of the Act scheduling the hearing on 15.11.2019 ("**Hearing**").

5. At the Hearing, the representative of the Appellant led extensive oral arguments addressing each of the objections raised in the Hearing Notice and discussed any possible claim amendments to be made to address the outstanding objections raised in the Hearing Notice. The post-Hearing written submissions along with the amended set of claims were filed by the representative of the Appellant on 28.11.2019.

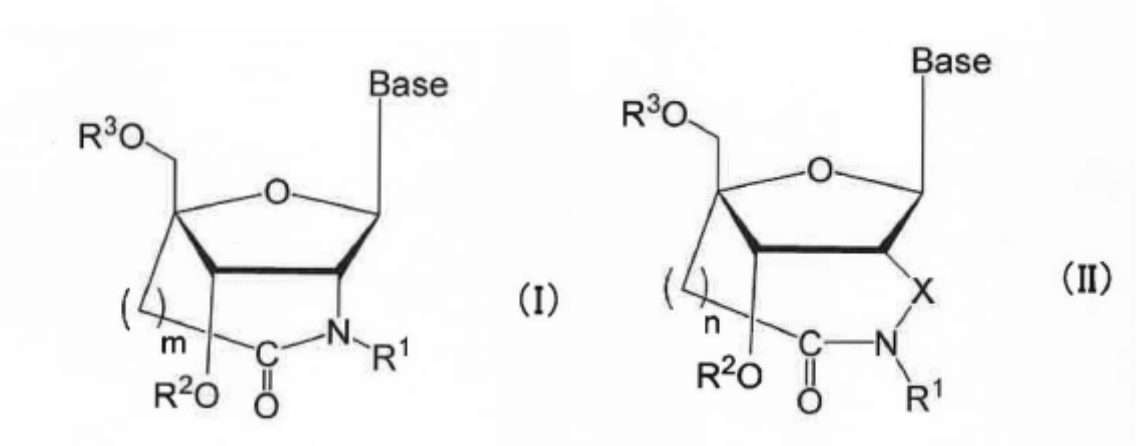
6. The Respondent passed the Impugned Order refusing the grant of patent in the Subject Application under Sections 2(1)(j) and 3(d) of the Act.

7. The present invention as contained in the Subject Application relates to novel bridged artificial nucleosides and nucleotides. More specifically, the present invention relates to the bridged artificial nucleosides and nucleotides

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having high binding affinities to single-stranded ribonucleases ("**RNA**") and high nuclease resistance. The 2',4'-bridged nucleoside analogues ("**BNA**") of the present invention may contain such a five to seven membered cyclic amide [-NR^1-C(O)-] structure between C2' and C4' positions.

8. The description of the present invention provides for the compounds represented by the following Formula I or Formula II and salts thereof:



9. The cited prior art documents are the following:

a. WO99/60855 ("**D1**") describes 2',4'-BNA which contain a six membered cyclic ether (-O-) structure between the C2' and C4' positions.

b. WO2005/021570 ("**D2**") describes 2',4'-BNA which contain a cyclic (-NR^3-0-) structure between the C2' and C4' positions as represented by Formula I above.

c. A. Yahara et al., Nucleic Acid Symposium Series, Vol. 53, pp.11-12 ("**D3**") which describes 2',4'-BNA which contain a seven membered cyclic -O-CH_2-O- structure, a seven membered cyclic carbamate [-O-C(O)-NH- or -NH-C(C)-O-] structure, or a seven membered cyclic urea [-NH-C(O)-NH-] structure between C2' and C4' positions.

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d. M. Nishida et al., Nucleic Acid Symposium Series, No. 51, pp.157-158 ("**D4**") describes 2',4'-BNA which contain a five membered cyclic ether (-O-) structure, a six membered cyclic (-O-NH-) structure, or a seven membered cyclic (-O-CH_2-O-) structure between C2' and C4' positions.

SUBMISSIONS ON BEHALF OF THE APPELLANT

10. The learned Counsel for the Appellant submitted that the problem solved by the present invention is to overcome the limitations of the prior art, i.e., to provide oligonucleotide containing the 2', 4'-BNA with high binding affinity for a single-stranded RNA and having increased nuclease resistance over LNA. Particularly, it is expected to be applied to nucleic acid drugs because of its much stronger binding affinity for single-stranded RNAs than phosphorothioate-oligo's affinity.

11. The learned Counsel for the Appellant submitted that the compounds of D1 nowhere disclose or suggest introduction of an amide bond into a bridge structure of 2', 4'-BNA / LNA as claimed in the present invention. Further, nucleoside analogues of D1 are a result of successful linkage between C2' and C4' positions of ribose in the nucleoside analogues and are conformationally locked nucleosides with a 3'-endo sugar pucker. In contrast, the compound represented by Formula I of the present invention contains a five to seven membered cyclic [-NR^1-C(O)-] structure between C2' and C4' positions as described in claim 1, which is nowhere the disclosed or suggested in D1.

12. The learned Counsel for the Appellant further submitted that D2 was never conveyed to the Appellant either at the time of FER or the Hearing or in fact during the Hearing. The comparison of the enzyme resistance of

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Table 6 of D2 with that of Example 13 of the Complete Specification is completely misplaced.

13. The learned Counsel for the Appellant submitted that a bare perusal from these disclosures, it is evident that D2 and the Complete Specification adopt the different oligonucleotide sequences. It is emphasized that the claimed compound has an excellent enzyme resistance as compared with D2 from the disclosure of the Complete Specification. The relevant paragraphs are reproduced hereunder:

> *"[0146] Under nitrogen stream, compound 30 from (3) above (213 mg, 0.315 mmol) was dissolved in dimethylformamide (1.5 mL), to which pyridinium dichromate (872 5 mg, 3.15 mmol) and 300mg of molecular sieves 4A were added, and the mixture was stirred for 17 hours at room temperature. Water and then acetic acid (1.5 mL) was added to the mixture which was then stirred, diluted with ethyl acetate and then filtered through Celite. The filtrate was extracted with ethyl acetate and the organic layer was washed with oxalate buffer and then dried over sodium sulfate. After the solvent was distilled away, the crude product 31 was given as a white solid (169 mg: yield 78%)."*
>
> *** *** ***
>
> *"[0289] (Example 13) Assessment of serum stability of the oligonucleotides (FBS)*
> *1 nmol of oligonucleotides (5'(XTXTXTXTXT) 3', where compound 65 from Example 9 was introduced at the position "X" in the sequence according to the method of Example 10) was mixed with 10 µL of 25% FBS, to which sterile water was added to make the whole volume to 25 µL. After the incubation of the solution for a given time 30 at 37°C, 5 µL of the sample was removed at regular time intervals, which was heated to 90°C and then cooled to inactivate the nucleolytic enzyme in FBS. These samples were stored at 80°C until the analysis with HPLC. For the HPLC analysis, sterile water was added to the sample to adjust the whole volume to 200 µL before determining the oligonucleotide degradation over time with HPLC (SHIMADZU LC-20AD, SPD-20A, CTO-20A, SIL-20AC). The employed budder contains degassed before measurement. The oligonucleotides where X is the sequence of*

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naturally occurred DNA-T or LNA-T were subjected to the same test as describes above for the comparison."

14. The learned Counsel for the Appellant submitted that Example 12 in Paragraph No. [0284] of the Complete Specification describes the enzyme resistance of the claimed compounds (amide NH, amide 6NH and amide NMe) were compared with that of the conventional, NC(NH), i.e., 2', 4'-BNA^{NC}(NH), corresponding to the compound represented by Formula I in D2. The relevant paragraph is reproduced hereunder:

> *"[0284] (Example 12) Assessment of the nuclease resistance Each oligonucleotide of compound 20 (amide NH) synthesized in Example 2 above, compound 55 (amide 6NH) synthesized in Example 6 and compound 69 (amide NMe) synthesized in Example 10 was subjected to the test for determining the resistance to an exonuclease which degrades an oligonucleotide in the direction from 3' to 5' direction. The conventional 2', 4' BNA/LNA and NC (NH) (2', 4'BNANC (NH): the structure with a bridging structure containing a nitrogen atom but not an amide) were used as a control."*

15. The learned Counsel for the Appellant further submitted that according to Figure 1, it is clear from the disclosure of the Subject Application that the claimed compound has significant technical advance as compared to D2 at least in the enzyme resistance. Therefore, the present invention has an inventive step over the cited prior art D2.

16. The learned Counsel for the Appellant submitted that D3 describes that the "Tm" values of oligodeoxynucleotides ("**ODNs**") 11-13 (containing a urea-type 2', 4'-BNA monomer 3) / DNA duplexes were lower than natural DNA 10 / DNA duplex and the ODNs 11-13/RNA duplexes showed higher "Tm" values than natural DNA 10 / RNA duplex. D3 also describes that natural DNA and the 2', 4'-BNA (LNA) modified ODN were degraded immediately, but the urea type 2', 4'-BNA ODN showed no gradation for at

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least one hour. In view of the above, D3 discloses that a urea-type 2', 4'-BNA monomer has a higher affinity to RNA than DNA and is more resistant to nuclease than DNA or 2', 4'-BNA (LNA). Further, there is no motivation provided in D3 which suggests the introduction of an amide bond into a bridge structure of 2', 4'-BNA / LNA.

17. The learned Counsel for the Appellant submitted that the Declaration from the inventor, Mr. Satoshi Obika dated 13.02.2013 ("**Declaration**") submitted before United States Patents and Trademarks Office ("**USPTO**") during the US prosecution has not been considered by the Respondent.

18. The learned Counsel for the Appellant submitted that the Respondent misconstrued the importance of Section 3(d) of the Act, wrongly applied its provisions to the Subject Application and has erroneously refused the present Subject Application. The premise behind holding that the compounds of the present invention are other derivatives of compounds of D2 is based on erroneous reasoning that compounds of present invention are derivative of compounds which are structurally similar to the compounds from which compounds of prior art D2 have been derived. Therefore, the Respondent has failed to show as to how the compounds of present invention are derivatives of the compounds disclosed in D2.

19. The learned Counsel for the Appellant placed reliance upon the following decisions in support of the submissions made above:

a. ***R. Muralidharan v. The Controller General of Patents***, 2016 SCC OnLine Mad 9667

b. ***F. Hoffmann-LA Roche Ltd & Anr. v. Cipla Ltd.,*** Neutral Citation: 2015:DHC:9674-DB

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c. ***Bristol-Myers Squibb Holdings Ireland Unlimited Company & Ors. v. BDR Pharmaceuticals International Pvt. Ltd. & Anr.***, 2020 SCC OnLine Del 1700

d. ***Agriboard International LLC v. Deputy Controller of Patents and Designs***, 2022 SCC OnLine Del 4786

e. ***Fresenius Kabi Oncology Limited v. Glaxo Group Limited & Anr.,*** ORA/17/2012/PT/KOL, Order No. 162/2013

f. ***DS Biopharma Limited v. The Controller of Patents and Designs and Anr.***, 2022 SCC OnLine Del 3211

20. Accordingly, it was prayed that the present Appeal be allowed, and the Impugned Order be set aside.

SUBMISSIONS ON BEHALF OF THE RESPONDENT

21. The learned Counsel for the Respondent submitted that the International Search Report ("**ISR**") issued by the World Intellectual Property Organization ("**WIPO**") in respect of Patent Cooperation Treaty ("**PCT**") application is not binding in view of Article 33(1) of the PCT, which provides that the object of the International Preliminary Examination ("**IPE**") is to formulate a preliminary and non-binding opinion. Article 35(2) of the PCT provides that the IPE Report shall not contain any statement on the question of whether the claimed innovation is patentable or not according to any national law. This Court in the decision of ***Ten Xc Wireless Inc and Another v. Mobi Antenna Technologies***, 2011 SCC OnLine Del 4648 has observed that the ISR issued by the WIPO in respect of PCT application is not binding in view of Article 33(1) of the PCT, which provides that the object of the IPE is to formulate a preliminary and non-binding opinion.

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22. The learned Counsel for the Respondent submitted that prior art D2 discloses a compound having a similar structure and activity to the compounds of the Subject Application. On the other hand, the Appellant fails to provide any technical explanations to invalidate the prior art D2. The Appellant has deliberately chosen not to respond to the objection raised against D2. The Appellant in its Reply to the FER and thereafter, in the present Appeal elaborates on the alleged 'binding' nature of the ISR, which is clearly an incorrect assertion.

23. The learned Counsel for the Respondent submitted that the Appellant during the Hearing submitted that the 2',4'-BNA having an amide linking group in the crosslinked structure of the present invention has a ΔTm per a modified residue of about +3 °C to +7 °C with regard to a target RNA as shown as 'ΔTm /mod.' in Tables 2, 4, 6 and 9 of the Subject Application, while a urea-type 2',4'-BNA monomer 3 of D1 has a ΔTm per a modified residue of about +2 °C with regard to a target RNA as converted in terms of 'per a modified residue' from values in Table 1 of D1. However, the Appellant did not compare ΔTm/mod. of the Subject Application with prior art document D2. 2',4'-BNA^{NC} modified oligonucleotides of D2 has a ΔTm per a modified residue of +4.7-+6.3, which is similar to Subject Application.

24. The learned Counsel for the Respondent further submitted that the enzyme resistance of D2 is higher than the Subject Application as shown in Example 13. It is clear that the present invention does not have significant technical advance as compared to cited prior art D2 as required under Section 2(1)(ja) of the Act.

25. The learned Counsel for the Respondent submitted that the claimed bridged derivatives are derived from compound 4 in the Subject Application.

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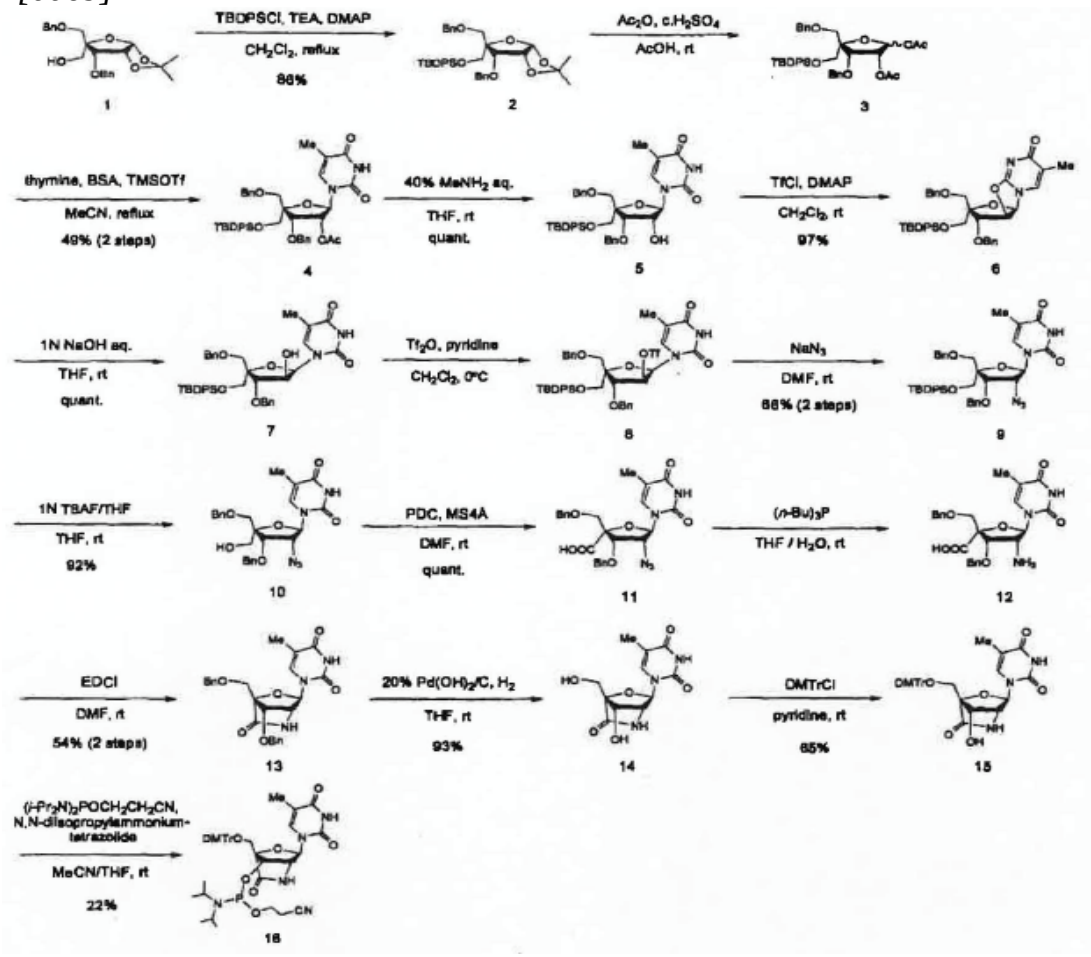
D2 also discloses the bridged derivative of nucleosides and nucleotides, which is derived from compound 1 of D2, which is similar to compound 4 of the Subject Application. D2 also disclosed compounds, having analogous basic structures and derived / obtainable from similar standard procedures, hence, compound of the Subject Application considers other derivatives of compounds disclosed in prior art D2. Compound 4 as in Paragraph No. [0069] of the Complete Specification of the Subject Application and compound 1 of D2 as in Paragraph No. [0065] of the Complete Specification are intermediate compounds from which final compounds synthesis. A compound represented by the Formula I of the Subject Application is analogous to the compound represented by the general Formula I of D2. The relevant paragraphs are reproduced hereunder:

> *"[0065] Particularly, for antisense therapies, both of a binding affinity for 5 complementary sense strand RNAs and a resistance to in vivo DNA are required. Generally, a nucleic acid in the form of a single .strand is known to constantly have a structural fluctuation of a sugar moiety between the form close to a sugar moiety in a double stranded DNA and the form close to a sugar moiety in a double stranded DNA RNA or a double stranded RNA When a single-stranded nucleic acid forms a double strand with the complementary RNA strand, its structure of the sugar moiety is fixed. Therefore, the 2', 4'bridged artificial nucleosides of the invention form readily double strands with the intended RNA strands, which may be then maintained stably, because the sugar moiety has been already kept to the structure capable of forming double strands. Furthermore, a double-stranded nucleic acid is known to be stabilized with hydrated water with a chain like structure referred to as "network of water molecules". The 2', 4'bridged artificial nucleosides of the invention have amide bonds which provide hydrophilicity to the bridges on their sugar moieties, as a result of which the nucleosides may be more stabilized. Moreover, an amide bond in the bridge of the sugar moiety in the nucleoside is thought to makes the nucleoside less recognizable to in-vivo enzymes, which contributes to its nuclease resistance."*

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*** *** ***

"*[0069]*



26. The learned Counsel for the Respondent submitted that in the present case, the claim was rejected because the subject matter of claim 1 in the Subject Application is not patentable under Section 3(d) of the Act. The bridged artificial compounds as claimed in claims 1 to 6 do not have enhanced therapeutic efficacy as required under Section 3(d) of the Act.

27. Accordingly, the present Appeal is liable to be dismissed, and the Impugned Order shall be upheld.

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ANALYSIS AND FINDINGS

28. The learned Controller through the Impugned Order has rejected the Subject Application under Sections 2(1)(j) and 3(d) of the Act.

29. That the present invention under the Subject Application relates to the bridged artificial nucleosides single-stranded RNAs and high nuclease resistance. The present invention under the Subject Application provides for compounds represented by Formula I or Formula II and salts. The present invention relates to oligonucleotide analogues, which have stable and excellent antisense / antigen activity or have excellent activities as reagents with respect to detection of particular genes.

30. Oligonucleotide (antisense molecule) inhibited infection by influenza virus. However, in case a natural DNA / RNA oligonucleotide was applied as an antisense molecule to this method, the problem arisen is that it gets hydrolyzed by an *in vivo* enzyme.

31. Even after making a lot of effort, none of the prior arts (artificial oligonucleotides) have obtained nucleoside and oligonucleotide analogues fully satisfactory in terms of a duplex-forming capacity with single-excels in a triplex-forming capacity with a double-stranded stranded RNA and DNA, *in vivo* stability / ease of synthesis of oligonucleotides, a triplex-forming capacity with double-stranded DNA.

32. Therefore, it is desired to provide a nucleotide analogue that highly penetrates the cell membrane *in vivo*, which minimally undergoes hydrolysis by enzymes and is which is easy to synthesize, and which is useful for the antisense method / antigen method, the RNA interference method, genetic homologous recombination method, and the decoy method.

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OBJECTION UNDER SECTION 2(1)(j) OF THE ACT

33. The learned Controller rejected the Subject Application on the ground of lack of inventive step under Section 2(1)(j) of the Act. To adjudicate the submissions of the Appellant that the Impugned Order is not reasonable, it is important to analyse the Impugned Order to find whether the learned Controller has sufficiently justified the objections. In ***Agriboard International LLC*** (*supra*), this Court has laid down the procedure to be followed while raising the objection on the ground of lack of inventive step under Section 2 (1)(ja) of the Act.

> *"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,***
> - ***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."*

34. Therefore, the learned Controller has to discuss the present invention disclosed in the cited prior art documents D1 to D4, the present invention

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disclosed in the Subject Application, and the manner in which present invention would be obvious to a person skilled in the art ("**PSITA**").

35. According to the Appellant, compound 4 in D2 is similar to starting compound of the Subject Application. The learned Counsel for the Respondent submitted that D1 discloses 2',4'-BNA, which contain a six membered cyclic ether (-O-) structure between the C2' and C4' positions.

36. However, there are two major distinctions between D1 and the present invention under the Subject Application. *Firstly*, the compound represented by Formula I in the present invention contains a five to seven membered cyclic [-NR^1-C(O)-] structure between C2' and C4' positions as described in claim 1, which is not disclosed / suggested in document D1. *Secondly*, the compounds of document D1 does not disclose / suggest introduction of an amide bond into a bridge structure of 2', 4'-BNA / LNA as claimed in the present invention.

37. The learned Counsel for the Respondent argued that document D2 discloses 2',4'-BNA, which contain a cyclic-NR3-O-structure between the C2' and C4' positions as represented by Formula I.

38. It is the case of the Respondent that D2 discloses a compound that has a similar structure and activity (2',4'-BNA^{NC} modified oligonucleotides of D2) to the compounds of the Subject Application and the Appellant has failed to provide any technical explanations to invalidate the prior art D2.

39. *Per contra*, the learned Counsel for the Appellant argued that the following objection raised with respect to D2 by the Respondent was never conveyed to the Appellant either at the time of issuing Hearing Notice or even during the Hearing.

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40. Further, the learned Counsel for the Appellant argued that the Impugned Order, under "*Controller's Remarks*", while referring to the Example 13 of the Complete Specification of the Subject Application, stated that the enzyme resistance of D2 (Table 6 of D2) is higher than the Subject Application. Further, the learned Counsel for the Appellant argued that the comparison of the enzyme resistance of D2 under Table 6 with that of Example 13 of the Complete Specification of the Subject Application is completely misplaced.

41. The learned Controller in the Impugned Order stated that the Appellant did not compare the ΔTm/mod of the present invention with the cited document D2. On the other hand, the learned Counsel for the Appellant while citing the Table 2 of the Complete Specification of the Subject Application, argued that the compound 21 is a natural compound. In compound 22, the Appellant has done modification at the 6th position and as the modification is increased, the binding affinity is also increased. The Table 2 of the document D2 is reproduced hereunder:

Table 2.

[0127] [Table 2]

Antisense strand	Sense strand			
	RNA complementary strand		DNA complementary strand	
	Tm (℃)	Δ Tm/mod.(℃)	Tm (℃)	Δ Tm/mod.(℃)
5'-TTTTTTTTTT-3' (Compound 21)	18.8		22.9	
5'-TTTTTYTTTT-3' (Compound 22)	25.5	+6.7	23.9	+1.3
5'-TTTTTXTTTT-3' (Compound 17)	24.9	+6.2	22.0	−0.9
5'-TTTYTYTTTT-3' (Compound 23)	35.1	+8.2	29.7	+3.4
5'-TTTXTXTTTT-3' (Compound 18)	33.7	+7.5	24.4	+0.8
5'-TTTYTYTYTT-3' (Compound 24)	41.5	+7.6	36.6	+4.6
5'-TTTXTXTXTT-3' (Compound 19)	41.7	+7.7	32.2	+3.1

Δ Tm/mod. = Δ Tm/modified base

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42. In respect to the Table 2 in Paragraph No. [0127] mentioned above, the range of ΔTm/mod.(c) for RNA complementary strand varies from +6.2 to +8.2 while for DNA complementary strand, the range is -0.9 to +4.6.

43. Although the binding affinity of the present invention is comparable with document D2, the maximum binding affinity for the present invention is +8.2 while for document D2, the maximum binding affinity is +7. Another reasoning provided by the learned Controller in the Impugned Order is that enzyme resistance of document D2 as shown in Table 6 of D2 is higher than the present invention under the Subject Application as shown in Example 13.

44. The learned Counsel for the Respondent submitted that document D3 discloses 2',4'-BNA, which contain a seven membered cyclic (-O-CH_2-O) structure, a seven membered cyclic carbamate [-OC(O)-NH- or -NH-C(C)-O-] structure, or a seven membered cyclic urea [-NH-C(O)-NH-] structure between C2' and C4' positions.

45. According to the Respondent, D4 discloses 2',4'-BNA that contain a five membered cyclic ether (-O-)-structure, a six membered cyclic (-O-NH-) structure / a seven membered cyclic (-O-CH2-O-) structure between C2' and C4' positions.

46. Additionally, the learned Counsel for Appellant referred to the Example 3 and Table 6 of document D2 and submitted that, the learned Controller has compared Table 6 with the present invention to discuss the enzyme resistance. The Table 6 of document D2 is reproduced hereunder:

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TABLE 6

Evaluation of enzyme resistance

	% of intact oligonucleotide					
oligonucleotide	0 min	5 min	10 min	20 min	40 min	90 min
D-oligo	100	0	0	0	0	0
2',4'-BNA	100	37	24	5	1	0
5-oligo	100	94	92	91	83	70
2',4'-BNA^{NC}	100	100	99	98	94	80

The results of Table 6 and FIG. 1 show that the oligonucleotide analogue of the present invention had excellent enzyme resistance as compared with natural and other nonnatural oligonucleotides.

47. In this experiment, the measures were taken at time 0 minutes, 5 minutes, 10, 20, 40 and 90 minutes. The 4th item in Table 6 is from document D2 that lasts 80% even after 90 minutes. The learned Controller has compared it with Example 13 of the Subject Application, which is unrelated to the enzyme resistance. The relevant paragraph of the Impugned Order is reproduced as hereunder:

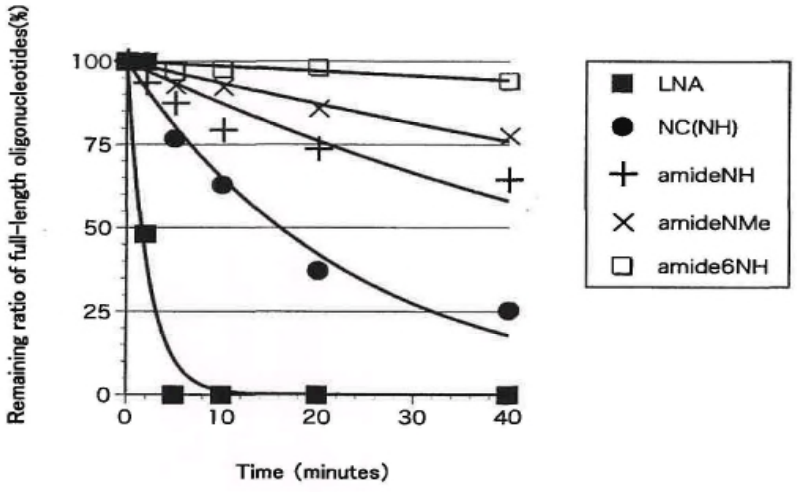
> "*Further enzyme resistance of D2 (Table 6 of D2) higher than present app1ication (example 13)*
>
> *In the view of above it is clear present claimed subject matter does not have significant technical advance as compared to cited prior art D2.*
>
> *Therefore, in view of the aforesaid, it is concluded that the subject matter of claims 1 through 6 in this instant application lacks inventive step u/s 2(1)(ja).*"

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48. The learned Controller has compared Table 6 of D2 with Example 13 of the Complete Specification of the Subject Application and Example 13 is unrelated to the nuclear resistance activity. Example 13 is *"[0289] (Example 13) Assessment of serum stability of the oligonucleotides (FBS)"* which talks about the assessment of serum stability of the oligonucleotides. Therefore, the learned Controller has chosen the wrong example from the Complete Specification of the Subject Application. According to the Appellant, the correct example for the assessment of nuclease resistance is Example 12 of the Complete Specification of the Subject Application which is titled as "*[0284] (Example 12) Assessment of the nuclease resist*ance".

49. Additionally, the Appellant the graph in Figure 1 in the Complete Specification of the Subject Application that illustrates a time course of remaining ratio of various oligonucleotides when digesting them with exonuclease. Here, the ratio of various oligonucleotides of the present invention of the Subject Application is higher as compared to the document D2. The Figure 1 is reproduced hereunder:

[Fig. 1]



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50. The combined reasoning provided by the learned Controller is that D1 to D4 discloses 2',4'-BNA that is almost similar to the present invention under the Subject Application. According the Impugned Order, the only difference is that 2',4'-BNA of present claims contain a five to seven membered cyclic amide [-NR^1-C(O)-] structure between C2' and C4' positions as described in claim 1. Apart from this, the Impugned Order does not discuss anything that how the documents D1 to D4 are to be read together.

51. Further, for D3 and D4, the Impugned Order does not mention anything. The only mentioning of D3 and D4 is in the Paragraph No. 2 which is a reproduction of the Hearing Notice. The relevant paragraph is reproduced hereunder:

> "*03 disclosesv2',4'-bridged nucleoside analogues which contain a seven membered cyclic -O-CH2- 0 structure, a seven membered cyclic carbamate (-0-C{O)-NH- or -NH-C{C)-0-) structure, or a seven membered cyclic urea (-NH-C(O)-NH-) structure between C2' and C4' positions. 04 discloses 2',4'-bridged nucleoside analogues which contain a five membered cyclic ether (-0-)~ structure, a six membered cyclic -0-NH- structure, or a seven membered cyclic -0-CH2-0- structure between C2' and C4' positions.*"

52. It is important note that the learned Controller has not discussed the document D3 individually in the Impugned Order. It is case of the Appellant that there is no reasoning provided on the documents D3 and D4. In the present invention under the Subject Application, the 2',4'-BNA with an amide linking group in the crosslinked structure of the present invention has a ΔTm per a modified residue of about +3 °C to +7 °C with regard to a target RNA. On the other hand, a urea-type 2',4'- BNA monomer 3 of D1 has a ΔTm per a modified residue of about +2 °C with regard to a target

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RNA. To this argument of the Appellant, learned Controller has referred to D2 again and stated that the Appellant as failed to compare ΔTm/mod. of Subject Application with the prior art document D2. The learned Controller has solely relied on D2 as D1, D3, and D4 are not discussed in the Impugned Order under the "*Controller's Remarks*."

53. The third step of the ***Agriboard International LLC*** (*supra*) which requires that the manner in which present invention would be obvious to a PSITA has to be discussed. This step is crucial to determine whether there is significant technical advancement in the present invention under the Subject Application as compared to cited prior art D2. Contrary to this, the learned Controller, under the "*Controller's Remark*" in the Impugned Order has primarily discussed the document D2 and has completely missed the relationship between the four cited prior arts D1 to D4. In the absence of such corelation, the above mentioned third step is challenging to determine.

54. Most importantly, it can be inferred from a bare perusal of the Impugned Order that the learned Controller has primarily relied on the document D2 to establish the objection under Section 2 (1)(j) of the Act. As discussed above, the learned Controller, to examine the "*Assessment of the nuclease resistance*", has wrongly compared Example 13 of the Complete Specification of the Subject Application with Table 6 of D2 where Example 13 is not related to the assessment of the nuclease resistance. Therefore, the Impugned Order has various infirmities.

55. Additionally, the learned Controller has also come up with additional reasoning that was not there in the FER and the Hearing Notice. Therefore, it would be appropriate to give the Appellant an opportunity to defend with respect to such new reasoning.

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OBJECTION UNDER SECTION 3(d) OF THE ACT

56. The learned Controller has stated that claims 1 to 7 are not patentable on the ground of failure of providing therapeutic efficacy and the reasoning is given for the first time in the Impugned Order. The reasoning provided under the Impugned Order is reproduced hereunder:

> "*The agent's submission not persuasive. Applicant fails to provide therapeutic efficacy data of present claimed compound. Controller is of opinion that the subject matter as described and claimed in the instant applicant do not meet the requirements of section 3(d) of the Patents Act, 1970*"

57. The learned Counsel of the Appellant submitted that the present invention, "Tm" measures binding affinity. The present invention under the Subject Application has good resistance. The reasoning provided in the Impugned Order with respect to the rejection under Section 3(d) of the Act is reproduced hereunder:

> "*Present application claims related bridged derivative of nucleosides and nucleotides. The claimed bridged derivatives derived from compound 4 present application.* ***D2 also discloses bridged derivative of nucleosides and nucleotides, which is derived from compound 1 of D2, which similar to compound 4 of present application. In view of above it is clear present claimed subject matter and subject matter discloses in D2 both related to bridged derivative of nucleosides and nucleotides, which is not same.*** *But both having common basic structure/skeleton and derived from same compounds or compounds having common basic structure/skeleton, hence compound of present application consider other derivative of compound disclosed in prior art D2.*
> *The bridged artificial nucleoside and nucleotide as claimed in claim 1-6 are other derivatives of compounds disclosed in D2. And bridged compound as claimed in claim 1-6 do not demonstrate the enhanced therapeutic efficacy.*
> *The agent's submission not persuasive.* ***Applicant fails to provide therapeutic efficacy data of present claimed compound.*** *Controller*

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is of opinion that the subject matter as described and claimed in the instant applicant do not meet the requirements of section 3(d) of the Patents Act, 1970."

58. The reasoning provided with respect to the same objection as mentioned above is in the Hearing Notice as well is reproduced hereunder:

"*Non-Patentability u/s 3*
The claims 1-6 attracts sec. 3(d) of the Indian Patents (Amendment) Act 2005 as the 2' ,4'-bridged nucleoside analogues as claimed in claim 1-6 are derivatives of analogues disclosed in D1-D4 and hence considered as same substance as per the act."

59. Further, the reasoning under FER provided by the learned Controller is reproduced hereunder:

"*Claim(s) (1-7) are statutorily non-patentable under the provision of clause (d) of Section 3 for the following the claims attracts sec. 3(d) of the Indian Patents (Amendment) Act 2005 as the pharmaceutical compound as claimed in claim 1-7 is mere a new form of known compound and considered as same substance as per the act.*"

60. There is no reasoning provided under the Hearing Notice and the prior art is not specified. Additionally, the FER also raised an objection under Section 3(d) of the Act without specifying the derivative compound and the prior art. Therefore, it can be seen that the learned Controller as brought up the reasoning for the first time in the Impugned Order.

61. In ***DS Biopharma Limited*** (*supra*), this Court held that to raise an objection under Section 3(d) of the Act, the learned Controller has to identify the known compound / derivative. The relevant paragraphs are reproduced hereunder:

"*14. The above observations were made by Justice Prabha Sridevan in a case where revocation of the patent was sought on the ground of non-patentability under Section 3(d). Though not in the context of a patent office objection, the observations would be relevant to*

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examine as to how the objection under Section 3(d) is to be raised. Section 3(d) bars patentability of a `new form' of `a known substance', without establishing enhanced therapeutic efficacy. ***For the said objection to be raised, the basic pre-condition would be the identification of the `a known substance'. The said `known substance' could be one substance or a compound/s derived from a Markush formula. However, it has to be identified. It cannot be left to the Applicant to deduce as to what is the known substance and thereafter give efficacy data qua that known substance, based on the said deduction. It is only new forms of substances which are derived from the same known substance that would attract the rigors of Section 3(d).*** *However, in this case, the compound which constitutes the `known substance' was not identified in the hearing notice. For the purposes of a Section 3(d) objection, the one specific known substance is to be identified and the manner in which the claimed compounds are 'new forms' ought to be mentioned by the Patent Office, even if not in detail but at least in a brief manner. The hearing notice does not mention so.*

15. The Appellant in the reply to the hearing notice submits that the Ld. Controller has not specified under which part of Section 3(d) of the Act does the objection fall. The Appellant goes on to assert that as per its understanding of the Fresenius Kabi judgement (supra), for an objection under nonpatentability to be raised, the patent office needs to specifically allege and identify at least the following:

(i) ***What is the specific 'known' substance in question?***
(ii) How and why the claimed molecule(s) or substance(s) is a derivative or is otherwise a new form of a known substance?
(iii) Basis to assert that the alleged 'known' substance and the claimed molecule or substance have the same 'known' efficacy?

*16. The Ld. Controller in the hearing notice has failed to identify any of the above three factors****. It is also submitted by the Appellant that in the absence of identification of the 'known' compound it is unable to respond clearly to this objection, severely hampering its right to be given a reasonable opportunity to defend its patent application.*** *It further submits that it is under no legal obligation under Section 3(d) of the Act to demonstrate the efficacy of the claimed compound in the absence of identification of the 'known' compound.*"

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62. In the present case, the known compound as well as the prior art was not specified by the learned Controller in the FER and the Hearing Notice. Thereafter, the learned Controller specified the prior art D2 and provided the reasoning while objecting the Subject Application under Section 3(d) of the Act. Therefore, the Appellant never got the opportunity to reply to the identified derivative of D2.

CONCLUSION

63. Accordingly, in view of the abovementioned infirmities in the Impugned Order dated 29.08.2020, the matter is remanded back to the learned Controller for a fresh consideration.

64. It is clarified that the merits of the case have not been examined and the Respondent shall decide the Subject Application in accordance with law without being influenced by any observations made by this Court in this Judgment and the same will be decided within a period of six months from the date. The Appellant shall be granted a fresh hearing before deciding the Subject Application.

65. Accordingly, the Appeal is disposed of with the aforesaid direction.

66. A copy of the Order shall be sent to the learned Controller General of Patents, Designs and Trademarks at the e-mail address – llc-ipo@gov.in for compliance.

TEJAS KARIA, J

DECEMBER 24, 2025
'KC'/'N'

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