2025:MHC:887

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **01.04.2025**

CORAM

THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

(T)CMA(PT) No.107 of 2023
(OA/10/2018/PT/CHN)

BIGTEC PRIVATE LIMITED
Through its Authorised Representative
2nd floor, Golden Heights,
59th 'C' cross, 4th 'M' Block,
Rajajinagar, Bangalore-560 010,
Karnataka, India. ... Appellant

-vs-

The Assistant Controller of Patents and Designs,
Patent Office Branch,
Intellectual Property Building,
GST Road, Guindy, Chennai - 600 032. ... Respondent

Prayer: Transfer Civil Miscellaneous Appeal (Patents) filed under Section 117-A of the Patents Act, 1970, to allow the present appeal and set aside/quash the impugned order dated 16.08.2017 passed by the respondent for Indian Patent Application No.625/CHE/2011 and direct grant of patent in respect of the said Indian Patent Application No.625/CHE/2011.

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For Appellant : Mr.Shatadal Ghosh
Mr.K.Muthu Selvam
for M/s. K and S Partners

For Respondent : Mr.J.Madanagopal Rao, SPC

JUDGMENT

This appeal is directed against order dated 16.08.2017 rejecting Indian Patent Application No.625/CHE/2011 for grant of patent for an invention titled "Nucleotide Sequences, Reaction Mixture, Method and Kit Thereof".

2. After filing the above-mentioned application, on the request of the appellant, First Examination Report (FER) dated 11.04.2014 was issued. In the said FER, objections were raised *inter alia* on the ground of lack of inventive step by citing prior art documents D1 to D6 and with reference to Section 3(c) and 3(e) of the Patents Act, 1970 (the Patents Act) as regards specific claims. The appellant responded to the FER on 08.04.2015. The prior arts cited in the FER were sought to be distinguished and the objections under Section 3 were also dealt with. This was followed by more than one hearing notice. All the hearing notices were substantially on the

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same terms. The objection with regard to lack of inventive step was maintained with specific reference to prior art document D7. In addition, the objection on the ground that the claimed invention is excluded from patent protection under Section 3(c) of the Patents Act was maintained. After the hearing, the appellant filed written submissions on 19.05.2017 along with amended claims. The order impugned herein was issued in the said facts and circumstances.

3. Learned counsel for the appellant submitted that the claimed invention is aimed at the efficient determination of the presence, including quantification, of the Hepatitis B Virus (HBV) in a biological sample. By referring to the current claims of the appellant and, in particular, independent claim 1, learned counsel submits that the claim is in respect of nucleotide sequences bearing SEQ ID No.1, SEQ ID No.2 and SEQ ID No.3. He further submits that SEQ ID No.1 is in respect of a probe and that SEQ ID Nos.2 and 3 are in respect of primers corresponding to the said probe. He also submits that SEQ ID No.1 is conjugated with a fluorophore at the 5' end and a quencher at the 3' end. By referring to hearing notice

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dated 09.03.2017, learned counsel submits that prior art document D7 was referred to therein. He further submits that it was stated therein that designing further oligonucleotide sequences would be normal routine work for the skilled person and cannot be considered inventive unless such sequences endow additional surprising effects with respect to the prior art sequences.

4. According to learned counsel, the appellant demonstrated that the sequences in the claimed invention result in additional surprising effects over prior art sequences. By way of substantiation, learned counsel referred to the written submissions and pointed out that the sequences were compared with table 1 of D7 at pages 254 to 258 of the paper book so as to establish that the probe in SEQ ID No.1 of the claimed invention is inventive over the probes of D7. He also referred to the amplification plots at pages 261, 272 and 310 by using the probes and primer(s) of D7 in comparison to the probe and primers of SEQ ID Nos.1, 2 and 3 of the claimed invention. With reference thereto, learned counsel contends that the amplification is greater on deployment of SEQ ID Nos.1, 2 and 3 in

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comparison to corresponding SEQ IDs of D7, thereby establishing unexpected effects by the use of the sequences of the claimed invention in comparison to that of prior art, including D7. By referring to the claims of D7 and the abstract relating thereto, learned counsel submits that D7 provides for the deployment of at least two nucleotide probes whereas the claimed invention involves the use of one probe and two primers. For all these reasons, learned counsel submits that the conclusions in the impugned order cannot be sustained especially on account of the unexpected and surprising effects of the claimed invention being disregarded therein. In this connection, learned counsel also points out that the probes of prior art D7 are fixed and immobile in contrast to the probe of the claimed invention.

5. As regards the conclusion that the claimed invention is excluded under Section 3(c) of the Patents Act, learned counsel submits that the said conclusion is patently erroneous inasmuch as the nucleotide sequences of the claimed invention were synthesised and were not merely discovered from a living thing or non-living substance occurring in nature. He also points out that this conclusion was recorded only in respect of SEQ ID

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Nos.2 and 3 and that no such objection was raised in respect of SEQ ID No. 1. In this regard, he also points out that the SEQ ID No.1 uses a fluorophore for detection of HBV and that the primers of SEQ ID Nos. 2 and 3 are designed for use with the said probe.

6. In response to these contentions, Mr.J.Madanagopal Rao relies on the counter affidavit of Dr.V.Parimalavarsini, learned Deputy Controller. In particular, he refers to paragraph 4 of the counter wherein reference was made to SEQ ID No.290 of D7 so as to conclude that it is 100% identical to SEQ ID No.1 and SEQ ID No.2 of the claimed invention. By further referring to paragraph 6 thereof, learned counsel submits that the sequence listing of SEQ ID Nos.2 and 3 were set out therein and that the species of origin has been shown as HBV therein. Therefore, he submits that the rejection under Section 3(c) is in order.

7. These contentions are refuted by learned counsel for the appellant by submitting that SEQ ID No.290 of D7 is an extremely long nucleotide sequence, which consists of 3215 base pairs (bp). By contrast, he submits

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that SEQ ID No.1 of the present invention is made up of only 21 bp and that SEQ ID.No.2 is made up of only 16 bp. As regards the contention that the species of origin in the sequence listing for SEQ ID Nos.2 and 3 were shown as HBV, learned counsel submits that the software used in relation to the sequence listing requires that the species which is closest to such sequence should be mentioned. Learned counsel referred to and relied upon the following authorities:

(i) *Sulphur Mills Limited v. Dharamaj Crop Guard Limited and another, judgment dated 02.08.2021 in CS(Comm)No.1225/2018 & CC(Comm) No.9/2019;*

(ii) *R.Muralidharan v. The Controller General of Patents, Designs, Trademarks and others, 2016 SCC OnLine Mad 9667;*

(iii) *Oncotherapy Science, Inc. v. Assistant Controller of Patents and Designs, order dated 18.02.2021 in OA/52/2014/PT/CH;*

(iv) *Helix Biomedix Inc. v. Assistant Controller of Patents and Designs, judgment dated 07.12.2023 in (T)CMA(PT)No.138 of 2023;*

(v) *Guidelines for Examination of Biotechnology Applications for Patents.*

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8. Upon considering the above submissions, at the outset, it is necessary to set out independent claim 1 of the current claims of the appellant, which is as under:

> *"1. Nucleotide sequence set forth as SEQ ID No.1, SEQ ID No.2 and SEQ ID No.3 for identifying Hepatitis B virus, wherein said SEQ ID No.1 is probe and said SEQ ID Nos.2 and 3 are primers corresponding to said probe; and wherein SEQ ID No.1 is conjugated with fluorophore at 5' end and quencher which can be an internal quencher within the probe or at 3' end."*

From the above independent claim 1, it is evident that SEQ ID No.1 relates to a probe and SEQ ID Nos.2 and 3 are primers corresponding to the said probe. It is also evident that SEQ ID No.1 is conjugated with fluorophore at the 5' end to facilitate detection of HBV by using fluorescence.

9. Upon considering the amended claims of the appellant, in hearing notice dated 09.03.2017, reference was made to prior art document D7. Thereafter, in relevant part, it was stated as under:

> *"The prior art documents disclose the detection of*

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HBV in sample by PCR based assay. However, considering the number of primers and probes already described in the prior art for the same purpose of HBV detection, designing further oligonucleotide sequences is normal routine work for the skilled person and cannot be considered inventive as such, unless such sequences endow additional surprising effects with respect to the prior art sequences."

It is noticeable from the above extract that the respondent recorded that the designing of further oligonucleotide sequences would be normal routine work for the skilled person and cannot be considered as inventive unless such sequences endow additional surprising effects with respect to the prior art sequences. In view thereof, it becomes necessary to examine whether the appellant provided evidence of the surprising effects of the sequences of the claimed invention over prior art.

10. In response to the hearing notice, by reply dated 19.05.2017, the appellant referred to the abstract of D7 and stated that D7 provides for a combination of at least two probes. The appellant further stated that the

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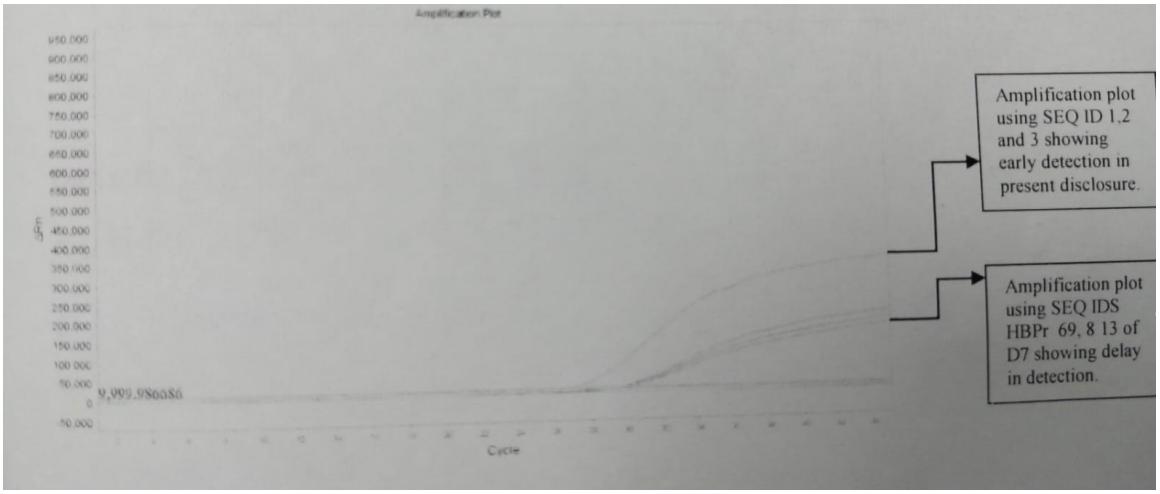
claimed invention uses a single probe along with corresponding primer pairs which are specific for a surface gene and X gene of HBV and not mutant target sequences. By comparing and contrasting the process of detection used in D7 with claimed invention, it was further stated that the claimed invention uses the Real-Time Detection-Polymerase Chain Reaction (RTD-PCR) based on TaqMan hybridization which is distinct from the process used in D7. Significantly, the appellant set out the amplification plots by performing a PCR using the probes and primer(s) of D7 in comparison to the probe and primers of the claimed invention. The relevant graphs are set out below:



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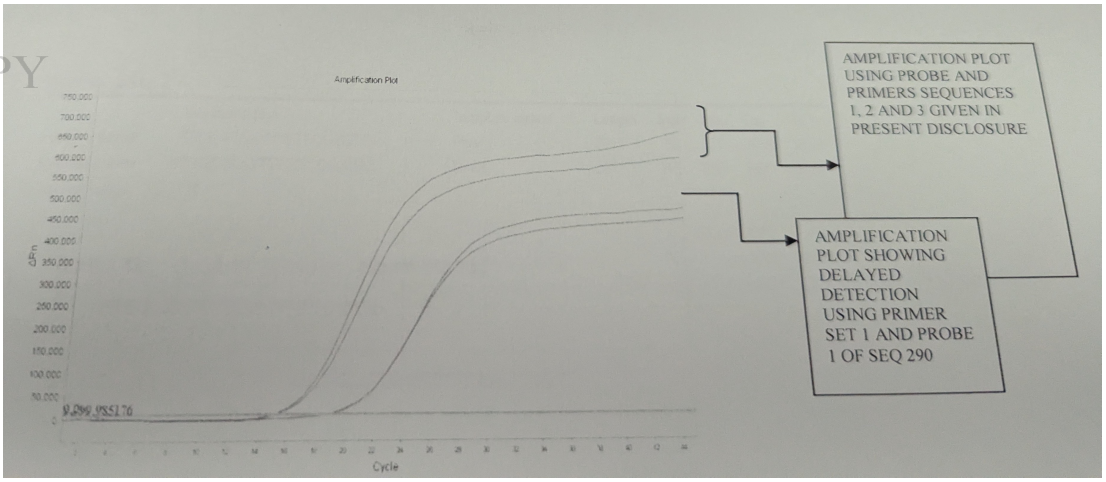

11. On closely examining the impugned order, it is noticeable that the amplification plots referred to by the appellant were noticed at internal page 24 of the impugned order. However, in the operative portion of the order, without making reference to the evidence on the surprising and unexpected effects of the sequences of the claimed invention over prior art D7, the following conclusion was recorded:

> *"It is well known practice and routine experimentation for a person skilled in the art for devising the probes for the detection of sequences and primer sequences for amplification on the basis of complementarity. Thus, the submissions in this regard in written submissions with a whole lot of comparative data*

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cannot explain why the claimed probe and primer sequences are not obvious to a person skilled in the art vis-a-vis disclosures of D7. Therefore, it is concluded that the probes and primer sequences claimed in amended claim 1 are obvious to a person skilled in the art vis-a-vis disclosures of D7. Hence, claim 1 does not involve any inventive step as required u/s 2(1)(ja) of the Patents Act, 1970."

In view of the failure to discuss and record findings with regard to the claimed unexpected effects by way of superior amplification while carrying out PCR using the claimed invention in comparison to prior art D7, the matter warrants reconsideration on this aspect.

12. As regards the conclusion that the claimed invention is excluded from patent protection under Section 3(c) insofar as SEQ ID Nos.2 and 3 are concerned, the impugned order discloses that such conclusion was recorded largely on the ground that the sequence listings relating to SEQ ID Nos.2 and 3 mention HBV as the species of origin. Section 3(c) of the Patents Act excludes an invention from patent protection if it *inter alia* qualifies as the

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mere discovery of any living thing or non-living substance occurring in nature. In other words, the exclusion will apply only in respect of a mere discovery of something by the isolation thereof from nature. In this case, the appellant has asserted that the nucleotide sequences were synthesised and even otherwise, the probe is conjugated with detectable labels. The appellant also stated that since the primers of claim 1 are employed in conjunction with the probe of SEQ ID No.1, and claims 6-8 are dependent on claim 1, the claimed invention is not excluded under Section 3(c). Although the respondent noticed these contentions, without recording any reasons for rejecting the contention that the nucleotide sequences had been synthesised and that the oligonucleotide probe of SEQ ID No. 1 contains synthesized compounds from the fluorescein group such as fluorophore and quencher for detecting HBV, the following conclusion was reached:

> *"The arguments stated by applicant's agent as above fails short to explain the artificialness of the claimed primer sequences of SEQ ID 2 and 3, as these sequences are not conjugated with detectable labels. Thus, the above submitted arguments by the Applicant's agent fail to prove or reveal the artificialness of the claimed primer sequences of SEQ ID 2 and 3. In the*

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absence it can be inferred that these claimed primer sequences of SEQ ID 2 and 3 are discovered (or taken) from the natural source. Hence, the alleged amended claim 1 and its dependent claim 4 of the instant patent application claiming for the nucleotide sequences of SEQ ID 2 and 3 are not patentable as per the provisions of clause (C) of Section 3 of Patents Act, 1970 in the absence of artificialness in them."

For reasons set out above, this conclusion also warrants re-examination.

13. As a result, impugned order dated 16.08.2017 is set aside and the matter is remanded for reconsideration on the following terms:

(i) In order to preclude the possibility of pre-determination, an officer other than the officer who issued the impugned order shall undertake reconsideration.

(ii) Such reconsideration shall be limited to objections maintained in the last hearing notice of the respondent.

(iii) After providing a reasonable opportunity to the appellant, a reasoned order shall be issued within four months from the date of receipt of a copy of this order.

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(iv) It is made clear that no opinion has been expressed herein on the merits of the patent application.

14. Therefore, (T)CMA(PT) No.107 of 2023 stands disposed of on the above terms, without any order as to costs.

01.04.2025

Index : Yes / No
Internet : Yes / No
Neutral Citation: Yes / No

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To

The Assistant Controller of Patents and Designs,
Patent Office Branch,
Intellectual Property Building,
GST Road, Guindy, Chennai - 600 032.

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