Intellectual Property Appellate Board
Guna Complex Annexe-I, 2nd Floor, 443 Anna Salai, Teynampet, Chennai-600 018.
Tele: 24328902/03 Fax: 24328905 email id: ipab.tn@nic.in Website: http://www.ipab..gov.in

OA/35/2020/PT/CHN

THURSDAY, THIS THE 24TH DAY OF DECEMBER, 2020

HON'BLE SHRI JUSTICE MANMOHAN SINGH **CHAIRMAN**
HON'BLE DR. B.P. SINGH **TECHNICAL MEMBER (PATENTS)**

INTERVET INTERNATIONAL B.V
WIM DE KÖRVERSTRAAT 35,
NL-5831 AN BOXMEER,
NETHERLANDS,
THROUGH ITS AUTHORIZED REPRESENTATIVE
MR. PROSENJIT CHATTOPADHYAY ...APPELLANT

(Represented by - Ms.Vindhya Srinivasamani)

Versus

DEPUTY CONTROLLER OF PATENTS AND DESIGNS,
PATENT OFFICE,
INTELLECTUAL PROPERTY BUILDING,
G.S.T. ROAD, GUINDY,
CHENNAI-600032 ...RESPONDENT

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 30/01/2020, passed by the Respondent, being the Deputy Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellants' Indian patent application no. 2681/CHENP/2014.

2. It is the case of the appellant that:

2.1 The impugned order violates the principles of natural justice since it is a non-speaking and unreasoned order.

2.1.1 It is submitted that a perusal of the impugned order of the Respondent indicates the utter lack of reasoning on the part of the Respondent as to how the invention as claimed in the instant Application lacks inventive step under Section 2(1)(ja) of the Act.

2.1.2 The substantive requirement of natural justice and the right to an effective opportunity of hearing envisages that the Respondent meaningfully deals with the contentions of the Appellant on their merits. All that the Respondent has done was to copy and paste extracts of the prior art documents D1, D2 and D3 and the arguments of the Appellant in the order without any analysis.

2.1.3 It is submitted that the Respondent has failed to even mention, let alone consider the importance of, the declaration of Mrs. Stephanie M. Cook, one of the inventors of the instant Application, annexed as Exhibit 1 to the written submissions filed by the Appellant and originally submitted before the USPTO during the prosecution of the corresponding US Patent Application No. 13/655858.

2.2 That the Respondent has failed to determine the lack of inventive step as per mandate expressed in the Act.

2.2.1 The method adopted by the Respondent with respect to the assessment of lack of inventive step in the impugned order, is not in consonance with the binding principles / steps laid down by the Hon'ble Delhi High Court in the said judgment. The impugned order is thus erroneous and is liable to be quashed on this basis alone.

2.2.2 The Respondent has merely concluded that the claimed invention would be obvious to a person skilled in the art, without first assessing the feature involving technical advance or economic significance. It is submitted that the Respondent erred in not determining the two important pre-requisite steps which were statutorily required while assessing inventive step.

2.3 The Respondent has concluded the lack of inventive step, without determining the "person skilled in the art", contrary to the statutory mandate.

2.3.1 It is submitted that the impugned order does not even discuss as to who is the person skilled in the art. There is no finding as to the relevant 'art' in this case and the Respondent has failed to assess the level of skill to be associated with this notional person. It is submitted that the correct identification of this skilled person is crucial since everything may be obvious or non-obvious to an incorrectly identified skilled person. This forms a

crucial factual foundation on which the legal question as to the existence of inventive step is to be assessed.

2.3.2 It is submitted that the failure to make this assessment materially vitiates the finding in the impugned order that "*....it is obvious to person skilled in art to construct recombinant nonpathogenic virus rMDVnp by inserting already known foreign DNA ILTV gD and NDV F gene at already known site such as US2 site, or UL54.5 site"* inasmuch this finding has been issued without even determining what is the level of skill this person should possess. It is submitted that the Respondent cannot substitute his or her opinion for that of a person skilled in the art and cannot fulfil the statutory mandate of assessing obviousness by merely just mentioning the phrase "person skilled in the art".

2.3.3 It is submitted that this failure of the Respondent to even determine and identify the "person skilled in the art" vitiates the impugned order.

2.4 The impugned order is in manifest error of law since it holds that the invention claimed in the instant Application lacks inventive step in the light of the disclosure in Document D1.

2.4.1 It is submitted that the claimed invention discloses a recombinant nonpathogenic Marek's Disease Virus (rMDVnp) comprising a first nucleic

acid inserted in a first nonessential site in the rMDVnp genome and a second nucleic acid inserted in a second nonessential site in the rMDVnp genome; wherein the first nucleic acid comprises both a nucleotide sequence that encodes an Infectious Laryngotracheitis Virus gD (ILTVgD) protein and a nucleotide sequence that encodes an Infectious Laryngotracheitis Virus gl (ILTVgl) protein; wherein the second nucleic acid comprises a nucleotide sequence that encodes a Newcastle Disease Virus fusion protein (NDVF); and wherein the first nonessential site and the second nonessential site are both the US2 site, or both the UL54.5 site, or only the first nonessential site is the US2 site. Further, the present invention relates to a vaccine comprising the recombinant nonpathogenic Marek's Disease Virus (rMDVnp).

2.4.2 It is submitted that the present invention addresses a major problem in the art associated with difficulties with generation of effective non-pathogenic vector-based vaccine such as, nonpathogenic Marek's Disease Virus (MDV) vector-based vaccine comprising multiple heterologous genes of the claimed invention that is genetically stable and able to remain stable upon several rounds of passaging in vitro and in vivo, replicate in a vaccinated target animal, and express its heterologous genes with an expression level that is able to induce a protective immune response in the target so as to provide the desired

vaccine efficacy. The present invention is able to solve the problem and reach the desired characteristics of stability, replication and antigen expression for robust and protective immune response due to the unique design of the nonpathogenic MDV vector with specific arrangement of heterologous genes and promoters at specific and special insertion sites of the nonpathogenic MDV.

2.4.3 It is submitted that the Respondent has failed to consider that prior to the filing of the instant Application, no multivalent vaccine comprising a recombinant HVT encoding antigens from more than one pathogen had been shown to be **stable and efficacious**, even though such vaccines had been speculatively suggested more than fifteen years before this filing date.

2.4.4 It is submitted that the design of a multivalent rHVT vector that can stably express both the NDV F protein and the ILTVgD and ILTVgI proteins is **not** a simple process that can be extrapolated from existing knowledge. It is submitted that even assuming but not conceding that if such stable and efficacious multivalent rHVT vectors were possible at all, their design needed to be premised on an unpredictable set of complex interactions minimally involving the relationship between the insertion sites used and the foreign genes to be inserted. This proved that the construction of

an efficacious and stable multivalent HVT was **not predictable** on the date of filing of the instant Application. Therefore, it is submitted that prior to the present invention, such design of rHVT constructs was not obvious from the cited art.

2.4.5 It is submitted that with respect to the rejection of the instant Application under Section 2(1)(ja) of the Act for lack of inventive step in the light of Document D1 in the impugned order, the Respondent has baldly concluded that in the light of the disclosure in Document D1, the *"distinguishing inventive feature of the invention"* as claimed in claim 1 of the instant application is not clearly defined and is thus obvious to a person skilled in the art, without first ascertaining [but stating that it is not clearly defined] that feature involving technical advance or economic significance or both. It is submitted that the Respondent has completely ignored the evidence of the technical advance and economic significance provided in the complete specification of the instant Application and the various submissions in response to the FER and Hearing Notice and in the oral arguments during the course of the hearing before the Respondent.

2.4.6 It is submitted that there is absolutely no reference in the impugned order to anything within the Document D1, published as on the

priority date of the claimed invention that would motivate a person skilled in the art to arrive at the instant Application. It is thus submitted that the conclusion as to lack of inventive step in the impugned order is simply a matter of hindsight bias phenomenon, which is legally impermissible.

2.4.7 It is submitted that although the Respondent has extracted certain portions of Document D1 in the impugned order, possibly assuming the same to be relevant, the Respondent has failed to appreciate that Document D1 is drawn to a recombinant chimeric vector, comprising a portion of HVT, namely the unique long viral genomic region which naturally occurs in HVT, but further comprises a portion of MDV1, the unique short viral genomic region that naturally occurs in MDV1. This chimeric vector was named the "novel avian herpes virus" (NAHV). The Respondent has failed to consider that such a chimeric vector is specifically excluded from the invention claimed in the instant Application.

2.4.8 It is submitted that such a chimeric construct, NAHV was found to be unstable. Thus, it is submitted that not only does the Document D1 fail to provide a stable and efficacious recombinant multivalent MDV viral, the Document D1 is not even drawn to a MDV viral vector as defined in the instant Application and therefore, is not a relevant prior art document for the assessment of the inventive step of the instant Application.

2.4.9 It is further submitted that there is no disclosure or teaching in Document D1 for the non-essential sites of insertion as in the claimed invention, characterized by the first nonessential site and the second nonessential site are both the US2 site, or both the UL54.5 site, or only the first nonessential site is the US2 site. Furthermore, it is submitted that unlike Examples 2, and 3 of the instant Application read with Tables 1 and 2 of the as-filed specification that demonstrates the efficacy of multivalent HVT/NDV/ILTV vaccine of the present invention comprising the non-pathogenic MDV constructs with heterologous antigenic genes as claimed against a virulent ILTV and NDV challenges; there is no such teaching or direction provided in Document D1. Similarly, it is submitted that Example 4 read with Table 3 of the as filed specification of the instant Application demonstrates the efficacy of multivalent HVT/NDV/ILTV vaccine of the present invention comprising the non-pathogenic MDV constructs with heterologous antigenic genes as claimed against a virulent ILTV and NDV challenge in day-old chicks, which is not at all made obvious by the disclosure of Document D1. Moreover, the invention as claimed in the instant Application demonstrates the efficacious use of the recombinant multivalent HVT/NDV/ILTV MDV construct of the present invention in combination with 89/03 bursal disease strain as a vaccine

against infectious bursal disease virus as seen with Tables 4 and 5 showing vaccines with the claimed construct in combination with 89/03 bursal disease strain being effective as compared to 89/03 bursal disease treatment alone, suggesting the absence of any interference due to the multivalent vaccine. It is submitted that none of the above is taught by the disclosure in Document D1.

2.4.10 It is thus submitted that the impugned order is in manifest error of law for failing to demonstrate that the required statutory ingredients of Section 2(1)(ja) of the Act are attracted in this case and in any case, it is submitted that the invention as claimed in the instant Application fulfils the requirements under Section 2(1)(ja) of the Act and demonstrates inventive step; thus, the impugned order suffers from serious non-application of mind, is patently incorrect and is liable to be set aside.

2.5 The impugned order is in manifest error of law since it holds that the invention claimed in the instant Application lacks inventive step in the light of the disclosure in Document D2.

2.5.1 It is submitted that although the Respondent has extracted certain portions of Document D2 in the impugned order and referred to SHVT-140 construct as disclosed therein; the Respondent has failed to appreciate and consider that there is no experimental data provided regarding either the

stability or the efficaciousness of the S-HVT-140 construct. Therefore, there was no reason for a person skilled in the art to pursue this particular construct over the large number of equally plausible alternatives to try. It is submitted that even more importantly, in the S-HVT-140, the coding sequences for the ILTV gD protein and ILTV gI protein are inserted in the UL 54.5 site and the coding sequence for the NDV F protein is placed into the US2 site. It is submitted that this construction was not even within the scope of the claimed invention. Thus, it is submitted that as per Document D2, in the HVT-140 construct, the ILTV gD and gI coding sequences are in the UL54.5 locus (i.e., the Xho1 site of the EcoR1 #9 - BamH1 #10 fragment of HVT), whereas the NDV-F gene in the US2 locus. In stark contrast to the above, the limited alternatives for the presently claimed invention are:

- the ILTV gD/gI and NDV-F inserts are all in UL54.5 locus, or
- the ILTV gD/gI and NDV-F inserts are all in US2 locus, or
- the ILTV gD/gI insert (the first nucleic acid) is in US2 locus (the first insertion site), and the NDV-F insert (the second nucleic acid) is in between the UL7 and UL8 (the second insertion site).

2.5.2 Thus, it is submitted that the impugned order is in manifest error of law for failing to demonstrate that the required statutory ingredients of Section 2(1)(ja) of the Act are attracted in this case and in any case, it is submitted that the invention as claimed in the instant Application fulfils the requirements under Section 2(1)(ja) of the Act and demonstrates inventive step; thus, the impugned order suffers from serious non-application of mind, is patently incorrect and is liable to be set aside.

2.6 The impugned order is in manifest error of law since it holds that the invention claimed in the instant Application lacks inventive step in the light of the disclosure in Document D3.

2.6.1 It is submitted that the Respondent by extracting certain portions of Document D3 in the impugned order presumably asserts that Document D3 discloses the use of the UL54.5 open reading frame of avian viruses and the UL 43 open reading frame of Marek's disease virus. It is submitted that presumably the Respondent further asserts that Document D3 discloses the insertion of ILTV gD and gI genes and the E.coli β-galactosidase (lacZ) marker gene inserted in a recombinant MDV1. It is submitted that however, the Respondent failed to appreciate and consider that Document D3 fails to teach a stable and efficacious recombinant HVT vector that encodes ILTV gD and gI, and the NDV F protein taught and claimed by the present

invention and fails to steer the person skilled in the art to the present invention.

2.6.2 It is submitted that a critical difference between the present invention and Document D3 is the fact that the vector constructs of the claims of the instant Application are genetically stable and immunologically effective as multivalent-insert HVT vector vaccines against NDV, ILTV, as well as MDV whereas no such vectors were provided by Document D3. It is submitted that whatever the value of the disclosure in Document D3 may be, these disclosures must be understood within the context of all of the alternative constructs presented, discussed, or proposed. It is thus submitted that Document D3 was not a pointer to the invention claimed in the instant Application. Accordingly, the selection of the specific constructs of the claims of the instant Application is neither indicated nor suggested in Document D3, and requires many unsuggested choices, from multiple lists of equally likely candidates.

2.6.3 Thus, it is submitted that the impugned order is in manifest error of law for failing to demonstrate that the required statutory ingredients of Section 2(1)(ja) of the Act are attracted in this case and in any case, it is submitted that the invention as claimed in the instant Application fulfils the requirements under Section 2(1)(ja) of the Act and demonstrates inventive step; thus, the impugned order suffers from serious non-application of

mind, is patently incorrect and is liable to be set aside.

2.7 The invention claimed in the instant Application has been granted in the United States of America and Europe.

2.8 That without prejudice to the above and alternatively, the Appellant has submitted by way of MP No. 24/2020 in the instant appeal and also annexed in, an alternative set of claims which independently conforms to the requirements under the Act. Having been denied an effective opportunity of hearing before the Respondent as detailed in the appeal, the Appellant herein has no choice but to make this request only at this stage. This request is being pursued at the earliest possible opportunity in this appeal procedure and the same may be in considered in the alternative, in the interests of justice.

3. We have analysed the submission *vis -a -vis* the order of the learned Controller. The operating portion of the order is quoted herein below:

> *"From the combined teaching of cited art D1 to D3, site of insertion such as UL54.5 and US2 site are already well known and there is contemplation in cited art D1 and D2 to have multivalent protection by inserting already known foreign DNA such as ILTV gD protein and NDV F in non essential region to construct recombinant chimeric virus. Distinguishing inventive feature in view of cited art D1 to D3 has not been clearly defined in claim 1. In my opinion, it is obvious to person skilled in art to construct recombinant nonpathogenic virus rMDVnp by inserting already known*

foreign DNA ILTV gD and NDV F gene at already known site such as US2 site, or UL54.5 site.

In view of above facts and finding and hearing proceedings under section 14, I refuse to grant patent on the Patent application, 2681/CHENP/2014 under Section 15 of the Patents Act, 1970 on the ground of

a) Not an invention u/s 2(1) (ja) of the Patents Act, 1970."

4. It is evident that the order of the leaned Controller does not keep pace with the settled principles of determination of inventive step. The method of determination of the inventive step is now well-settled through various judicial pronouncements as well as the Manual of Patent Office Practice and Procedure -2019[1] which has incorporated various court orders in this regard. This Board has recently emphasized the method to be adopted for determination of inventive step in series of orders i.e. PHARMACYCLICS, LLC case[2]. For the sake of brevity we incline not to repeat it here again.

5. We have reviewed that all the three citations relied by the learned Controller, is also referred to in the ISR Report and the patent has been granted in various other jurisdiction as indicated by the appellant and also informed to the respondent through Form 3 filed dated 20/05/2019.

6. The appellant, through their Miscellaneous Petition, requested us to consider the suggested amendment of the claims. Without going through the merit of the case, we accept the amendments as submitted by the appellant. We have found that they have incorporated features of claim 5 in the principal claim and tried to restrict the claims. Further, the appellant is also directed to incorporate the features of existing claim 2 suitably in the principal

[1] Available at http://ipindia.nic.in/manual-patents.htm

[2] OA/46/2020/PT/DEL

claim to make the claim properly definitive. Also, any further amendments of the claims should be made, if required by the learned Controller.

7. We, therefore, direct the appellant to file the amended set of claims to the respondent within 3 week from the issuance of this order.
8. We set aside the order of respondent no.2 and direct her to decide the matter on merit afresh, in accordance with law, based on the amended set of claims, within 2 months of issuance of this order and if required, after giving an opportunity of being heard to the appellant.
9. Keeping in view the above facts and circumstances, the instant appeal is allowed on the above mentioned conditions. No cost.

-Sd/-

(Dr. B.P. Singh)
Technical Member (Patents)

-Sd/-

(Justice Manmohan Singh)
Chairman