2024:MHC:3902

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 14.11.2024

Pronounced on : 21.11.2024

CORAM:

THE HON'BLE MR. JUSTICE ABDUL QUDDHOSE

(T) CMA (PT) No.119 of 2023

1.Intervet International B.V.
Through its Authorised Representative
J.J.L.Mestrom

2.Microbial Chemistry Research Foundation,
Through its Authorised Representative
Masakatsu Shibasaki .. Appellants

-vs-

Deputy Controller of Patents & Design,
Intellectual Property Office Building,
CP-2 Sector V, Salt Lake City,
Kolkata - 700 091. .. Respondent

Prayer: This Civil Miscellaneous Appeal filed under Section 117-A of the Patents Act, 1970 prays that this Court may be pleased to allow the present appeal, pass an order setting aside the impugned order of the respondent dated 29.12.2017 and pass an order granting a patent on Indian Patent Application No.449/CHENP/2010 and issue consequential directions to effectuate such grant.

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For appellants : Ms.Vindhya S.Mani for
Mr.Lakshmi Kumaran and
Mr.Sridharan

For respondent : Mr.A.R.Sakthivel,
SPCGSL

JUDGMENT

This appeal has been filed, challenging the order dated 29.12.2017 refusing to grant patent to the appellants for their invention on the ground that the so called invention claimed by the appellants is not patentable under Section 3(d) and 3(e) of the Patents Act, 1970.

2.According to the appellants, the impugned order is a non-speaking order and by total non-application of mind, the claimed invention of the appellants, which relates to solvated and non-solvated crystalline forms of 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide, which exhibits advantageous physical and chemical stability, thermodynamic, kinetic and filtration properties, which has technical advancements as well as economic significance and is also not obvious to a person skilled in the art, grant of patent to the appellants has been refused by the respondent by wrongly applying Section 3(d) and 3(e) of the Patents Act, 1970.

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3.Learned counsel for the appellants drew the attention of this Court to the impugned order and would submit that the impugned order violates the principles of natural justice as the reasoning, provided by the respondent to arrive at the conclusion, is insufficient. According to her, the respondent failed to take into consideration the declaration of the expert Dr.Ralf Warrass, who clearly demonstrated the higher stability of the claimed crystalline form 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide, the claimed invention of the appellants, which is advanced than the amorphous forms disclosed in the cited prior arts and also the other polymorphous forms. According to her, the respondent, under the impugned order, has arbitrarily held that superior stability data does not constitute enhancement of the known efficacy and therefore, Section 3(d) of the Patents Act gets attracted. According to the learned counsel for the appellants, none of the facts as to superior stability of the claimed crystalline form of 20, 23 - dipiperidinyl-5-O-mycaminosyl-tylonolide are in dispute and it is not the case that the respondent has questioned the correctness of these submissions.

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4.Learned counsel for the appellants, in support of the aforesaid submission, relied upon a judgment of the Delhi High Court in the case of **Regents of University of California vs. Union of India and others reported in 2019 (79) PTC 55 (Del)** and would submit that as per the said decision, the Controller should indicate the reasons as to how he has rejected the affidavit of known experts. According to her, in the impugned order, no reasons have been given by the respondent for ignoring the declaration of the expert Dr.Ralf Warrass and therefore, the impugned order is a non-speaking order. Learned counsel for the appellants also submitted that stability plays an important role in the therapeutic efficacy of a drug. According to her, a more stable drug will not decompose into its by products resulting in higher and longer bio-availability, which in turn results in higher therapeutic efficacy.

5.In support of her submission, she relies upon Section 7.2.4.3 of Chapter 7 of the Book titled Nanoscale Fabrication, Optimization, Scale-up and Biological Aspects of Pharmaceutical Nanotechnology. According to her, the pending claims 1-9 of the appellants' patent application are fully in

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compliance of the statutory requirements for grant of patent and therefore, the respondent's finding is contrary and therefore, the impugned order has to be set aside.

6.Learned counsel for the appellants also contended that the impugned order is in manifest error of law and ex facie erroneous because the respondent has not followed the guidelines issued by the Patent Office. According to her, in paragraph No.1.17 of the guidelines for examination of Patent Applications in the field of Pharmaceuticals, issued by the Controller General of Patents, Designs and Trademarks in October 2014, guidelines have been given to the respondent for examination of pharmaceuticals patents. But the said guidelines have not been followed by the respondent under the impugned order. According to the learned counsel for the appellants, the respondent has effectively admitted in the impugned order that the instant claimed polymorphic form of the compound of Formula 1 is a new/novel form (crystalline form) of dipiperidinyl-5-O-mycaminosyl-tylonolide. Therefore, having admitted that the appellants' claimed invention is a new form of known substance, the respondent ought to have granted patent to the appellants. According to the learned counsel for the appellants,

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the respondent has erred in applying Section 3(e) of the Patents Act as well to the invention claimed by the appellants.

7.According to her, Section 3(e) of the Patents Act is not attracted. According to the learned counsel for the appellants, the active ingredient of the claimed composition i.e. 20,23 dipiperidinyl-5-O-mycaminosyl-tylonolide is admittedly a new or novel ingredient and there is data on record suggesting that the active ingredient has unexpected qualities of superior stability and is technically advanced over the other forms of cited prior arts. Learned counsel for the appellants would also submit that Section 64(1)(h) of the Patents Act further elaborates the requirement under Section 10(4)(a) of the Act, such that it provides the description of the method or the instructions for working of the invention with complete specification, which is sufficient to enable a person skilled in the art, to work on the invention. According to her, the said requirement does not in any manner mandate providing synergistic data of the related activities of the individual constituents of the claimed composition. Therefore, according to her, the respondent had committed an error by applying Section 3(e) of the Act for

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refusing to grant patent.

8.Learned counsel for the appellants would submit that the respondent has faltered at the stage of examination itself and that there has been no application of mind whatsoever on the part of the respondent in determining the patentability of the subject matter, claimed by the appellants in the Patent Application. To summarise her submissions, learned counsel for the appellants would submit that it is amply clear that the claimed invention is an important technical advancement over the existing prior arts. Further, according to her, the respondent, under the impugned order, has erroneously held that the subject matter of the appellants' invention is not patentable as the provisions of Sections 3(d) and 3(e) of the Patents Act is attracted. Learned counsel for the appellants would also submit that a similar patent application has been granted in multiple jurisdictions including USA, Russia, Japan, Australia and other countries.

9.Learned counsel for the appellants also relied upon a judgment of the Hon'ble Supreme Court in the case of **Manohar vs. State of Maharashtra and another reported in 2012 (13) SCC 14** and would submit that the application of mind and recording of reasoned decisions are

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the basic elements of natural justice. Relying upon the aforesaid decision, learned counsel for the appellants would submit that since the impugned order has been passed by total non-application of mind and the same is not supported by reasons, the impugned order has to be set aside by this Court on account of violation of principles of natural justice.

10.Learned counsel for the appellants also drew the attention of this Court to a decision rendered by the Delhi High Court dated 30.08.2022 in **C.A. (Comm.IPD-PAT)6/2021 and I.A. 12828 of 2021 in the case of DS Biopharma Limited vs. The Controller of Patents and Designs and another** and would submit that there is no necessity for the appellants to plead that there is an enhanced therapeutic efficacy in the appellants' invention and it would suffice if the appellants are able to prove that there is an enhanced therapeutic efficacy in their invention. According to her, as per the aforesaid decision, it is clear that only in cases of application seeking for revocation of the patent, the said applicant must plead as well as prove that the invention is not patentable. According to the learned counsel for the appellants, the appellants, having proved that their invention has enhanced therapeutic efficacy, the respondent ought to have granted patent to the

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appellants.

11.On the other hand, the learned SPCGSL (Special Panel Counsel) for the respondent would reiterate the contents of the impugned order and would submit that only due to the fact that the appellants failed to satisfy that their invention has enhanced therapeutic efficacy, the appellants have been refused to be granted with the patent under the impugned order. According to him, the appellants completely failed to establish before the respondent that the enhanced stability resulted in enhanced therapeutic efficacy. He also relied upon a judgment of the Hon'ble Supreme Court in the case of **Novartis AG vs. Union of India and others reported in MANU/SC/0281/2013** and would submit that the claimed invention of the appellants has failed to meet the standards prescribed by the Hon'ble Supreme Court for the grant of patent to a new form of pharmaceutical substance. By relying upon the said judgment, he further submitted that since the enhanced therapeutic efficacy is the only measure of enhanced efficacy, the increased stability is insufficient unless it is shown to result in enhanced therapeutic efficacy. Learned SPCGSL for the respondent also submitted that every aspect of the appellants' claimed invention has been considered by the respondent and only thereafter, the impugned order came

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to be passed refusing to grant patent to the appellants. According to him, the impugned order is a speaking order and the respondent has not committed violation of principles of natural justice.

Discussion:

12.The subject matter of the claimed invention relates to solvated and non-solvated crystalline forms of 20, 23 dipiperidinyl-5-O- mycaminosyl-tylonolide. The appellants claim that their invention exhibits increased physical and chemical stability, thermodynamic, kinetic and filtration properties. The appellants also claim that their invention has technical advancements as well as economic significance over what is known in art and is also not obvious to a person skilled in art. A categorical assertion has been made by the appellants that the prior art Documents relied upon by the respondent, namely, D1 and D2 do not disclose all the elements of the claimed invention.

13.According to the appellants, the document D1 does not disclose the crystalline 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide or solvates, as claimed in the pending claims 1-9 of the instant patent application and the same has also been acknowledged by the respondent in the First

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Examination Report dated 21.10.2016 stating that "D1 does not disclose crystalline 20, 23 dipiperidinyl-5-O-mycaminosyltylonolide, according to the current claims 1-4 or solvates according to claims 5 and 6. D1 does not disclose the use of said crystalline forms or solvates for treating disease in an animal." Under the settled rule of novelty, it is necessary that the prior art is an enabling disclosure, i.e., each element of the application must be disclosed in the prior art document. However, under the impugned order, no reasons have been given as to why the prior art document D1 was taken into consideration for refusing to grant patent despite the fact that the respondent in the First Examination Report dated 21.10.2016 has observed that "D1 does not disclose crystalline 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide, according to the current claims 1-4 or solvates according to claims 5 and 6. D1 does not disclose the use of said crystalline forms or solvates for treating disease in an animal". The prior art document D2 cited by the respondent was published on 31.01.2008, which is later than the priority date of the instant application submitted by the appellants i.e. on 26.07.2007. However, under the impugned order, without giving any reason, the respondent has relied upon the prior art document namely, D2, which is subsequent to the date of the appellants' patent application i.e. on

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26.07.2007.

14.Therefore, this Court is of the view that the objections raised by the appellants with regard to the prior art documents, namely, D1 and D2, referred to supra, have not been considered, on merits and in accordance with law. The requirement to show enhanced efficacy by the appellants arise as per Section 3(d) of the Patents Act, 1970, which reads as follows:

> *3....*
>
> *(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'*

15.The respondent, under the impugned order, has not given an opportunity for the appellants as per the explanation to Section 3(d) of the Act to prove that the appellants' claimed invention is a new form of known substance, having enhanced therapeutic efficacy. Having not being granted with such an opportunity as per explanation to Section 3(d) of the Act, it is clear that the impugned order has been passed in violation of Section 3(d) of

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the Patents Act, 1970 and also in violation of principles of natural justice. There is no reasoning whatsoever found in the impugned order to indicate that the crystalline form 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide as claimed by the respondent in the pending claim 1 of the patent application constitutes mere discovery of a new form of the known substance. The appellants had submitted a declaration of Dr.Ralf Warrass, an expert, which according to them, clearly demonstrated the higher stability of the claimed crystalline form 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide and the stable crystalline forms of tylonolide compound (as claimed in claim 1) is technically advanced than the amorphous forms, disclosed in the cited prior arts and also the other polymorphous forms. But the Expert Affidavit of Dr.Ralf Warrass has not been given due consideration in the impugned order.

16.The decision of the Delhi High Court in the case of **Regents of University of California vs. Union of India and others reported in 2019 (79) PTC 55 (Del)** supports the case of the appellants as in the said decision also, the impugned order refusing to grant patent was completely silent on the affidavit of experts, submitted by the appellants. The Delhi High Court

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held that the affidavit of the experts submitted by the appellants cannot be considered to be irrelevant without giving any reason for coming to such a conclusion and the Controller was required to indicate the reasons as to why the affidavit of experts, submitted by the appellants, has been rejected. Stability plays an important role in the therapeutic efficacy of a drug. The appellants claim that a more stable drug will not decompose into its by-products resulting in higher and longer bio-availability, which in turn results in higher therapeutic efficacy. The appellants therefore submitted that the pending claims 1-9 of the instant patent application is fully in compliance with the provisions of Section 3(d) of the Act and the respondent's finding is contrary to the same. There is no reasoning given by the respondent in the impugned order with regard to the aforesaid contention of the appellants. The guidelines issued by the Patent Office in October 2014, which makes it clear in paragraph 1.17 that "for examination of pharmaceutical patents, incorporating the analysis of the Courts with the objective that the guidelines will help improve the examination standard and will introduce harmonious practice amongst the technical officers of the system", has not been adhered to as the impugned order suffers from violation of principles of natural justice and it is a non-speaking order with regard to the contentions of the

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appellants.

17.In paragraph 10.12, Section 3(e) of the guidelines for examination of Patent Applications in the field of Pharmaceuticals, issued by the Controller General of Patents, Designs and Trademarks in October 2014 is simply a codification of the intent to prevent patents on the mere placing together of old integers. This Court fails to understand as to why under the impugned order, the respondent having admitted that "the instant claimed polymorphic form of the compound of Formula 1 by the appellants is a new/ novel form (crystalline form) 20, 23 dipiperidinyl-5-O-mycaminosyl-tylonolide for an already known compound has refused to consider the case of the appellants for grant of patent. No reasons have been given by the respondent under the impugned order for arriving at such a conclusion. Section 64(1)(h) of the Patents Act further elaborates the requirement under Section 10(4)(a) of the Act such that it provides the description of the method or the instructions for working of the invention with complete specification, which is sufficient to enable a person skilled in the art to work on the invention.

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18.Moreover, as seen from Section 10(4)(a) of the Patents Act, it does not mandate providing synergistic data of the related activities of the individual constituents of the claimed composition. No reasons have been given by the respondent with regard to the contentions of the appellants in the impugned order for applying Section 3(e) of the Patents Act, 1970. In the impugned order, the respondent has observed that superior stability data can never be interpreted as superior therapeutic efficacy. The reasons for coming to such a conclusion with regard to the appellants Patent Application has not been given by the respondent under the impugned order. The appellants categorically contend that their claimed invention has enhanced therapeutic efficacy and in support of the said contention, they have produced materials, which includes the Declaration of Dr.Ralf Warrass, an Expert in the field. Since the respondent has not given reasons as to why the appellants' claimed invention will not have enhanced therapeutic efficacy and the appellants have also not been provided with an opportunity to submit further explanation to prove that their invention has enhanced therapeutic efficacy, this Court is of the considered view that the impugned order is a non-speaking order and has been passed in violation of principles of natural justice.

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19.In the decisions, relied upon by the learned counsel for the appellants in the case of **Novartis AG vs. Union of India (UOI) and others reported in MANU/SC/0281/2013** and in the case of **DS Biopharma Limited vs The Controller of Patents and Designs and another reported in C.A. (Comm.IPD-PAT) 6/2021 dated 30.08.2022**, it has been held that it would suffice if the applicants are able to prove that their claimed invention has enhanced therapeutic efficacy and there is no necessity to take a specific plea in their application that the claimed invention has therapeutic efficacy. Only in cases of revocation of patents, a specific plea will have to be taken that the invention does not have enhanced therapeutic efficacy and the person seeking revocation also has to prove that the invention does not have therapeutic efficacy and therefore, it is hit by Section 3(d) of the Patents Act. The Patents Act also provides for amendment of the patent application under Section 59, which reads as follows:

> *'59. Supplementary provisions as to amendment of application or specification -*
> *(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made*

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except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment;

(2) Where after the date of grant of patent any amendment of the specification or any other documents related thereto is allowed by the Controller or by the Appellate Board or the High Court, as the case may be —

(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;

(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and

(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.

(3)In construing the specification as amended, reference may be made to the specification as originally accepted.'

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20.As seen from the aforementioned Section, it is clear that by way of disclaimer, correction or explanation, the amendment application can be filed. In the case on hand, the appellants categorically state that their invention has enhanced therapeutic efficacy and therefore, it will not be hit by any of the subsection of Sections 3 and 4 of the Patents Act. The case, as pleaded by the appellants is not a case of altering the appellants' Original Patent Application. The appellants, at no point of time, claims to have changed their stand with regard to the contents of the Original Patent Application, submitted by them. Therefore, in order to strengthen their case for the grant of patent as prayed for in the Patent Application, the appellants are legally entitled to seek for amendment of their Original Patent Application to give further explanation to strengthen their case for the grant of patent as per the Original Application.

21.Section 59 of the Patents Act, 1970 legally empowers the appellants to file an Amendment Application by way of disclaimer, correction or explanation in respect of their Original Patent Application. In the impugned order, the respondent has not emphasised enough on the

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points raised by the appellants and no proper analysis has been done on the contentions of the appellants before arriving at the impugned decision. The reasoned orders are the mandate for refusing to grant patent by the respondent. The principles of natural justice are also indispensable and compliance with the doctrine of audi alteram partem are mandatory in the cases of this nature. This Court understands that it cannot assume the role of Controller and substitute the decisions given by the quasi-judicial authority without any valid reason. However, it must be essentially noted that the law is clear as to decision-making process of quasi-judicial authorities should adhere to the principles of natural justice and should pass speaking orders.

22.For the foregoing reasons, the impugned order dated 29.12.2017 passed by the respondent, refusing to grant patent to the appellants, suffers from violation of principles of natural justice and it is a non-speaking order with regard to the contentions of the appellants, which was also raised before the respondent and therefore, the impugned order has to be quashed and the matter has to be remanded back to the respondent for fresh consideration, on merits and in accordance with law, within a time frame to be fixed by this Court.

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23.In the interest of justice, this Court deems it fit to direct the respondent to appoint an Officer other than the officer, who issued the impugned order for the purpose of adjudicating the appellants' Patent Application and in order to avoid the possibility of pre-determination.

24.In the result, the impugned order dated 29.12.2017 passed by the respondent is set aside and this appeal is disposed of and the matter is remanded back for re-consideration, on merits and in accordance with law, within a period of six months by issuing the following directions:

a)In the ends of justice and in order to avoid the possibility of pre-determination, an officer other than the officer, who issued the impugned order, shall undertake the re-consideration;

b)Such re-consideration shall be undertaken by taking into account the observations set out in this judgment;

c)Amendment applications, if any, to the complete specification or claims shall be permitted if within the frame work of the complete specification;

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d)A fresh order in Indian Patent Application No.449/CHENP/2010 shall be issued within six months from the date of receipt of a copy of this order.

No costs.

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Index : Yes/ No
Speaking Order : Yes/ No
NCC : Yes/ No

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To

Deputy Controller of Patents & Design,
Intellectual Property Office Building,
CP-2 Sector V, Salt Lake City,
Kolkata - 700 091.

pre-delivery judgment in
(T) CMA (PT) No.119 of 2023

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