IN THE HIGH COURT AT CALCUTTA
ORIGINAL JURISDICTION
ORIGINAL SIDE
[COMMERCIAL DIVISION]

BEFORE:
The Hon'ble Justice Ravi Krishan Kapur

IPDPTA 61 OF 2023

BIOTRON LIMITED
VS
THE CONTROLLER GENERAL OF PATENTS & DESIGNS & ANR

For the Appellant : Mr. S. Majumdar, Advocate
Mr. Paritosh Sinha, Advocate
Mr. K.K. Pandey, Advocate
Mrs. Mitul Dasgupta, Advocate
Ms. A. Majumdar, Advocate
Ms. Enakshi Saha, Advocate

For the Controller of Patents : Mr. Swatarup Banerjee, Advocate
Mr. T. Bhanja, Advocate

Reserved on : 17.07.2023

Judgment on : 17.11.2023

Ravi Krishan Kapur, J.:

1. This is an appeal under section 117A of The Patents Act, 1970 against an order passed by the Assistant Controller of Patents and Designs dated 17 September 2015 rejecting the appellant's Patent Application No. 290/KOLNP/2008.
2. The subject invention pertains to novel compositions of compounds claimed to be effective against treating and preventing viral infections. It is alleged that the subject invention is potent against HIV, HCV and Dengue virus. It is also contended that compounds with cyclic substitutions are

better than compounds with non-cyclic substituents. Thus, the subject invention is technically advanced as compared to other known compounds.

3. The application was filed on 21 January 2008. Upon request for examination on 18 June 2009, the First Examination Report (FER) was issued on 29 May 2012 raising an objection on the ground of lack of inventive steps with reference to prior arts D1-D5. Thereafter, a response was submitted by the appellant with amendments. Being dissatisfied with the response, the respondent authorities provided the appellant with an opportunity of hearing on 28 August 2015. Ultimately, the impugned order was passed rejecting the patent application on the ground of lack of inventive steps under sections 2(1)(j) and 2(1)(ja) of the Act, insufficient disclosure under section 10(4) of the Act and non-patentable subject matter under section 3(d) of the Act.

4. It is contended that the impugned order is erroneous insofar as it is based on a selective reading of the specifications of the subject invention. The prior arts cited in the FER and at the hearing were prior arts which the appellant had themselves relied on. The prior arts were made available after search and preliminary examination carried out by the International Searching Authority (ISA). Any reliance on the views of the ISA and IPER are also misplaced. It is contended that all the prior arts were common in all other countries where the respective Patent Offices had granted patent to the appellant. Nevertheless, it is only the respondent authorities which have rejected the appellant's claim despite considering the same prior arts. It is also contended that the amended claims were restricted to

acylguanidines with a naphthoyl substitution having cyclic group substitutions and that there was comparative scientific data relied on by the appellant to demonstrate that the compounds with cyclic substitutions have better activity than compounds with acyclic substitutions.

5. In respect of the objections raised under section 3(d) of the Act, the appellant contends that the compounds in the subject invention are not derivatives of the compounds of the prior art as has been recorded in the impugned order. The impugned order does not indicate as to how a new form of a known substance can be derived from a known substance and also how the known substance does not differ significantly in properties with regard to efficacy. It is also claimed that the compounds in the subject invention are novel and are not derivatives of a known substance. In support of their contentions, the appellant relies on the decision in *Novartis AG vs UOI & Ors, AIR 2013 SC 1311.*

6. It is further contended that in view of section 10(4) of the Act, the appellant has disclosed the best methods for working of the subject invention. The specifications provided by the appellant enable the preparation of the compounds and also provide for vitro data as regard to the activity of the claimed compounds as well as compounds with non-claimed acyclic substituents which amount to comparative data. It is further contended that the proposal to delete compounds by the appellant with non-cyclic substitutions does not amount to self-admission of lack of inventive steps. Such amendments are permissible under section 59(1) of the Act by way of disclaimer, correction or explanation. However, the

finding that the appellant failed in amending the description has only been raised in the impugned order. The amendments carried out by the appellant were declined by the respondent without providing any reasons. In support of their contentions, the appellant relies on *May & Baker Limited Vs Boots Pure Drug Co Ltd, (1950) 67 RPC 23* to contend that amendments may be carried out to an application and such amendments cannot be considered as admissions. It is also contended that the respondent authorities have failed to consider the fact that similar patent applications had been granted in other countries despite having been compared with the same prior arts.

7. On behalf of the respondent it is contended that the appellant has failed to demonstrate that the subject invention involves any inventive step or technical advancement. The compounds in the subject invention are the same as that of the prior art except for the fact that the position of bonding of the substituents are different. The amendments carried out by the appellant also do not demonstrate any enhanced efficacy as contemplated under section 3(d) of the Act. It is contended that no clinical comparative study with the prior art compounds were disclosed to the respondents. The appellant has also failed to demonstrate any change in the nature of the compound which would have shown “hydrophbicity of the ring system” and that the appropriate length of the substituents were changed or were significantly different from compounds in the subject application in comparison with the prior arts D1 and D2. It is further contended by respondent that in terms of section 10(4) of the Act the appellant ought to have disclosed the best method for performing the

invention which is only known to the appellant for which the appellant claims protection. It was also the duty of the appellant to provide clinical comparative data which would demonstrate that the said application compound was more efficacious and inventive than the prior arts. The respondent also contends that repeated amendments were carried out resulting in change of the original product. In support of their contentions, the respondent relies on *Nippon A and L Inc vs. Controller of Patents, 2022 SCC Online Delhi 1909* and *Novartis AG vs. UOI & Ors, AIR 2013 SC 1311.*

8. Drug development is a lengthy and complex process. Once new classes of compounds have been found and shown to have some degree of activity a patent application is filed to secure the priority date following which further screening is required before a compound ultimately makes its way to clinical trials. The extent of activity of the said compound being one of the many factors in this trial process, drug availability profiles, *in vitro* toxicity, modelling, acute toxicology studies and *in vivo* activity are some of the other major factors taken into consideration. Only upon achieving satisfactory levels are such compounds marketed after fulfilling the market regulatory norms. Thus, the proposal to make additions, alterations or deletions after filing of the subject patent does not amount to self-admission or acceptance of lack of novelty or inventive steps. Such amendments are permissible under section 59(1) of the Act whether by way of disclaimer, correction or explanation. Additionally, disclaimers are also provided with an object to limit the scope of the invention claimed or to remove doubts as to the meaning of the specification. This further

reduces the ambit of monopoly renouncing the previous claim in its fullest scope and limit. Hence, the finding in the impugned order that amendments carried out by the appellant is proof or admission of lack of novelty is erroneous.

9. Moreover, the finding that amongst the five prior arts cited, prior art D1 & D2 are identical and similar to the subject invention is also without basis and untenable. The unique activities of the subject compound were demonstrated in Table 1 and 2 wherein a comparative study had been provided showing that the cyclic substitutions have a better activity than the compounds with acyclic substitutions. On the basis of the comparative study, it was alleged that the cyclic substituents demonstrate an average bacterial score of the compounds against 3 viral antigens Vpu, HCV p7 and Den M as compared to the non-cyclic substitutions which do not have any activity against the said antigens. Thus, there was comparative scientific data relied on by the appellant to show that compounds with cyclic substitutions have a better activity than compounds with acyclic substitutions. The impugned order fails to consider and deal with the comparative studies disclosed and relied on by the appellant. On the contrary, the Controller has in passing the impugned order arrived at a finding only on a selective reading of the subject specification.

10. It has been held in the impugned order that the disclosure made in terms of section 10(4) of the Act was insufficient. Specifications enable a skilled person to have access to the knowledge of the best ways for preparation of the claimed compounds and also provide *in vitro* data as regards to the

activity of the claimed compound along with its comparative data. Despite all necessary descriptions having been sufficiently furnished by the appellant and subsequent amendments being carried out, the impugned order fails to deal with this aspect of the matter. In order to appreciate the enhanced efficacy of a claimed compound, the Controller was bound to take all such amendments into consideration and provide reasons for rejecting the same. The guidelines to analyse the enhanced efficacy of chemical and pharmaceutical compounds have been laid down in *Novartis AG vs. UOI & Ors AIR 2013 SC 1311*:

> *87. The amended portion of Section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.*
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> *168. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment.*

Accordingly, section 3(d) of the Act does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances. This aspect of the matter has also not been dealt with in the impugned order.

11. Moreover, although the appellant's claim has been rejected on the ground of non patentability under section 3(d) of the Act, the impugned order does not indicate the known substance or its known efficacy or the new form of the known substance in arriving at such a conclusion. Section 3(d) of the Act requires the existence of a "known compound" and not

"known compounds". The impugned order does not deal with this aspect of the matter.

12. Section 8 of the Act mandates that an applicant is to file all necessary details and undertakings in respect of the same or substantially same invention pending prosecution in other Patent Office in any other country outside India. In this context, the Ayyangar Report had recommended as follows:

> *"It would be of advantage therefore if the applicant is required to state whether he has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent Offices of such countries on the ground of want of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries upto the date of acceptance of the application."*

13. Thus, every applicant is bound to furnish information relating to objections raised in such prosecution, both in respect of novelty and patentability of the subject invention and all other information as and particulars which may be required by the Controller to adjudicate the said application. Admittedly, the appellant had complied with the mandate of the above section and provided all details of all such patent applications applied for and granted in other jurisdictions. In such circumstances, although not binding, this aspect of the matter ought to have been considered before passing of the impugned order (*Stempeutics Research Pvt Ltd vs. Assistant Controller of Patents (OA/3/2017/PT/CHN).*

14. For the foregoing reasons, the impugned order dated 17 September 2015 is unsustainable and set aside. The matter is remanded to the respondent authorities to adjudicate the subject patent application afresh including

the question of patentability after giving an opportunity of hearing to the appellant. It is made clear that any finding insofar as the merits of the case are concerned are *prima facie* and not binding. With the aforesaid directions and to the aforesaid extent, IPDPTA 61 of 2023 stands allowed.

(Ravi Krishan Kapur J.)