

M/s Medimpex (India) Pvt. Ltd.

Vs

Drug Controller-Cum-Chief Licensing Authority and Others

Civil Appeal No. 4914-15 of 1989

(S. Ranganathan, N. D. Ojha, J. S. Verma JJ)

05.12.1989

JUDGMENT

OJHA, J. –

1. Special leave granted.

2. These appeals by special leave have been preferred against the judgment of the Patna High Court dated February 17, 1989 in C.W.J.C. No. 5943 of 1985 and C.W.J.C. No. 4788 of 1986. The appellant was granted a licence in 1969 under the Drug and Cosmetics Act, 1940 (the Act) and the Drugs and Cosmetics Rules (the Rules) to manufacture nine drugs. The said licence was renewed from time to time. On an application being made in this behalf by the appellant six more drugs were included in the licence by order of the Licensing Authority dated January 25, 1975. One much item was Santonin and Calomel tablets or any brand name. According to the appellant before the order dated January 25, 1975 was passed by the Licensing authority another application was made on April 15, 1974 by the appellant stating that it had decided to manufacture Santopar brand name instead of Santonin and Calomel tablets and that the said product may be considered as one of the items of manufacture. It, however, appears from the list enclosed to the order dated January 25, 1975 that the request made in the said application was not granted and the item added was Santonin and Calomel tablets or any brand name as initially applied for. Subsequently the appellant made an application for the renewal of the licence for the period between January 1, 1975 and December 31, 1976. However, along with this application no application for inclusion of any additional item as contemplated by Rule 69(5) of the Rules was made. This fact as is apparent from the judgment appealed against was not disputed by the appellant. In the year 1982 M/s. Nawa Dawakhana, respondent 2 applied for and was granted licence for manufacture of the drug Santopur. This grant of licence to respondent 2 was challenged by the appellant before the High Court in C.W.J.C. No. 2747 of 1983. The said writ petition was opposed by respondent 2 and one of the questions arose as to whether the appellant had ever been granted licence to manufacture Santopar on account of which the grant of licence to respondent 2 could be held to be illegal. Reliance on behalf of the appellant seems to have been placed on a list attached to a certificate dated June 9, 1976 containing Santopar tablets also. This certificate, according to the appellant, was issued to it along with a letter dated June 10, 1976 granting renewal of its licence for the period between January 1, 1975 and December 31, 1976. For respondent 2 it was contended that the said certificate was forged. The High Court took the view that since disputed questions of fact were involved a thorough probe was needed in the matter. On this view the writ petition was disposed of on August 2, 1984 by issuing a direction to the Drug Controller to hold an inquiry after giving reasonable opportunity to the parties to adduce evidence in support of their respective claims and to pass final orders in the matter after hearing them. The Drug Controller held an inquiry as directed by the High Court and inter alia found that

the photostat copy of the renewal certificate relied on by the appellant did not bear any impression of the signature of the Chief Licensing Authority and that the list of 23 items including Santopar appeared to be fabricated and forged document. In this connection he pointed out that no duplicate copy of the said list was available in the relevant file which was serially numbered. He also held that the appellant had been manufacturing the drug Santopar with effect from April 15, 1974 without any licence and thereby contravened the provisions of the Act and the Rules. He further held that M/s. Naya Dawakhana, respondent 2 was legally manufacturing the drug Santopar under a valid licence dated June 11, 1982.

3. Aggrieved by the aforesaid order the appellant filed C.W.J.C. No. 169 of 1985 in the High Court. The said writ petition was however, by order dated February 25, 1985 permitted to be withdrawn with liberty to take recourse to any other remedy which may be available to the appellant. Subsequently, an appeal was preferred by the appellant before the Health Minister against the aforesaid order dated December 22, 1984. This appeal allowed on October 15, 1985 in pursuance whereof the Drug Controller passed an order November 11, 1985 whereby respondent 2 was informed that its licence to manufacture Santopar stood cancelled. Respondent 2 was also directed to stop manufacturing the said drug. C. W.J.C. No. 5943 of 1985 which is one of the writ petitions decided by the judgment appealed against, was filed by M/s. Naya Dawakhana, respondent 2 challenging the aforesaid orders dated October 15, 1985 and November 11, 1985.

4. By subsequent orders dated May 6, 1986 and May 7, 1986 issued by the Drug Controller the entire stock of Santopar tablets produced by the appellant was seized. Aggrieved by this seizure the appellant filed C.W.J.C. No. 4788 of 1986 namely the other writ petition decided by the judgment appealed against with a prayer to quash the aforesaid orders and also to direct the Drug Controller to issue licence to the petitioner in pursuance of the order passed by the Health Minister and to restrain respondent 2 from manufacturing and selling Santopar tablets. C.W.J.C. No. 5943 of 1985 files by the appellant 2 has been allowed whereas C.W.J.C. No. 4788 of 1986 filed by the appellant has been dismissed by the High Court. As already stated above, these appeals have been preferred by the appellant against the said order of the High Court.

5. Before we deal with the submissions made by Shri Bimal Chandra Sandhya, the Managing Director of the appellant-company who has appeared in person we may point out that the High Court has held :

"Upon perusal of the records of the case, as also the records maintained in the office of the Drug Controller produced by the learned advocate before us, we do not find any application having been filed by M/s. Medimpex in this regard for manufacturing the Drug "Santopar" along with its renewal for the year 1975-76."

6. It has also held that nothing was pointed out by counsel for the appellant to indicate that the findings of the Drug Controller were perverse or unsustainable. It has further been held by the High Court that the findings of the Drug Controller in his order dated December 22, 1984 that no such licence as claimed by the appellant for manufacture of Santopar was granted in its favour, could not obviously be treated as an order whereby either the licence of the appellant had been cancelled or its renewal had been refused. That being so, the appeal filed by the appellant before the Health Minister against the order of the Drug Controller dated December 22, 1984 was not maintainable inasmuch as Rule 84-A of the Rules which contained the necessary provision for appeal to the State Government contemplated an appeal only against an order of the Licensing Authority refusing to grant or renew a licence. It was held that since right to file an appeal was a creature of statute and no

appeal had been provided for against an order such as the order dated December 22, 1984 passed by the Drug Controller in the inquiry held in pursuance of a direction of the High Court that no licence at all had been granted to the appellant to manufacture Santopar tablets, the order passed by the Health Minister was obviously without jurisdiction and consequently the order of the Health Minister dated October 15, 1985 and the subsequent order dated November 11, 1985 were liable to be quashed and as a necessary corollary the writ petition filed by the appellant deserved to be dismissed.

7. It has been urged by Shri Sandhya that the order of the Drug Controller dated December 22, 1984 was, on the face of it, erroneous and the High Court committed an error in upholding it. In support of this submission reliance was placed on a document filed as Annexure A to I.A. No. 2 of 1989 made in the special leave petitions purporting to be a true copy of a certificate said to have been issued on January 20, 1984 by Shri Y. K. Sinha to the effect that the certificate or renewal and the list attached thereto as Annexure issued along with letter dated June 10, 1976 relating to the issue of licence for manufacturing of non-biological drugs to the appellant bore his signature and the same were signed June 9, 1976. According to Shri Sandhya in view of this certificate the finding of the Drug Controller that the photostat copy of the renewal certificate and the list attached thereto were forged and fabricated was patently erroneous. Suffice it to say, so far as this submission in concerned, that the said certificate does not appear to have been produced during the course of inquiry before the Drug Controller. The order of the Drug Controller is completely silent about it and nothing has been brought to our notice to indicate that the said certificate was indeed produced before the Drug Controller. So far as the writ petition filed by the appellant which has been decided by the judgment appealed against is concerned, on a specific question being put by us to him Shri Sandhya stated that the said certificate was not produced in the said writ petition. This being the position we are not inclined to take into consideration the said certificate particularly in the absence of any affidavit by Shri Y. K. Sinha vouchsafing the genuineness of the said certificate. On merits we find no justification to interfere with the finding recorded in this behalf by the Drug Controller and affirmed by the High Court, the same being essentially a finding of fact based on material placed before them.

8. It was then urged by Shri Sandhya in the alternative that since an application had been made on behalf of the appellant on April 15, 1974 already referred to above containing information that the appellant had decided to manufacture Santopar brand name instead of Santonin and Calomel tablets or any brand name with a prayer that the said product may be considered on the appellant's manufacturing item it fulfilled requirement of making an application for endorsement and even if no order was passed thereon it should be deemed that endorsement as prayed for had been granted. We find it difficult to agree with this submission either. The question as to whether as endorsement of making an addition in the licence should or should not be granted apparently requires an application of mind and an order making such endorsement is needed. Even in the case of the appellant the Licensing Authority had passed an order on January 25, 1975 specifically granting the appellant's application made for adding six more drugs in its licence, after considering the merits of the application.

9. We also do not find any substance in the submission made by Shri Sandhya that the High Court committed an error in holding that no appeal lay to the State Government against the order passed by the Drug Controller on December 22, 1984. The finding by the Drug Controller that no licence had ever been granted to the appellant to manufacture Santopar tablets recorded in the order dated December 22, 1984 passed by him in the inquiry made in compliance with the direction of the High Court could not obviously be treated as an order either refusing to grant licence or to renew it. Since

an appeal lay to the State Government only against an order either refusing to grant a licence or to renew it the High Court, in our opinion, cannot be said to have committed any mistake in taking the view that the appeal filed by the appellant against the said order of the Drug Controller dated December 22, 1984 was not maintainable. On the writ petition filed by respondent 2 being allowed by the High Court the reliefs prayed for by the appellant in its writ petition could not obviously be granted.

10. In view of the forgoing discussion, we find no substance in these appeals and they are liable to be dismissed.

11. Before parting with the case, however, we may point out that it has been brought to our notice by Shri Sandhya that a prosecution is pending against the appellant in connection with the manufacture of Santopar tablets without a licence. In order to ensure that the defence of the appellant is not prejudicated we wish to make it clear that since we have not taken into consideration the certificate said to have issued by Shri Y. K. Sinha referred to above, it would be open to the appellant to rely on the said certificate in proceedings for prosecution after proving the same in accordance with law.

12. In the result, these appeals fail and are dismissed but there shall be no order as to costs.

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