(1990) 04 MAD CK 0028

In the Madras High Court

Case No : Writ Petition No. 5398 of 1989

Antox India (P) Ltd. — APPELLANT

Vs

State Drug Controller, Tamil Nadu and others — RESPONDENT

Date of Decision : 06-04-1990

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 17, 17A, 17B, 18, 27

Citation : (1990) 04 MAD CK 0028

Hon'ble Judges : S. Ramalingam, J

Bench : Single Bench

Advocate : Mr. U.N. Rao and Mr. C. Daniel, for the Appellant; Mr. M. Govindaranjan, Mr. R. Krishnamoorthy and Mr. C. Francis Louis, for the Respondent

Judgement

S. Ramalingam, J.—The prayer in the writ petition as originally filed read as follows :-

..... to issue a Writ of Mandamus or any other Writ, order or direction in the nature of a Writ directing the first respondent to cancel the

manufacturing licence issued in favour of respondent 2 on 2.4.1987 to manufacture the drug the brand name of Cal-De-Ce ....

In view of the orders passed by the State Drug Controller, Tamil Nadu on 2.12.1989 on the complaint preferred by the petitioner, the petitioner

has amended the prayer as follows :

.... to pass on order of Certiorarified Mandamus or direction in the nature of a Writ, call for the records and quashing the order passed by

respondent-1 on 2.12.1989 in reference No. 7771/IW/1/89, dated 4.12.1989 to the Registrar, High Court, Madras and cancel the manufacturing

licence No. 290 date 2.2.1987 issued by respondent-1 to respondent-2 to

manufacture the drug under brand name Cal-De-Ce ....

2. A few facts necessary are as follows : The third respondent and the petitioner entered into an agreement dated 28.3.1986 under which the

petitioner was authorised to manufacture a pharmaceutical product and affix the trade mark Cal-De-Ce which is the trade mark used by the third

respondent. The petitioner applied to the Drug Controller, karnataka, for a licence to manufacture Cal-De-Ce tables consisting of Calcium,

Vitamin-D and Vitamin-C. On this application, the Drug Controller, Karnataka by his letter dated 20.6.1986 informed the petitioner as follows :

With reference to your application for the grant of permission to manufacture the additional product ""CAL-DE-CE Tablets"" you are hereby

informed that you application can be considered if M/s. Wander Limited surrender the permission granted to them and authorise you to use trade

name.

In response to that the third respondent by his letter dated 21.6.1986 addressed to the Drug Controller, Karnataka gave a letter of undertaking as

follows :

We hereby undertake not to authorise the use of the trade mark ''CAL-DE-CE'' by any other company for the above referred product. We also

undertake not to manufacture Cal-De-Ce either by ourselves or under loan licence with any company with effect from 1st July, 1986.

It is not in dispute that thereafter, the Drugs Controller, Karnataka issued licence under the Drugs & Cosmetics Act, 1940 (hereinafter referred to

as the ''Act'') to the petitioner to manufacture under loan licence in Form 28 A the product Cal-De-Ce. The formula for this product was also

specified as gluconate I.P. 500 mg., Vitamin C (Coated) I.P. 35 Mg. cholecalciferol I.P. 200 I.U. While so, the petitioner came to know that the

third and second respondents had entered into an agreement under the terms of which the third respondent had authorised the second respondent

to manufacture a pharmaceutical product under the same trade name Cal-De-Ce with the same formula. On the strength of that agreement the

second respondent obtained a licence under the Drugs and Cosmetics Act from the Drug Controller, Tamil Nadu and started manufacturing and

selling the pharmaceutical product Cal-De-Ce. The petitioner appears to have instituted a criminal case against the respondent No. 2 and 3 before

the Metropolitan Magistrate''s Court, Madras for an offence u/s 27(c) read with 17(B) of Drugs and Cosmetics Act. Simultaneously, the petitioner

has also filed C.S. No. 1220/88 on the original side of this Court an action for passing off against the respondents 2 and 3 herein. In that suit, the

petitioner obtained an order of interim injunction against the respondents 2 and 3, which was subsequently vacated. But in O.S.A. 111 and 112 of

1989, the petitioner obtained favourable orders against which the respondents 2 and 3 appear to have filed appeals in the Supreme Court. In the

said suit, the defence which appears to have been taken by the respondents 2 and 3 is that the third respondent had cancelled the agreement dated

28.3.1986 entered with the petitioner herein and consequently it was contended that the petitioner would have no right to manufacture the

pharmaceutical product called Cal-De-Ce. It was in that context the Division Bench of this Court directed the respondent 2 and 3 to file necessary

application before the Drug Controller, Karnataka for cancellation of the licence granted to the petitioner to manufacture Cal-De-Ce. But by

orders dated 23.10.1989, the Drug Controller, Karnataka rejected the complaint preferred by the third respondent. In the meanwhile, the

petitioner had given a complaint to the State Drug Controller, Tamil Nadu to cancel the licence granted to the second respondent herein to

manufacture Cal-De-Ce. He filed this writ petition praying for a Mandamus to direct the State Drug Controller, Tamil Nadu to cancel the

manufacturing licence issued in favour of the second respondent to manufacture Cal-De-Ce. But even as early as on 2.12.1989 the state drug

controller, Tamil Nadu had rejected the complaint of the petitioner observing as follows :

There is a dispute between the parties to the agreement/Contract and parties to the contract/agreement have to settle themselves as per the

contractual obligations. In view of the above, as the product in question had been permitted to be manufactured by a licencing authority under the

provisions of Drugs and Cosmetics Rules, it may not attract the Section 17(B) of the Drugs and Cosmetics Act, 1940.

The amended prayer in the writ petition is to quash this order of the Drugs Controller of the Tamil Nadu.

3. It has been seen that the petitioner had already been granted a licence by the Drugs Controller, Karnataka in exercise of his statutory powers

under the Drugs and Cosmetics Act, 1940 to manufacture the pharmaceutical product called Cal-De-Ce tablets. It is not in dispute that the licence

granted by the Drugs Controller, Karnataka would have validity and efficacy throughout out India because the licence was granted under the

Central Enactment by the competent by the competent authority. It is also not in dispute that the licence so granted to the petitioner stands and its

validity had not in may manner been affected even as on dated. It is also not in dispute that the second respondent is manufacturing an identical

pharmaceutical product containing Calcium, Vitamin-D and Vitamin-C and selling the same under the trade name Cal-De-Ce. It is case of the

petitioner that the second respondent has no authority to manufacture the pharmaceutical product under the trade name Cal-De-Ce. It is also his

case that the third respondent had no authority to authorities the second respondent to manufacture the said drug.

4. In this writ petition, we are not concerned with the validity or otherwise of the authorization given by the third respondent to the second

respondent for manufacturing Cal-De-Ce. We are concerned with the validity of the orders passed by the State Drugs Controller, Tamil Nadu

(first respondent) in granting a licence to the second respondent to manufacture Cal-De-Ce. It is the case of the petitioner that by reason of the

second respondent also being allowed to manufacture and sell an identical product Cal-De-Ce, his business in adversely affected and therefore, as

an aggrieved person, he can approach this Court with a prayer for a Mandamus to direct the first respondent herein to cancel the licence issued to

the second respondent to manufacture Cal-De-Ce because, according to the petitioner, the very issue of the licence to the second respondent was

illegal.

5. In the Statement of objects and Reasons of Act 23 of 1940 it is seen that it was enacted in order to give effect to the recommendations of the

Drugs Enquiry Committee in so far as they relate to matters with which the Central Government is primarily concerned, to regulate the import of

drugs into British India to provide for uniform control of the manufacture and distribution of Drugs as well as import. This act was amended from

time to time and by Act 68 of 1982 Section 17-B as it now stands was introduced. The object of Act 68 of 1982 is to incorporate a new

provision for the purpose of defining certain terms like ''spurious drugs'' and ''spurious cosmetics'' and for making suitable and consequential

amendments in the definitions of expressions like ''misbranded drugs'', ''adulterated drugs'' and ''mis-branded cosmetics''. The Act defines the word

''drug'' in Section 3(b) as follows :

3(b) ''drug'' includes :-

(i) all medicines for internal or external use of human beings or animals and all substances to be used for or in the diagnosis, treatment, mitigation or

prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling

insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction

of vermin or insects which cause disease in human beings or animals as may be specified from time to time by the Central Government by

notification in the Official Gazette;

(iii) all substances obtained for use as components of a drug including gelatin ; and

(iv) such devices intended for internal or external; use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human being or

animals as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

The word ''manufacture'' which is more relevant for the purpose of this case is defined in Section 3(f) as follows :

(f) ""manufacture in relation to any drug or cosmetic includes any process or part of a process for making or altering, ornamenting, finishing,

packing, labelling, breaking up or otherwise treating on adopting any drug of cosmetic with a view to its sole distribution but does not include the

compounding or dispensing of any drug, or the packing of any drug or cosmetic in the ordinary course of retail business; and to ''manufacture'' shall

be construed accordingly.

The word ''patent'' or ''proprietary medicine'' is defined u/s 3(h) as follows :

(h) ""patent or proprietary medicine"" means :-

(i) in relation to Ayurvedic, Sidha or Unani Tibb systems of medicine all

formulations containing only such ingredients mentioned in the formulae

described in the authoritative books of Ayurvedic, Sidha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a

medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in Clause (a);

(ii) in relation to any other system of medicine, a drug which is a remedy or prescription in a form ready for internal or external administration of

human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia

authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted u/s 51 .

A reading of the above definition would show that Cal-De-Ce manufactured by the petitioner as well as by the second respondent is a drug as

defined in the Act and that it is also a patent or proprietary medicine. It can also be mean that the word ''manufacture'' would include packing and

labelling. Chapter IV of the Act in dealing with the manufacture, sale and distribution of Drugs and Cosmetics deals with misbranded drugs in

Section 17. Section 17A deals with Adulterated drugs while Section 17B which is more relevant, deals with spurious drugs. Section 18 states that

no person shall himself or by any other person on his behalf manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or

distribute any drug which is not of a standard quality, or is misbranded, adulterated or spurious. Section 27 provides for penalty for violation of

Section 17A or 17-B.

6. It is the case of the petitioner that the second respondent in manufacturing Cal-De-Ce, be it under the authority of the third respondent or

otherwise, in manufacturing a spurious drug because the licence to manufacture a pharmaceutical product under the trade name Cal-De-Ce lies

exclusively with petitioner by reason of the licence granted by the State Drugs Controller, karnataka in his order dated 10th July 1986 which is still

in force. The claim of the petitioner is that he is manufacturing the said pharmaceutical product with the formula already mentioned containing

Calcium, Vitamin-D and Vitamin-C in a particular proportion and he is selling the same after completing the manufacturing process by packing and

labelling the containers with the trade name Cal-De-Ce which he is legitimately

entitled to do. But at the same time second respondent purporting

to manufacture the same product with the same label on the strength of the licence issued by the State Drugs Controller, Tamil Nadu has

committed violation of Section of Section 17B of the Act and the licence so obtained by the second respondent from the State Drugs Controller.

Tamil Nadu was without disclosing the fact that the petitioner had already been authorised to manufacture the same drug under a valid licence. It is

the case of the petitioner that when same drug under a valid licence. It is the case of the petitioner that when once a person has been authorised

and issued with a licence to manufacture a particular drug and sell the same under a particular trade name, if any order person manufactures and

sells and the same drug under the same trade and the same label, then he is manufacturing and selling a spurious drug and the licence issued to him

for such manufacture, should be ordered to be cancelled. According to the petitioner, there cannot be two licensees to manufacture the same

product. It is the claim of the petitioner that the gullible public would suffer if two different manufactures are allowed to manufacture an identical

product because one manufacturer may maintain a very high standard and quality control while another may not be so meticulous, with the result if

indiscriminately the pharmaceutical products are sold by different manufacturers in the same trade name, ultimately, the public will suffer. It is his

contention that the very object of the enactment is to provide a control over the manufacture and distributions of the drugs and that control can be

maintained only if after the licence is granted to one manufacturer there is a prevention of some other manufacturer being allowed to sell the

product under the same trade name.

7. Section 17-B(a) of the Act is a follows :

For the purpose of this Chapter, a drug shall be deemed to be spurious.

(a) if it is manufactured under a name which belongs to another drug.

The word ''name'' would include both the proper name and the trade name. The distinction between the proper name and the trade name (patent

or proprietary medicines) has been explained in the decision reported in Albert David Ltd. v. Union of India AIR 1966 Calcutta 101 in these

words :

The British Pharmacopoeia contains a list of drugs with directions for their preparations. Pharmacists often combine drugs prescribed by

Pharmacopoeia or other pharmacopoeias and product drugs bearing a patent or proprietary nomenclature. Let as take, for example, a commonly

used drug known as ANACIN. The cover of that drug, containing the formula, was produced before me during a combination of the following

drugs, all recognised by Pharmacopoeia in different close namely; Quinine-sulphate. Acetylsalicylie Acid, Phenacetin, Caffeine.

The components drugs are all to be found named in the British Pharmacopeia of 1958 (vide pp. 17, 108, 475 and 580). But the compound drug

ANACIN does not find any place in the British Pharmacopoeia. This is because the does of the different drugs used in the responsibility of the use

of the 4 drugs together as a remedy for certain types of physical maladies .....".

The petitioner''s contention is that they are manufacturing, which terms would include not only manufacturing process but also packing and labelling

the medical preparation under the trade name Cal-De-Ce and they have a right to use the name Cal-De-Ce which is their proprietary name for

their pharmaceutical product. This according to the petitioner, is their exclusive privilege. If another person were to manufacture and sell a similar

product under the same name, it will lead to an offence u/s 17-B(a) of the Act because the other manufacture will be found to manufacturer a

spurious drug (because the name, Cal-De-Ce belongs to the first person). If without reference to the licence already granted to the petitioner by

the Karnataka State Drugs Controller, the Tamil Nadu State Drugs Controller grants licence to the second respondent to manufacture Cal-De-Ce,

that licence should be cancelled when facts are brought to the notice of the State Drugs Controller of Tamil Nadu. It is on this basis, the petitioner

gave a complaint to the first respondent herein. But by the impugned order dated 2.12.1989 that complaint had been rejected. Hence the petitioner

prays that the order dated 2.12.1989 should be quashed and the State Drugs Controller, Tamil Nadu should be directed to cancel the licence

granted to the second respondent because it was given without knowledge of the similar licence already having granted to the petitioner.

In answer to the above submission. Mr. R. Krishnamoorthy, learned counsel for the respondents 2 and 3 would submit that the licence once

granted can be cancelled only under Rule 85 of the Rules framed under the Drugs and Cosmetics Act. Rule 85 reads as follows :-

85. Cancellation and suspension of licence. - (1) The licensing authority may, after giving the licensee on opportunity to show cause why such on

order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this part of suspend it for such period

as he thinks fit, either wholly or in respect of some of the substances to which it relates if, in his opinion, the licensee has failed to comply with any

of the conditions of the licence or with any provisions of the Act or rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may within three months of the date of the order under sub-rule (1), prefer an

appeal to the State Government, who shall decide the same.

He would submit that it is not case of the petitioner that the second respondent has failed to comply with any of the conditions of the licence or with

any of the provisions of the Act or the Rules and when such is not the case, the licence granted to the second respondent should not be cancelled.

He would support the reasoning contained in the impugned order and would state that since the case of the petitioner does not come under Rules

85 the licence granted to the second respondent should not be cancelled.

Secondly, he would submit that Section 17-B(a) of the Act would be attracted only in cases where a manufacturer manufactures a product which

is really not a drug, but sells it as if it is a drug of a particular kind. As an illustration, he would submit that if a person sells chalkpowder by

branding it as calcium, then he would be guilty of an offence u/s 17-B(a) and the case put forward by the petitioner cannot come under the scope

of Section 17-B(a) of the Act. He would then submit that under the Drugs and Cosmetics Act each State has a separate Drug Controller and each

of these drug controllers has jurisdiction to grant licence. He would submit that there is no prohibition under the Drugs and Cosmetics Act against

the Drug Controller of a particular State in granting licence to manufacturer a pharmaceutical product which product has already been licenced to

be manufactured by the Drug Controller or another State. Lastly he would submit that even assuming that the petitioner has made out a case, his

remedy is only for damages for which he has already filed a civil suit.

8. Having regard to the above submissions made by the respective counsel, the crucial question to be decided is whether the case of the petitioner

can be brought u/s 17-B(a) of the Act. The drug manufactured by the petitioner under the licence is called Cal-De-Ce. So long as that licence is in

force, the petitioner has a right to manufacture and sell Cal-De-Ce which name belongs to him While so, the second respondent is also

manufacturing and selling a drug in the same name, Cal-De-Ce. But he seeks to gain strength for such manufacture only on the basis of the licence

issued by the State Drug Controller Tamil Nadu. If the petitioner is able to establish that the licence so obtained by the second respondent was not

validity issued to him, then the petitioner should be given the relief, because the manufacture of the same drug by the second respondent would be

in violation of Section 17-B(a) of the Act. It is in the context, the petitioner states that once the licence is issued under the Central Act by a

competent authority, that licence would be valid and operative throughout India. In other words, the licence so issued by the Drugs Controller of

Karnataka will have efficacy in other states also. If therefore the petitioner was granted a licence as early as on 10th July, 1986 to manufacture

Cal-De-Ce, then no Drug Controller of any other State would have jurisdiction to grant a licence to manufacture an identical product to be sold

under the same name. The petitioner submits that when the Drug Controller of Tamil Nadu gave licence to the second respondent it was either due

to inadvertance or ignorance of the fact that the petitioner had already been licenced to manufacture a similar drug. It is in the context, the counter

affidavit, filed by the first respondent is relevant. In para 7 of the counter affidavit, it is stated as follows :

When M/s. Alfred Berg and Company applied for permission to manufacture it to the Drugs Controller of Tamil Nadu they applied without any

reference to existence of the product already as they propose to manufacture under an agreement with trade marks owners.

The above sentence in the counter-affidavit indicates that the first respondent probably was unaware of the fact that the petitioner had already been

licensed to manufacture Cal-De-Ce. A question whether there could be one licence to manufacture an identical pharmaceutical product with the

same trade name indirectly came up for consideration before the Supreme Court and in the decision reported in M/s. Medimpex (I) P. Ltd. v.

Drug Controlled-cum-Chief L.A. , the Court stated as follows :

In the year 1982 M/s. Naya Dawakhana, respondent No. 2 applied for and was granted licence for manufacture of the drug Santopar. This grant

of licence to respondent No. 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 No. 2 and one of the questions which arose was as to whether the appellant had ever been granted licence to manufacture

Santopar on account of which the grant of licence to respondent No. 2 could be held to be illegal .....

Even on first principles, when the Act had been with the object of exercising control over manufacture and distribution of drugs and quality control

and purity of the drugs manufactured is of paramount importance and vital to the Society, it would be undesirable if more than one manufacturer is

licenced to manufacture and sell a pharmaceutical product under the same trade, name, because all of them cannot maintain the same standard of

quality. It is apparently in this view of the above object, that Section 17-B(a) of the Act prohibits manufacture of a pharmaceutical product in the

name which belongs to another. Therefore, there is considerable force in the contention of the petitioner that the licence granted by the first

respondent to second respondent to manufacture an identical product as manufactured by the petitioner under a valid licence, has been obtained

contrary to the provisions of the Act.

9. It is true, as contended by the Counsel for the first respondent that Rule 85 if strictly interpreted, would enable cancellation of a licence only for

contravention of the provisions of Act and the Rules and conditions of the licence. But that rule need not be confined to supervening

disqualifications. If there was a disqualification to obtain a licence even at the initial stage, then the grant of such licence in contravention of the

provisions of the Act, would be bad and the competent authority should have power to cancel the licence which was granted under mistake. Such

interpretation of Rule 85 would enable the competent authority under the Act to effectively function and discharge his obligations. Otherwise, as the

first respondent has stated in the impugned order dated 2.12.1989 he could simply express his inability to act on the ground that the licence had

already been granted. The contention of the first respondent''s counsel that Rule

85 would not enable the first respondent to cancel the licence

cannot be sustained.

10. The last of the submissions of the respondent''s counsel is that the remedy of the petitioner is only to sue for damages cannot be sustained. It is

not a question of damages alone. It is a question of safeguarding the public interest and of preventing too many manufacturers from manufacturing

pharmaceutical products under the same trade name. It is the duty of the Drug Controller to exercise his jurisdiction in implementing the provisions

of the Act in spirit and substance.

11. For the foregoing reasons, there will be an order in this writ petition quashing the impugned orders dated 2.12.1989 issued by the first

respondent in his Reference No. 7771/IW/1/89 and directing the first respondent to pass orders by exercising powers for cancellation of the

licence issued to the second respondent to manufacture a drug under the brand name Cal-De-Ce in the light of the observation contained above,

after affording a fair and reasonable opportunity to the second and third respondents to state their respective case. Orders in this regard should be

made on or before 10th May, 1990. No costs.

