(2007) 01 AHC CK 0053

In the Allahabad High Court

Cattle Remedies and Another — APPELLANT

Vs

Licensing Authority/Director of Ayurvedic and Unani Services — RESPONDENT

Date of Decision : 18-01-2007

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 17B, 2, 3, 33EEA, 5

Citation : (2007) 2 ADJ 12 : (2007) 2 AWC 1093

Hon'ble Judges : Yatindra Singh, J;Ran Vijai Singh, J

Bench : Division Bench

Judgement

Yatindra Singh, J.—The controversy involved in these two writ petitions revolves around two of the intellectual property rights (I.P.Rs.) namely Patents and Trade marks; it also involves their interplay with the Drugs and Cosmetics Act, 1940 (the Drugs Act). It arises in connection of grant of licence to manufacture Ayurvedic drugs for animals.

The Facts:

2. M/s. Cattle Remedies, Araon Road, Sirsaganj, Firozabad (the petitioner) as well as M/s. Bio-Herbs Pharma, Chamar Gate, Hathras (the contesting respondents) manufacture Ayurvedic drugs for animals.

3. They have licence to manufacture many Ayurvedic drugs but controversy here is in regard to the grant of licence for the following three Ayurvedic drugs (the disputed drugs) for the animals that both of them have given same name. They are:

(i) Catone : It is a powder. It is for cleaning stomach and improving digestion

(ii) Catcough : It is a paste. It is for ''cough and cold''

(iii) Uterotone : It is a syrup. It is for facilitating reproduction and problems relating to it.

These names are being referred to as the disputed names in this Judgment.

4. The petitioner''s firm was first one to start and sometimes in 1971, the partners of the contesting respondents were inducted in the petitioner''s firm. However, it was dissolved in the year 1981 and the petitioner''s firm was reconstituted. The firm of the contesting respondent was also formed at that time. Both of them started manufacturing Ayurvedic drugs for animals.

Earlier Litigation Regarding Licence:

5. The petitioner applied for and was granted licences to manufacture the disputed drugs under the Drugs Act on 13.12.1984. It appears that the contesting respondent did not have any licence under the Drugs Act to manufacture the disputed drugs and some prosecution was being launched against it. The contesting respondent filed Writ Petition No. 41152 of 1992 for declaration that it is a deemed licensee for the disputed drugs under the Drugs Act. During pendency of this writ petition, two separate orders were passed:

(i) The contesting respondent was granted licences under the Act to manufacture the disputed drugs. However, it was subject to decision in Writ Petition No. 41152 of 1992

(ii) The petitioner''s licences for the disputed drugs were cancelled. The petitioner filed Writ Petition No. 7230 of 1995 against these two orders.

6. These two writ petitions were decided together on 27.11.2000. The Court held that:

(i) There is no deemed licence in favour of the contesting respondent and the application of the contesting respondent for grant of licence should be considered in accordance with law.

(ii) The order dated 10.3.1995, cancelling the licence of the petitioner was quashed and authorities were directed to pass a fresh orders after affording opportunity to the petitioner.

7. The licensing authority by its order dated 22.2.2001, upheld the licence of the petitioner and rejected the application of the contesting respondent. Nevertheless, the licensing authority also observed that the contesting respondent is permitted to sell the quantity of the disputed drugs already manufactured. The petitioner filed Writ Petition No. 8746 of 2001 against this part of the order. In this writ petition, an interim order was obtained by the petitioner restraining the contesting respondent from selling the disputed drugs in terms of the order dated 22.2.2001.

8. The contesting respondent filed an appeal against the order dated 22.2.2001. It was dismissed by the State Government on 31.1.2002. The contesting respondent filed Writ Petition No. 11986 of 2002 against this order. It was also dismissed on 21.3.2002. The contesting respondent filed SLP (S.L.P.) No. 11833 of 2002 against it. However, it was withdrawn on 24.3.2003 with liberty to seek appropriate remedy from the competent authorities. Subsequently, the licensing

authority granted licence to the contesting respondent to manufacture the disputed drugs on 10.2.2005. The petitioner has filed Writ Petition No. 32158 of 2005 against this order.

Litigation regarding Trade Mark:

9. Both the parties have obtained licenses for the disputed drugs under the name of Catone, Catcough and Uterotone (the disputed names). Both of them want to sell the disputed drugs under the same name. It is yet not clear if these names are the brand/trade marks of any of the parties or are such names over which no one can have trade mark (generic names). However, at present both the parties are claiming trade marks over them.

10. The contesting respondent was granted trade mark for the disputed names on 17.2.1981 under the Trade and Merchandise Marks Act. The petitioner filed a Suit No. CO. 14/1991 before the Delhi High Court for cancelling them. This suit was decreed on 4.9.1995 and the trade marks in favour of the contesting respondent were cancelled.

11. The contesting respondent filed an application to recall the aforesaid order. During pendency of this application, the Trade and Merchandise Marks Act was substituted by the Trade Marks Act, 1999 (the Trade Marks Act); This Act also established an appellate board. The application filed by the contesting respondent to recall the order dated 4.9.1995 was transferred to the appellate board. This application was rejected on 9.2.2005. The contesting respondent has filed Writ Petition (C) No. 9639 of 2005 against these orders before the Delhi High Court and has obtained an interim order.

12. The petitioner also filed an application for obtaining trade marks for the disputed drugs by the same names. In this application an objection was filed by the contesting respondent. The objection of the contesting respondent was rejected and the petitioner was granted trade marks for the disputed names on 20.11.2002. The contesting respondent filed a review application and then an appeal before the appellate board, however, both were dismissed on 13.5.2004 and 9.2.2005 respectively. The contesting respondent has filed Writ Petition No. 9641 of 2005 against ''these orders before the Delhi High Court. However, no interim order has been granted to the contesting respondent in this writ petition.

Points for determination:

13. We have heard Sri Rahul Sripat, counsel for the petitioner; Sri Tej Pal and Sri Sukendru Pal Singh for the contesting respondent and Ms. Subhash Rathi for State officials. The following points arise for determination.

(i) What is the meaning of patent or proprietary medicines'' u/s 3(h) of the Drugs Act?

(ii) Whether the disputed drugs are ''patent or proprietary medicines'' within the meaning of Section 3(h) of the Drugs Act.

(iii) Whether the licence under the Drugs Act can be granted only in the name of brand/trade name?

(iv) Whether the petitioner is entitled to any relief.

(v) Whether the contesting respondent is disentitled to get licence to manufacture the disputed drugs due to the earlier litigation.

1st and IInd point : Disputed drugs are patent or proprietary medicines:

14. The Drugs Act is enacted to regulate import, manufacture, distribution, and sale of drugs and cosmetics. It not only prohibits sale of misbranded, adulterated, spurious and substandard drugs but also prohibits manufacture of any drug except under a licence granted under the Drugs Act. Boradly, it provides uniform control of distribution and manufacture of drugs. It ensures that the person manufacturing the drug has expertise and capability to manufacture drugs of the standard laid down in the Drugs Act.

15. So far as manufacturing a drug is concerned, the Drugs Act conceives of two kinds of drugs:

(i) The drugs that are ''patent or proprietary medicine'' (Anubhut Yog)'';

(ii) The drugs that are not ''patent or proprietary medicine'' or in other words are Ayurvedic Pharmaccopial Medicines (Shastreey Aushadhi).

Drugs that are not patent and proprietary medicine:

16. The Drugs Act defines the words ''Ayurvedic, Siddha and Unani Drugs'' in Sub-section (a) of Section 3, Section 3(a) of the Drugs Act (See Appendix-I). It is an inclusive definition. It includes a drug for treatment of a disease or disorder in human beings or animals, manufactured exclusively in accordance with the formulae prescribed in the authoritative books mentioned in the First Schedule of the Drugs Act (the Authoritative books).

17. These Authoritative books describe different medicines, their ingredients and their formulation. Subject to the licence under the Drugs Act, the medicines mentioned in the Authoritative books can be manufactured by any one and they have to be sold under the name mentioned in the Authoritative Book [Rule 161(3) (i) of the Drugs and Cosmestic Rules 1945 (the Drugs Rules). These medicines are the ones that are not ''patent or proprietary medicine''. They are Ayurvedic Pharmacopial medicines or Shastreey Aushadhi. The names mentioned in the Authoratitative books are Ayurvedic Pharmacopial names or generic names. These medicines have to be sold under generic name however, the name of the manufacturer is to be mentioned. This is in order to distinguish it from the product of other manufacturer.

Patent or proprietary medicine:

18. The Drugs Act defines the word patent or proprietary medicine in Sub-section (h) of Section 3 (Section 3(h) of the Drugs Act (See Appendix-I). Apart from the

aforesaid medicines mentioned in the Authoritative books the other Ayurvedic, Unani and Siddha medicines can be made using the ingredients mentioned in the different formulae of the Authoritative books. This can be done by using formulations different than those that are mentioned in the Authoritative books. These are patent or proprietery medicines under the Drugs Act provided they are not administered by parenteral route. Thus, the patent or proprietary medicines under the Drugs Act are those medicines that:

(i) use the same ingredient as mentioned in any of the formulae in the Authoritative books; but

(ii) do not use any formulation included in the Authoritative books; and

(iii) are not administered by parenteral route.

19. The ingredients and their quantity in the disputed drugs of the parties is mentioned in Appendix II to IV of the judgment. It is admitted that:

? The ingredients used by the parties are mentioned in the formulae used in the authoritative books;

? The parties are using formulations that are not mentioned in the Authoritative books.

? These medicines are not given by parenteral route;

Thus, the disputed drugs are patent or proprietary medicines of the parties within the meaning of the Drugs Act.

IIIrd point : Names--In consonance with the trade marks:

Drugs of the parties--Different:

20. A study of appendix II to IV will indicate that though some of the ingredients used by the parties in the disputed drugs are the same, however their quantity is different. Many ingredients are not common. These two drugs may be for the same disease or problems yet they are different. They have to be distinguished from each other. This can only be done if they have different names.

21. In case of Shastreey Aushadhi ingredients and the formulations are the same; they are the same medicines. Thus, same name has to be given. The only distinguishing feature is the manufacturer, It is for this reason that details about manufacturer are to be mentioned. Here the medicines have to be distinguished by different names as their ingredients are different and the quantity of the same ingredient is different.

22. The disputed, drugs do not use formulations of the Authoritative books. Neither their description nor their names are found in the Authoritative books : they cannot be sold under any name mentioned in the Authoritative books. Nevertheless, they have to be given some name. The question is, ''what names can they be given?''

23. Before we enter into controversy regarding names of the "patents or proprietary medicines'', it will be instructive to have a bird''s eye view of the law relating to patents and trade marks.

Intellectual Property Rights (I.P.Rs.):

24. About a century ago, Paterson, J. in University of London v. University of Tutorial Process Ltd. 1916 (2) Ch 601, observed:

What is worth copying, is prima facie worth protecting.

This is the genesis of all I.P.Rs. These rights refer to the property that is a creation of the mind namely inventions, literary and artistic works, symbols, names, images, and designs used in commerce.

25. I.P.Rs. are broadly divided into two categories:

? Copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, drawings, paintings, photographs, sculptures, and architectural designs. It lies in description of some.

? Industrial property, which includes inventions (patents), trademarks, industrial designs and geographic indications.

26. India is a member of the World Trade Organisation (W.T.O.) and is bound by ''Agreement on Trade and Related aspect of Intellectual Property Rights'' (T.R.I.P.S.). She had to amend laws accordingly and according to the Government this has been done. At present, we are protecting I.P.Rs. under the following specific statutes dealing with them:

(i) The Biological Diversity Act, 2002.

(ii) The Copyright Act, 1957. (iii) The Design Act. 2000.

(iv) The Geographical Indications of Goods (Registration and Protection) Act, 1999.

(v) The Patents Act, 1970.

(vi) The Protection of Plant Varieties and Farmers Rights Act, 2001.

(vii) The Semiconductor Integrated Circuits Layout Design Act, 2000.

(viii) The Trade Marks Act, 1999.

I.P.Rs. are also dealt under two more areas namely, the trade secret and the Indian Contract Act. We have yet to enact any statutory law governing the trade secret. However, we are protecting trade secrets under our common law.

Patents:

27. Among the I.P.Rs., the Patents is the most powerful of all I.P.Rs. Patents can prevent a process or manufacture of a product. It is an exclusive right given by

law to the inventors to make use of, and exploit their inventions for a limited period of time in exchange for a full description of the method to perform the invention. Nevertheless the patent, before it can be effective, has to be registered under the Patents Act.

28. Historically the word ''patent'' has come from the Latin phrase litterae patents'', literally meaning letters patent. Patent means open and letters patent'' was used to refer to the open letters conferring privileges, rights, ranks, or titles by sovereign bodies/rulers. They were official documents and as they were publicly announced, they were open also. (See End note-2).

29. Initially, these letters were issued (around the sixth century) in Europe for the discovery and conquest of foreign lands on behalf of the ruler. Patents came to be related to inventions around the 15th Century and the first patent law--as we understand it today--was passed on March 14. 1474 by the Venetian Senate (See End note-2).

30. The grant of exclusive privilege to inventors spread from Italy to other European nations. Countries (that lacked technology) started granting exclusive patents (rights) to foreign inventors in exchange of introducing the technological innovation in that country. However, the unlimited duration of exclusive rights created unfair monopolies, and the British Parliament enacted the Statute of Monopolies in 1623; it prohibited royal monopolies but reserved right to grant "letters patent" for inventions up to 14 years.

31. In the United States, Article I Section 8 of the Constitution authorises Congress to create a national patent system to promote the Progress of Science and useful Arts : by ''securing for limited times to...Inventors the Exclusive Right to their respective...Discoveries''. Congress passed the first U.S. Patent Statute in 1790. The following year France also enacted its patent law. By the end of the 19th century many countries, including India, enacted patent laws.

Patents Law in India:

32. The first Patents Act in India was Act No. VI of 1856. It was an Act for granting exclusive privilege to inventors. It received the assent of the Governor General on 25th February, 1856. This Act was repealed by Act No. IX of 1857 on the ground that it was passed without obtaining the previous sanction of Her Majesty. This is the reason indicated in the preamble (see End note-3) of Act No. 15 of 1859, which was passed by the Legislative Council of India to encourage inventions of new manufacturers and for protecting their privileges.

33. Act No. 15 of 1859 was replaced by Inventions and Designs Act, 1888 (Act No. 5 of 1888). This was further replaced by the Indian Patents and Designs Act, 1911 (Act No. 2 of 1911). In 1967, the Government of India, introduced a Patent Bill that culminated in the Patents Act, 1970 (the Patents Act). The Patents Act has been amended by three amending Acts, namely:

(i) Act No. 17 of 1999;

(ii) Act No. 38 of 2002;

(iii) Act No. 15 of 2005.

34. Patents can be granted for inventions. The word ''invention'' (Section 2(1)(j) of the Act) read with the word ''inventive step'' (Section 2(1)(ja) of the Act) means a new product or process that is capable of industrial application. Invention must be novel and useful. It must involve technical advance as compared to the existing knowledge or having economic significance or both. It should not be obvious to a person skilled in the art.

35. In the developing countries, generally patents for product in medicine, or drugs or substances produced by chemical process were not granted. In India also Section 5 permitted patents for processes only for the following substances. No patents could be granted for the product of theses substances.

(a) Intended for use or capable of being used as food or as medicine or drug,

(b) Prepared or produced by chemical processes.

36. T.R.I.P.S. does not make any such distinction. It permits patents for the aforesaid substances and their products. The distinction in our law had to be removed by 31.12.2004 and according to the Government it has been so done. The result is that now medicines can also be patented. This is a relevant distinction and we have some suggestions in this regard (see under the heading suggestion).

Trade Mark:

37. Trade mark is a mark that distinguishes goods and services of one person from another. In other words, trade marks identify goods or services with any particular person. With this preliminary, let''s consider what names may be given to the medicines that fall under the category of patent or proprietary medicines'' under the Drugs Act.

Same names as Trade Marks:

38. Section 3(h) of the Drugs Act has defined ''patent or proprietary medicines'' at the time when medicines could not be patented. Now medicines can be patented and trade mark has gained importance. The medicines that fall u/s 3(h) of the Drugs Act may or may not be patented under the Patents Act. In the present case, the disputed drugs fall u/s 3(h) of the Drugs Act yet they are not patented under the Patents Act : anyone can manufacture them. The parties cannot restrain each other or any one else from manufacturing it.

39. The formulations used by the parties is different than the Authoritative books, and as such the names used in the Authoritative books cannot be used for the disputed drugs. Medicines are also goods and medicine manufactured or produced by one person has to be differentiated from the medicines of another. This can only be done by providing a trade name or by a trade mark. This aspect

is neither governed by the Patents Act nor by the Drugs Act; it is in the domain of the Trade Marks Act. Both the parties are giving same names to the disputed drugs. At present they have licenses also under the Drugs Act to manufacture these medicines in the same name. This is not permissible; only that party can give this name that is entitled to use these names as the trade mark.

40. Trade mark is dealt with under the Trade Marks Act. In case of any violation of the trade marks, not only civil remedies are available but criminal prosecution can also be launched under the Trade Marks Act. The Drugs Act does not deal with trade marks directly but deals with it indirectly. This is done, when it explains as to what is meant by the spurious drugs.

41. Spurious drugs are defined u/s 17B and Section 33EEA of the Drugs Act. Though, these sections, do not use the word trade marks but they say that spurious drugs is the one that resembles another drug in a manner likely to deceive. We have already held that the disputed drugs manufactured by the parties are different (see discussion under sub-heading ''Drugs of the Parties--Different'' of the 3rd Point). In case same names are given then there is likelihood of the persons being deceived. And a medicine that is patented under the Patents Act cannot be manufactured by any one else except under a licence. In our opinion the licensing authority while granting licence to manufacture ''patent or proprietary medicine'' under the Drugs Act should not grant licence in the trade name/mark of any other party. At the time of grant of licence, the licensing authority should consider the following two points:

(i) Whether the name is trade mark of any one else or not, and

(ii) Whether the medicines are patented under the Patent Act or not.

It is for this reason that the Supreme Court made the following observations in Cadila Health Care Ltd. Vs. Cadila Pharmaceuticals Ltd.,

It is but proper that before granting permission to manufacture drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark Office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion.

42. Chapter IVA of the Drugs Act and Parts XVI to XIX of the Drugs Rules, deal with Ayurvedic, Unani and Siddha Tibb drugs. Rule 153 provides for application to grant licence for manufacture. It is to be given in form 24D, whose only requirement is:

(i) to give address of the premises where the drugs is to be manufactured;

(ii) the name of the drugs to be manufactured along with details;

(iii) name, qualifications and experience of the technical staff employed for manufacture and testing of drugs.

43. The form nowhere requires any declaration that:

(i) the drugs applied for are patented by any one else or not, and

(ii) The names given to it are trade mark of any other person or not.

It is appropriate that the Drugs Rules be amended and declaration be required that medicines are not patented under the Patent Act and the name is not a trade mark of any other person.

IVth point : Relief:

44. The licensing authority should grant licence to manufacture medicine in the name of Catone, Catcough and Uterotone only to that party which is entitled to use these names as the trade marks. The trade mark dispute is pending before the Delhi High Court. It is not final. However, the appellate Board under the Trade Marks Act has decided in favour of the petitioner. Till the order is set aside or clear orders are passed prohibiting it from using these names, it will not be proper to permit any one else from using these names.

45. The parties may approach the Delhi High Court to consolidate the writ petitions and may request the Delhi High Court either to expedite the hearing of matter or suitably modify/ clarify the interim orders so that only one of the parties can keep the trade marks.

46. However, in case trade mark dispute is decided in favour of the contesting respondent or the petitioner is restrained from using these names as trade marks then we grant liberty to the contesting respondent to file application before the licensing authority to ask the petitioner to change the name of the drugs in the licence and to grant licence to the contesting respondent in the same name. In such an event the licensing authority shall ask the petitioner to change the name of the medicines and if the petitioner fails to modify the name cancel the licence and grant licence to the petitioner. Of course it goes without saying that in case the Court refuses to modify the order or the trade mark dispute is decided in favour of the petitioner then the licence of the petitioner will not be touched.

47. We will also like to point out Rule 159 which is titled as Cancellation and suspension of licences''. It provides grounds for cancelling the licence. The only ground is that the licensce has failed to comply with any of the conditions of the licence or with any provisions of the Act or the Rules made thereunder.

48. Trade mark violation not only provides civil remedy but also provides criminal remedy to a party concerned. Apart from it, such a drug can also be treated as spurious drugs under the Act. No licensing authority is empowered to permit an act which has civil as well as criminal consequences. We clarify that in such event the grant of licence will be in violation of the Drugs Act and it can be cancelled.

Vth point : Earlier litigation does not bar:

49. It is correct that the licence to manufacture the disputed drugs to the

contesting respondent was earlier refused; should it be refused to manufacture the medicines. We do not think so. We have decided this case on merits for the following reasons:

(i) the contesting respondent was permitted to withdraw the SLP to seek relief from the authorities; and

(ii) He has got relief from the authorities;

(iii) The contesting respondent should only be restrained if he is barred under the law to manufacture the disputed drugs. The medicines are not patents of anyone under the Patents Act. Neither the contesting respondent nor anyone else is barred to manufacture them.

(iv) The contesting respondent is only barred to market them under the names that are trade mark of any other person. In our opinion the earlier litigation does not debar the petitioner or for that matter the partners of the contesting respondent if they reconstitute the firm or any one else from manufacturing the disputed medicines; it is only marketing under the Trade Marks of anyone else which is barred. It is for this reason that we have proceeded to decide this dispute on merits.

Suggestions:

50. We have already explained that now the medicines can also be patented (sub-heading ''Patent Law in India'' of the 3rd Point). The definition in Section 3(h) of the Drugs Act defines the words ''patent and proprietary medicine''. This was done at the time when medicines could not be patented under the Patents Act. It does not consider this aspect. The Drugs Act also does not pay any specific attention to the Trade Marks Act. The Union Government may consider.

? Amending the Act and the Rules in light of the Patents Act and the Trade Marks Act.

? Requiring the persons applying for licence to file declaration that medicines are neither patents nor the name is trade mark of any other party.

Clarification:

51. We wish to clarify that we have not expressed any view on the trade mark dispute. That dispute may be decided on its own merit. We wish to further clarify that the contesting respondent or for that matter anyone else is not prohibited to manufacture these medicines as they are not patents of any one under the Patents Act. however that can be marketed and licence can be granted in the disputed names to that party only which has trade mark over the disputed name.

Conclusions:

52. Our conclusions are as follows:

(a) The licence to manufacture drugs that fall under the category of ''patents and

proprietary medicines'' cannot be granted:

(i) if these drugs are patents of any one else; or

(ii) the name of the medicine is trade mark of anyone else.

(b) The medicines manufactured by the parties are in the category of ''patents and proprietary medicines'' under the Drugs Act. At present, the trade mark in the name of Catone, Catcough and Uterotone is with the petitioner. Neither the contesting respondent nor anyone else can use it or get the licence to manufacture the drugs in these names till it stands.

53. In view of our conclusions, the part of the order dated 22.2.2001, granting permission to the contesting respondent to sell the already manufactured medicines in the name of Catone, Catcough and Uterotone as well as order dated 10.2.2005, granting licence to the petitioner to manufacture the disputed drugs in these names is quashed. However, it will be open to the contesting respondent to:

(i) file suitable application as indicated in the discussion under fourth point relating to relief,

(ii) obtain the licence in the name which is not trade mark of any other party and then sell the medicines.

With these observations, both the writ petitions are allowed.

End note-1 : We are thankful to Sri Rahul Sripat, Sri Sukendra Pal Singh counsel for the parties and Ms. Subhash Rathi, standing counsel for checking part of this judgment under heading ''The Facts, ''Points for Determination'' and the Appendices''.

End note-2 : The British Parliament had enacted an Act in the nineteenth century for establishing High Courts, in India. It was among the other things enacted that it should be lawful for Majesty to erect and establish a High Court by Letter Patent under the Great seal of the United Kingdom. The High Court of Calcutta, Madras, Bombay and Allahabad were established by issuance of Letters Patent.

The law passed by Venetian Senate stated:

We have among us men of great genius, apt to invent and discover ingenious devices....Now, if provisions were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventors'' honour away, more men would then apply their genius, would discover, and would build devices of great utility for our Common Wealth.

End note-3 : The preamble of the Act narrates the reason for repealing the earlier Act No. VI of 1856 and enacting this one. It is as follows:

Whereas Act VI of 1856, entitled "An Act for granting exclusive privileges to Inventors," was passed by the Legislative Council of India without the sanction of

Her Majesty to the passing thereof having been previously obtained and signified in pursuance of the Statute passed in the seventeenth year of the reign of Her Majesty, entitled "An Act to provide for the Government of India:" and whereas Her Majesty''s Law Officers having given it as their opinion that the Legislative Council of India was not competent to pass Act VI of 1856 without previously obtaining the sanction of the Crown, and the Court of Directors of the East India Company having In pursuance of the power vested in them by law disallowed Act VI of 1856 and having signified to the Governor General of India in Council their disallowance thereof, the said Act was repealed by Act IX of 1857; and whereas it is expedient, for the encouragement of Inventors of new manufacturers that certain exclusive privileges in their inventions should be granted to them in India, and that exclusive privileges obtained under the said Act should be protected : It is enacted as follows):

Appendix-I

Sections 3(a), 3(h) and 33EEA of the Drugs and Cosmetics Act, 1940, are as follows:

3 (a) "Ayurvedic, Siddha or Unani Drugs" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals manufactured exclusively in accordance with the formulae prescribed in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule.

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

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha 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 systems of medicine, a drug which is a remedy or prescription presented 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 5.

33EEA. Spurious drugs.--For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be spurious:

(a) if it is sold, or offered or exhibited for sale, under a name which belongs to another drug ; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles

another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious does not exist; or

(d) if it has been substituted wholly or in part by any other drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Rule 159 of the Drugs and Cosmetics Rules, 1945 is as follows:

159. Cancellation and suspension of licences.--(1) The licensing authority may, after giving the licensee an opportunity to show cause, within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this part or suspend It for such period as he thinks fit, either wholly or in respect of some of the drugs 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 the Rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

