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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

***Date of decision: 6th February, 2019***

\+ **CS (COMM) 1071/2018**

CUREWELL DRUGS & PHARMACEUTICALS PVT. LTD. & ANR. ..... Plaintiffs

Through: Mr. Sagar Chandra, Ms. Ishani Chandra, Mr. Ankit Rastogi and Ms. Shubhie Wah, Advocates. (M:8130910708)

versus

RIDLEY LIFE SCIENCE PRIVATE LIMITED & ANR. ..... Defendants

Through: Mr. Rishi Kant Singh, Advocate for UOI/DCGI. (M: 9810186857).
Mr. Shiva Lakshmi, Advocate for Ministry of Health. (M: 9818054806).
Ms. Prabhsahay Kaur and Ms. Shruti Gola, Advocates for GNCTD, Drug Control Department (M: 9810158581).

**CORAM:**
**JUSTICE PRATHIBA M. SINGH**

**Prathiba M. Singh, J. (Oral)**

1. The present suit for permanent injunction was filed by the Plaintiff No.1 - Curewell Drugs and Pharmaceuticals Private Limited and Plaintiff No.2 - Horizon Bioceuticals Pvt. Ltd. seeking protection of the trademark and packaging in relation to their product '*BEVITAL*' which is a multivitamin supplement. The Defendant - Ridley Life Science Private Limited had adopted an identical mark with identical packaging. This Court on 14th August, 2018 had granted an interim injunction. A Local

Commissioner was also appointed to prepare an inventory of the infringing products. Defendant No.1 had initially entered appearance and on 20th November, 2018 had placed on record a new carton, which it intended to adopt. The carton was acceptable to the Plaintiffs and after taking the new carton and packaging on record, a decree of permanent injunction was passed in terms of paragraph 28 (i) to (v) of the plaint vide order dated 20th November 2018.

2. The sales of the Defendant no.1 were not on record and an affidavit was called from Defendant No.1 in respect of the following facts:-

> "*2. An affidavit shall be filed of the Managing Director of the Defendant No.1 placing on record the following information: -*
>
> *(a) The date from which the Defendants' 'Bevital' product consisting of B-Complex Forte with Lysine was approved by the Drug Controller General of India (DCGI) or any other State FDA.*
> *(b) The specific sales of 'Bevital' since the date of approval/production of the formulation.*
> *(c) Total sales of 'Bevital' (B-Complex Forte with Lysine) on an annual basis."*

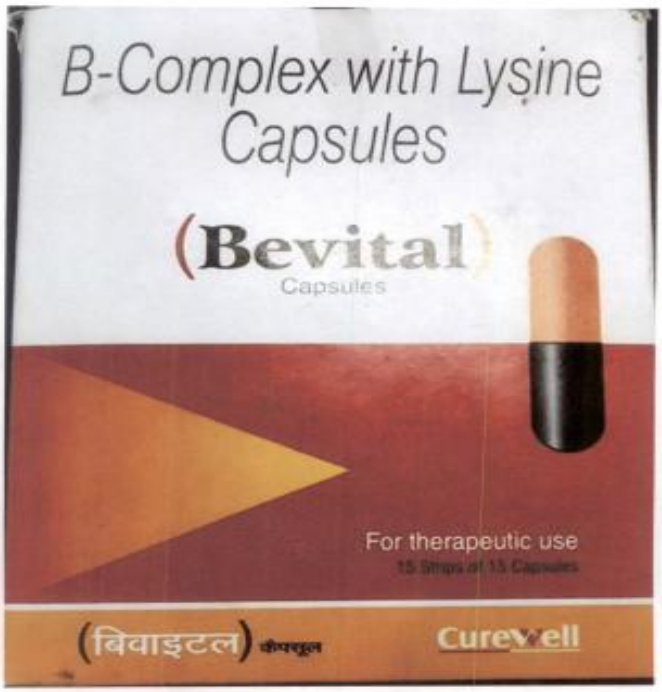
3. Defendant No.1 has now placed on record an affidavit of its Managing Director stating that the approval for the product was given by the State FDA on 4th August, 2017 and Defendant No.1 commenced manufacturing of the product from 31st January, 2018. The affidavit also states that out of the total 2020 boxes that were manufactured, only 1385 boxes were finally sold. This position is disputed by the ld. counsel for the Plaintiffs. Ld. Counsel for the Plaintiffs submit that Defendant No.1 being a habitual violator of various trademarks as observed in the order dated 3rd October, 2018 by a Ld. Single Judge of this Court in CS (COMM)

726/2018, punitive damages ought to be imposed.

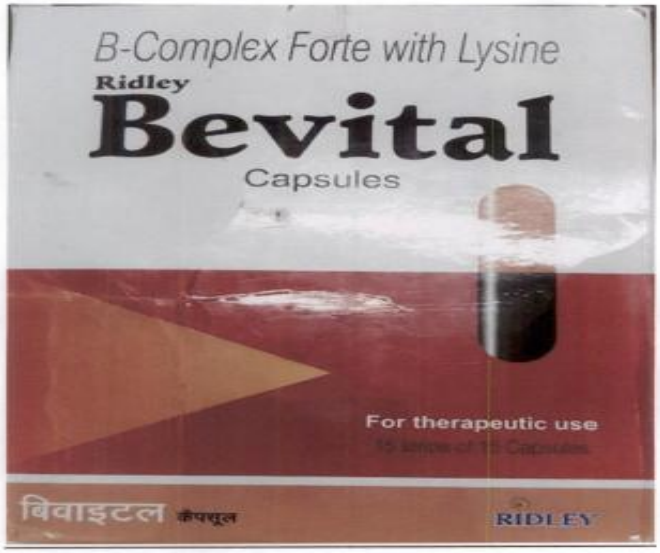
4. Considering the facts in the present case and the further undertaking given by Defendant No.1 at the initial stage of the suit itself, insofar as damages and costs, is concerned, it is directed that the Defendant No.1 shall pay to the Plaintiffs a sum of Rs. 2,00,000/- within three weeks from today. The Plaintiffs shall be, in addition, entitled to refund of the court fee to the extent of 50% under Section 16A of the Court Fee Act. If the Defendant No.1 is found to be in violation of any of the Plaintiffs' trademarks in future, Defendant No.1 would, without disputing the liability, be liable to pay a sum of Rs.10,00,000/- to the Plaintiffs. Such an order is being passed in the unique facts and circumstances of this case as the Defendant No.1 has not only been found to be violating the trademarks of third parties but this is the second occasion where the Plaintiffs have had a grievance against the Defendant's adoption of an identical mark. The suit is, accordingly, decreed in the above terms against Defendant No.1 - Ridley Life Science Private Limited.

5. In addition to the disputes between the Plaintiffs and the Defendants no.1, this Court had also taken notice of the fact that in the present case, the Drug Authorities had approved the Defendant's mark '*BEVITAL'* though it was identical to the Plaintiff's pre-existing mark '*BEVITAL'*, both for multi-vitamin supplements. The competing product labels are set out below:

***Plaintiff's Packaging***




***Defendant's packaging***




6. In order dated 14th August, 2018, this Court had observed as under:-

> "*14. The present case raises a very important issue as to the role of Drug Controller General of India (hereinafter, 'DCGI') and the state FDAs in approving a drug which has identical or almost identical brand*

*names. Under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945, the DCGI is the licensing authority in respect of new drugs and the state FDAs are the licensing authorities in respect of drugs which are more than four years old. It is noticed that the Defendant in the present case has a state FDA registration, issued to them by the Delhi Government. At the time of registration, there needs to be a check to ensure that an identical name is not registered. Such a procedure is also encapsulated at the time of allowing registration of names of Companies, under Section 20 and Section 22 of the Companies Act, 1956.*

*15. The issue of identical brand names being registered, had arisen in several cases and in the judgment of the Supreme Court in* ***Cadila Health Care Ltd. v. Cadila Pharmaceutical Ltd. (2001) 5 SCC 73****, the Supreme Court had directed as under:*

> *"34. Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates that an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a 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."*

*16. As per the above dictum of the Supreme Court, authorities ought to demand from applicants who seek drug approvals to submit a search report issued by the trademark authorities prior to giving them registration.*

*17. This matter was taken up yesterday on 13th August, 2018 and notice was issued to the DCGI. Today, the Ld. Counsel for DCGI, under instructions from the Addnl. Director, DCGI's office, Mr.Somani submits that*

*there is no mechanism in place to implement the decision of the Supreme Court, given as far as back in 2001. It is gainsay that all authorities have to implement the directions of the Supreme Court and all Courts have to ensure that such directions, are given effect to and take strict action against authorities not giving effect to them. Moreover, the DCGI has an obligation under the statute to ensure the quality, safety and efficacy of medicines and if products are sold with identical brand names, that basic purpose stands defeated. The authorities ought to bear in mind that if identical brand names are used, especially for different pharmaceutical compositions, the results could be life threatening to a patient who may consume a drug with an identical name but with a different composition.*

*18. In the opinion of this Court, the DCGI and the state FDAs ought to implement an action plan in which drugs with identical or near identical brand names or marks are not given licenses, so as to ensure that no confusion is created amongst doctors, chemists and patients. Moreover, the manner in which identical packaging is also being used is a cause for concern.*

*19. Accordingly, it is directed that, the Secretary Ministry of Health along with the DCGI and state FDAs shall hold an inter-se consultation amongst themselves and also take suggestions from other stake holders, if needed, as to the manner in which the approval of identical brand names for medicinal preparations can be avoided and the process of granting approval is streamlined. The DCGI may also call the officials of the Controller General of Trade Marks for the said consultation. A responsible officer shall be deputed by Secretary, Ministry of Health and Family Welfare to ensure that an action plan is prepared in consultation with the Central Government and the relevant state authorities. An affidavit shall be filed as to in what manner the directions given by the Supreme Court can be immediately implemented so as to ensure that identical brand names are not allotted to multiple parties and such confusion is avoided.*

> *20. The drug inspector who regularly inspects the manufacturing facilities of various pharmaceutical companies also ought to be provided with a data base of the brand names already registered and their packaging, in order to ensure that imitative packaging is not permitted to be manufactured, printed and sold in the market. DCGI and the Secretary, Ministry of Health to file their affidavits within 8 weeks, on this aspect as well.*
> *21. It is deemed appropriate to implead the Drug Controller General of India and the Secretary, Ministry of Health and Family Welfare and the Government of NCT of Delhi, as proforma Defendants to the present suit along with the Chief Secretary, GNCTD. Ms. Shiv Lakshmi, CGSC accepts notice on behalf of the Secretary, Ministry of Health and Family Welfare. Mr. Rishi Kant Singh accepts notice for the DCGI. Let the amended memo of parties be filed by the Plaintiff within two weeks."*

7. The Drug Controller General of India (hereinafter '*DCGI*') and the GNCTD were, thereafter, impleaded in this matter. On 20th September, 2018, Ld. counsel appearing for the GNCTD had submitted that drug licences are now being granted only under the generic name. The DCGI was, thereafter, directed to file a comprehensive affidavit dealing with the issue of identical brand names being approved. An affidavit was filed by the DCGI which had set out an action plan to deal with the issues highlighted in the orders passed by this Court. Thereafter, an additional affidavit was directed to be filed with a further status report.

8. The additional affidavit has now been filed on record by Mr. K. Bangarurajan, who is the Joint Drugs Controller (India). It is stated in the said affidavit that the orders of this Court were placed before the Drugs Technical Advisory Board (*'DTAB'*) constituted under Section 5 of the Drugs and Cosmetics Act, 1940 as also the Drugs Consultative Committee

(*'DCC'*) constituted under Section 7 of the Drugs and Cosmetics Act, 1940. The minutes of the meeting held on 29th November, 2018 by the DTAB and the agenda for the DCC's meeting, which was scheduled on 31st January, 2019 and 1st February, 2019, have been placed on record. The relevant minutes of the DTAB and agenda of the DCC are set out herein below:

> ***"AGENDA NO.5***
> ***CONSIDERATION OF THE PROPOSAL TO DEVISE A MECHANISM UNDER THE DRUGS AND COSMETICS RULES, 1945 TO AVOID SAME TRADE NAME FOR DIFFERENT DRUGS***
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> *DTAB was apprised that, the Hon'ble High Court of Delhiin the matter of M/S. Curewell Drugs & Pharmaceuticals Pvt. Ltd. & Anr. Vs. Ridley Sciences Pvt. Ltd, CS (COMM) 1071/2018, has issued order dated 14.08.2018 that the DCG(I) and the state FDAs ought to implement an action plan in which drugs with identical or near identical brand names or marks are not given licenses, so as to ensure that no confusion is created amongst doctors, chemists and patients. Moreover, the manner in which identical packaging is also being used is a cause for concern.*
>
> *The court has also highlighted the judgment of the Supreme Court in Cadila Health Care Ltd. v. Cadila Pharmaceutical Ltd. (2001) 5 SCC 73, in which the Supreme Court had directed as under:*
>
> > *"34. Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates that an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a 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."*

*Accordingly the court has directed the Government to ensure that an action plan is prepared to ensure that identical brand names are not allotted to multiple parties and such confusion is avoided.*

*Subsequently, in compliance with the order / direction of the Hon'ble High Court of Delhi, a meeting was held under the chairmanship of Additional Secretary & Director General (CGHS), Ministry of Health & Family Welfare on 13.11.2018.*

*During the meeting it was discussed that the brand name / trade name in case of pharmaceuticals is neither controlled by the Licensing Authority under the Drugs and Cosmetic Act 1940 & Rules 1945, nor the Trademarks office at present which leave scope for having same trade names for different drugs manufactured and sold in the Country, which may create a situation which is very detrimental to patient safety and the trade names which are not registered and repeated for different drugs can create confusion. Therefore, the Drugs and Cosmetic Rules 1945 may be amended to include the provisions for regulating brand names / trade names by the Central and State Licensing Authorities.*

*DTAB after detailed deliberation, recommended for devising a mechanism under the Drugs and Cosmetic Rules 1945 to include provisions for regulating the brand names / trade names of Pharmaceutical Products.*

**Agenda of DCC for the meeting scheduled on 31st January 2019 and 1st February 2019.**

***AGENDA***
***55th MEETING OF DRUGS CONSULTATIVE COMMITTEE***
***31st JANUARY & FEBRUARY, 2019***
***AT 10:30 AM***
***CONFERENCE HALL***
***FIFT FLOOR***
***F.D.A. BHAWAN***

***NEW DELHI-110002***

***AGENDA NO.15***

***CONSIDERATION OF THE PROPOSAL TO DEVISE A MECHANISM UNDER THE DRUGS AND COSMETICS RULES, 1945 TO AVOID SAME TRADE NAME FOR DIFFERENT DRUGS***

*The Hon'ble High Court of Delhi in the matter of M/s Curewell Drugs & Pharmaceuticals Pvt. Ltd. & Anr. Vs Ridley Sciences Pvt. Ltd., CS (COMM) 1071/2018, has issued order dated 14.08.2018 that the DCG(I) and the state FDAs ought to implement an action plan in which drugs with identical or near identical brand names or marks are not given licenses, so as to ensure that no confusion is created amongst doctors, chemists and patients. Moreover, the manner in which identical packaging is also being used is a cause for concern.*

*The court has also highlighted the judgment of the Supreme Court in Cadila Health Care Ltd. v. Cadila Pharmaceutical Ltd. (2001) 5 SCC 73, in which the Supreme Court had directed as under:*

> *"34. Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates that an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a 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."*

*Accordingly the court has directed the Government to ensure that an action plan is prepared to ensure that identical brand names are not allotted to multiple parties and such confusion is avoided.*

*Subsequently, in compliance with the order / direction of the Hon'ble High Court of Delhi, a meeting was held under the chairmanship of Additional Secretary & Director General (CGHS), Ministry of Health & Family Welfare on 13.11.2018.*

*During the meeting it was discussed that the brand name/trade name in case of pharmaceuticals is neither controlled by the Licensing Authority under the Drugs and Cosmetic Act 1940 & Rules 1945, nor the Trademarks office at present which leave scope for having same trade names for different drugs manufactured and sold in the Country, which may create a situation which is very detrimental to patients safety and the trade names which are not registered and repeated for different drugs can create confusion. Therefore, the Drugs and Cosmetic Rules 1945 may be amended to include the provisions for regulating brand names / trade names by the Central and State Licensing Authorities.*

*Accordingly, the matter was deliberated by DTAB in its 81st Meeting held on 29.11.2018. The Board has recommended for devising a mechanism under the Drugs and Cosmetic Rules 1945 to include provisions for regulating the brand names/ trade names of Pharmaceutical products. Accordingly draft rules were prepared and forwarded to the Ministry. The copy of the draft is placed as* ***ANNEXURE-6.***

*DCC may deliberate on the matter and give its recommendation."*

9. A perusal of the minutes of the DTAB meeting shows that an in-principle decision has been taken to recommend draft Rules to be notified under the Drugs and Cosmetics Act to deal with the regulation of identical brand names. The DCC was to meet on 1st February, 2019 as per the agenda. However, the outcome thereof is not known.

10. Mr. Rishi Kant, ld. counsel appearing for the DCGI submits that the draft Rules have, in fact, been circulated and forwarded to the Ministry and

the matter is currently being discussed internally.

11. The issue of pharmaceutical preparations and medicines being sold under identical brand names has been a concern in a large number of disputes. The said issue is not just one which concerns statutory rights or trademark rights of a particular IP owner, but has a larger impact on the health of the patients. Stringent quality control mechanisms ought to be put in place and implemented in the manufacture and sale of medicines. If medicines are allowed to be sold with identical brand names and that too in identical packaging, it is not just violative of the rights of IP owners but dangerous for consuming patients.

12. The Supreme Court had taken serious note of this and had held almost 18 years ago, in ***Cadila Health Care Ltd. v. Cadila Pharmaceuticals Ltd. (2001) 5 SCC 73*** *(hereinafter, 'Cadila Health Care')* that there ought to be some coordination between the Trademark registry and the drug authorities. In ***Cadila Health Care (supra),*** the Supreme Court had observed that ***"Drugs are poisons, not sweets"***. The observations of the Supreme court have been set out in the order dated 14th August, 2018 extracted above.

13. Under the Drugs and Cosmetics Act, 1940 (`DC Act'), the DCGI and the State FDAs are vested with powers to supervise and overlook the manufacture and sale of drugs. Section 17 and Section 17A of the DC Act deal with misbranded and adulterated drugs. The Central and State Governments are empowered to appoint inspectors who have vast powers as stipulated under Section 22. They have powers to inspect any premises, take samples, search any premises, search any vehicle, seek production of records. In fact, the powers are extremely wide so as to ensure that sub-standard medicines are not manufactured and sold. Such inspectors,

therefore, ought to keep regular supervision on all the manufacturing units falling within their territories, to ensure maintenance of the quality of medicines. The draft rules which are under consideration ought to take into consideration the situation of the ground and ensure that medicines with identical brand names and identical packaging are not allowed to be manufactured or sold.

14. Apart from the draft Rules, the following directions are issued for consideration by the authorities in order to regulate and better supervise the quality of medicines being manufactured and sold.

i) Creation of a secured platform, to be under the supervision of the DCGI, which is accessible to all State FDAs, both for access of data and for uploading of data;

ii) Creation of a `master electronic database' of all the approved brand names for manufacture and sale of drugs issued both by the DCGI and the State FDAs and making the same available to all state FDAs and Drug controllers through a secured platform. The list to be maintained and made available both brand wise and manufacturer wise, on the secured platform;

iii) List of registered trade marks under Class 5 for pharmaceutical and medicinal preparations be obtained from the Controller General of Patents, Trade marks and designs and be made available to the approving authorities at the Central level and State level. The said list ought to be updated bi-annually i.e., on 1st January and 1st July every calendar year;

iv) Access to the data be given to Drug Inspectors/Drug Controllers across the country;

v) Drug Inspectors/Drug Controllers to conduct regular and periodic inspections as per the Act and the Rules to ensure that the drugs that are being manufactured in a particular unit are duly licensed for. The reports of the said inspections to be submitted through the secured platform;

vi) Periodic and regular reports of drug inspectors should be compulsorily submitted to the respective licensing authorities on the secured platform and a mechanism be set up for review of the said reports at the State level;

vii) Periodic meetings ought to be held at the central level, to review the status of manufacture and sale of drugs across the country, under the aegis of the DCGI;

viii) Strict action in accordance with law ought to be taken against those manufacturers who manufacture drugs without licences, who indulge in adulteration or contamination of drugs etc. A periodic report as to the number of actions taken, ought to be uploaded on the secured platform of the DCGI.

15. It is clarified that the above directions are not exhaustive in nature.

16. The DCGI/DCC/DTAB and the Ministry of Health and Family Welfare, to take a comprehensive decision in respect of the draft rules and notify the draft rules for public comment within a period of three months from today. The draft rules so notified shall also be placed on the record of this Court. Copies of the same shall be supplied to the Ld. Counsels for the parties. After the draft rules are put up for public comments and are finalised, authorities to take expeditious action to amend the rules, notify the same in accordance with law, not later than 31st December, 2019. If the draft

rules are not placed before this Court within three months, the suit shall be listed by the Registry before the Court on 15th May, 2019. No further orders are called for in this suit. Decree sheet be drawn qua Defendant No.1 in terms of paragraph 4 above.

**PRATHIBA M. SINGH**
**JUDGE**

**FEBRUARY 06, 2019**
MR/*Rahul/dk/Agastya*

***(Corrected and released on: 13th February 2019)***