JUDGEMENT SHEET

IN THE ISLAMABAD HIGH COURT, ISLAMABAD
JUDICIAL DEPARTMENT

Writ Petition No. 3227/2022

Vifor (International) AG, Vifor (International) Ltd. and Vifor (International) Inc. through Authorized Signatory
Vs.
Drugs Appellate Board through its Chairman/Secretary, Islamabad & others

PETITIONER BY:	M/s Hasan Irfan Khan and Saqib Asghar Baig, Advocates.
RESPONDENTS BY:	Syed Muhammad Ghazanfar and Mr. Asad Ali Khan, Advocates, along with Hafiz Bilal Bin Akbar, Deputy Director (Legal Affairs), and Mr. Shoaib Khan, Assistant Director (Legal Affairs), DRAP. Mr. Akhtar Aziz Khan, Advocate for respondent No.4. Mr. Aqeel Akhtar Raja and Raja Muhammad Jawad Arslan, Assistant Attorney General. Mr. Shoaib Ali Khan, Deputy Director (Legal), Ministry of National Health Service Regulation & Coordination, Islamabad.
DATE OF HEARING:	31.10.2024.

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BABAR SATTAR, J.- The petitioner is aggrieved by the order of the Drug Registration Board (respondent No.2) dated 29.07.2021 pursuant to which an application filed by the petitioner for cancellation of the registration of a drug produced by respondent No.4 was dismissed, and the appeal against such dismissal order was also dismissed by the Drugs Appellate Board (respondent No.1) in its meeting held on 23.06.2022 as communicated to the petitioner by reasoning dated 18.07.2022.

2. The learned counsel for the petitioner submitted that respondent No.4 sought the registration of a drug called FERIJET which was registered by the Drug Registration Board on

31.01.2005. The trademark of FERIJET being used by respondent No.4 to manufacture and market its drug was deceptively similar to that of the petitioner's drug called FERINJECT, which was registered as a trademark with registration No.214400 dated 12.10.2005. The petitioner filed a suit for trademark infringement against respondent No.4 on 25.03.2010. The suit was decreed on 13.04.2018 and the Intellectual Property Tribunal restrained respondent No.4 from manufacturing, marketing and selling the pharmaceutical product under the trademark FERIJET, while also directing it to recall all stock of the product. He submitted that respondent No.4 did not challenge the judgment and decree of the Intellectual Property Tribunal dated 13.04.2018, which had attained finality. The petitioner was seeking execution of the decree in which various directions had been issued by the Intellectual Property Tribunal but respondent No.4 was yet to implement the judgment and was refusing to appear before the Intellectual Property Tribunal. He submitted that in its judgment the Intellectual Property Tribunal noted that FERIJET has been registered by the Drug Registration Board but rejected that as a defence on part of respondent No.4 on the basis that the registration of a drug or its name was no basis to assert that such trademark or tradename did not infringe the intellectual property rights of another person.

3. Respondent No.4 had appeared before the Intellectual Property Tribunal and had filed a written statement. Subsequently, it chose not to appear before the Intellectual Property Tribunal due to which an ultimate judgment was *ex-parte*. The Intellectual Property Tribunal held that there were

"graphic, phonetic, visual and structural similarities" between the two drugs and respondent No.4 was manufacturing and marketing FERIJET, which was deceptively similar to the petitioner's drug FERINJECT and was likely to call confusion with regard to the source of these products. The Intellectual Property Tribunal concluded that respondent No.4 had *"dishonestly adopted deceptively similar mark FERIJET in respect of the same product"*. He submitted that the petitioner filed an application dated 23.06.2024 before the Drug Regulatory Authority of Pakistan **("DRAP")** seeking cancellation of respondent No.4's drug FERIJET and the application was not decided. The petitioner then filed Writ Petition No.1483/2021 aggrieved by the inaction of DRAP and Drug Registration Board. During the pendency of said petition by order dated 17.06.2021 this Court directed that the petitioner's application be decided, which was then decided by impugned order dated 29.07.2021 passed by the Drug Registration Board. The said order was challenged before the Drugs Appellate Board, which appeal was dismissed by impugned order dated 18.07.2022. Both the orders have been impugned in the instant petition. He submitted that the order of the Intellectual Property Tribunal, being a Court of competent jurisdiction established to adjudicate disputes with intellectual property infringement including trademark infringement, had been disregarded by DRAP through orders dated 29.07.2021 and 18.07.2022. DRAP and the Drug Registration Board were executive authorities and could not sit in judgment over a ruling and decree issued by the Intellectual Property Tribunal setting its determination at naught. He submitted that the registration of a certain drug with a certain name could not be pleaded as a

defense in a trademark infringement dispute as held by the Sindh High Court in ***Novartis AG through Authorized Signatory vs. Nabiqasim Industries (Private) Limited through Chief Executive/Director/Company Secretary and another*** ***(2017 CLD 1136)*** *and* ***The Welcome Foundation Limited vs. Messrs Karachi Chemical Industries (Private) Limited*** ***(2000 YLR 1376)***. The Courts had deprecated the tendency of the parties to use registration under various other laws as a basis to deliberately infringe the rights of a counterparty protected through trademark registration. For this proposition he relied on ***M/s Farooq Ghee and Oils Mills (Pvt.) Ltd. Vs. Registrar of Trade Mark Registry and others (2015 CLD 1245)***, ***Pakistan Drug House (Pvt.) Ltd. Vs. Rio Chemical Company and another*** ***(2003 CLD 1531)*** *and* ***M/s ADT Services AG through Attorney and another Vs. M/s ADT Pakistan (Pvt.) Ltd.*** ***(2005 CLD 1546)***. He submitted that in case of trademarks related to pharmaceutical products any confusion caused due to similarity of the trademark/trade name under which the drug was manufactured and distributed could have fatal consequences, and consequently in such cases trademark rights had to be strictly enforced. He finally submitted that DRAP was an executive body which could not undo or override a determination of infringement made by the Intellectual Property Tribunal as a Court of law and was bound to give effect to the judgment of the Intellectual Property Tribunal. He submitted that the Drug Registration Board had erred in interpreting the provisions of the Drugs Act, 1976 **("Drugs Act")**, and the Drug Regulatory Authority of Pakistan Act, 2012 **("DRAP Act")**, without taking into consideration the fact that

the production, import and marketing of a counterfeit drug and/or a spurious drug was prohibited being an offence under Section 27 read with Section 23 of the Drugs Act. And as FERIJET had been declared to be deceptively similar to FERINJECT for which the petitioner had a registered trademark, the Drug Registration Board could not disregard the judgment of the Intellectual Property Tribunal and hold to the contrary that FERIJET was not a counterfeit drug within the meaning of Section 3(f) of the Drugs Act or that such counterfeit drug was not liable to cancellation in terms of Section 7(11) of the Drugs Act.

4. The learned counsel for respondents No.1, 2 and 3 submitted that the Drug Registration Board had registered FERIJET in terms of the Drugs Act and DRAP Act read with the Drugs (Licensing, Registering and Advertising) Rules, 1976 **("Drugs Registration Rules")** on 31.01.2005, which was prior to the trademark registration of FERINJECT later in 2005. He submitted that DRAP was not party to the suit filed by the petitioner against respondent No.4 and in the judgment and decree issued by the Intellectual Property Tribunal no direction had been issued to the DRAP to execute the judgment and decree. He submitted that the petitioner could also not use the constitutional jurisdiction of this Court as a means to seek the execution of the judgment and decree passed in its favor by the Intellectual Property Tribunal. He submitted that the Drug Registration Board in its order dated 29.07.2021 had correctly appreciated that the Drugs Act and the DRAP Act operated in their own domain and were to be given effect independently without being influenced by any proceedings or determinations

made under the Trade Marks Ordinance, 2001 **(Trade Marks Ordinance")**. For purposes of registration of drugs and regulating their production, import, marketing and sale, the Drugs Act and DRAP Act were special laws whose provisions were to be given overriding effect over the Trade Marks Ordinance. And the registration of a drug could not be cancelled merely on the basis that it has been found by a Tribunal under provisions of the Trade Marks Ordinance that the name of such drug infringes a registered trademark. He submitted that for purpose of a registration of a drug, the Drug Registration Board focused exclusively on therapeutic quality, safety and efficacy of the drug and not on related intellectual property rights. He submitted that the composition of respondent No.4's drug FERIJET was different from the composition of the petitioner's drug FERINJECT, which reduced the possibility of any confusion. He submitted that FERINJECT had been registered by the Drug Registration Board on 12.02.2013 and such registration certificate stated that in the event that there was any similarity with the name of another drug, the manufacturer would be obliged to change the name of its drug. He submitted that FERINJECT was registered as a drug on 12.02.2013 and FERIJET was registered as a drug on 31.01.2005, it was the petitioner that was obliged to change the name of its drug in the event of any confusion between its drug and not that produced by respondent No.4. He submitted that in view of these facts the Drug Registration Board had correctly dismissed the application seeking cancellation of the drug of respondent No.4. As doing so was neither in public interest nor had it been found that there was any misrepresentation on part of respondent No.4 in

seeking the registration of its drug. Further the circumstances in which respondent No.4's drug had been registered had not changed significantly in terms of Section 7(11)(b) of the Drugs Act and consequently no ground was made out to cancel the drug FERIJET.

5. The counsel for respondent No.4 defended the orders of the Drug Registration Board and the Drugs Appellate Board. He submitted that there was no warrant for cancelling the registration of its drug FERIJET, which was registered with the Drug Registration Board prior in time to the petitioner's drug FERINJECT. He adopted the legal arguments made by the learned counsel for DRAP.

6. The questions that arise in the instant petition are the manner in which provisions of the Drugs Act and DRAP Act are to be read with provisions of the Trade Marks Ordinance. And whether the provisions of the drug-related laws and the intellectual property laws can be read harmoniously to give effect to their respective provisions without concluding that there exists a conflict between them. The second question that arises is whether a judgment of the Intellectual Property Tribunal vested with jurisdiction over the question of trademark infringement, declaring that a trademark being used by a drug manufacturer infringes the trademark of another drug manufacturer, is conclusive and binding for purposes of the Drug Registration Board in determining that the infringing drug, as declared by the Intellectual Property Tribunal, is to be treated as a counterfeit drug within the meaning of Section 3(f) of the Drugs Act.

7. It is not contested that using a counterfeit trademark is prohibited under the Trade Marks Ordinance and manufacturing the counterfeit drug is prohibited and declared to be an offence under the Drugs Act. Further the use of a false trademark has also been declared to be an offence under the Pakistan Penal Code, 1860 **("PPC")**.

8. Let us state the relevant definitions from the Trade Marks Ordinance, the Drugs Act and the Pakistan Penal Code.

> ***Section 2(xlvii) of the Trade Marks Ordinance.***
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> *"Trade mark" means any mark capable of being represented graphically which is capable of distinguishing goods or services of one undertaking from those of other undertakings.*
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> ***Section 2(ix) of the Trade Marks Ordinance.***
>
> *"Counterfeit trade mark goods" means any goods including packaging bearing without authorization a trade mark which is identical or deceptively similar to the trade mark validly registered in respect of such goods or which cannot be distinguished in its essential aspects from such a trade mark and infringes rights of the owner of the trade mark under this Ordinance.*
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> ***Section 2(xii) of the Trade Marks Ordinance.***
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> *"deceptively similar" in relation to a trade mark, means such near resemblance between it and another trade mark that it is likely to deceive or cause confusion.*
>
> ***Section 3(f) of the Drugs Act***
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> *"Counterfeit drug" means a drug the label or outer-packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture.*
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> ***Section 28 of PPC***
>
> *"Counterfeit". A person is said to "counterfeit" who causes one thing to resemble another thing, intending by means of that resemblance to practice deception, or knowing it to be likely that deception will thereby be practiced.*

9. Let us also reproduce for convenience provisions from the Trade Marks Ordinance, the Drugs Act and PPC relevant for our purposes.

Section 39 of the Trade Marks Ordinance: *Rights conferred by registration.-*

(1) A registered trade mark shall be a personal property.

(2) The proprietor of a registered trade mark shall have exclusive rights in the trade mark which are infringed by use of the trade mark in Pakistan without his consent.

(3) Without prejudice to the rights of the proprietor of a registered trade mark to obtain any relief under any other law for the time being in force, the proprietor shall also have the right to obtain relief under this Ordinance if the trade mark is infringed.

Section 40 of the Trade Marks Ordinance: *Infringement of registered trade mark.-*

(1) A person shall infringe a registered trade mark if such person uses in the course of trade a mark which is identical with the trade mark in relation to goods or services which are identical with those for which it is registered.

(2) A person shall infringe a registered trade mark if such person uses in the course of trade a mark where because-

(a) the mark is identical with the trade mark and is used in relation to goods or services similar to the goods or services for which the trade mark is registered; or

(b) the mark is deceptively similar to the trade mark and is used in relation to goods or services identical with or similar to the goods or services for which the trade mark is registered, there exists a likelihood of confusion on the part of public, which includes the likelihood of association with the trade mark.

Section 7 of the Drugs Act: *Registration of drugs-*

(11) If the Registration Board, on the basis of information received or an f inquiry conducted by it, is of opinion that-

(a) the registration of a drug was procured by fraud or misrepresentation; or

(b) the circumstances in which a drug was registered no longer exist; or

(c) there has been a violation of the conditions subject to which a drug was registered; or

(d) it is necessary in the public interest so to do;

Section 23 of the Drugs Act: *Import, manufacture and sale of drugs.*

(1) No person shall himself or by any other person on his behalf:-

(a) export, import or manufacture for sale or sell:

(i) any spurious drug;
(ii) any counterfeit drug;
(iii) any misbranded drug;
(iv) any adulterated drug;
(v) any substandard drug;
(vi) any drug after its expiry date;
(vii) any drug which is not registered or is not in accordance with the conditions of registration;
(viii) any drug which, by means of any statement, design or device accompanying it or by other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;
(ix) any drug if it is dangerous to health when used in the dosage or with the frequency, or for the duration specified, recommended or suggested in the labelling thereof; or
(x) any drug in contravention of any of the provisions of this Act or any rule;

(2) Nothing in sub-section (1) shall apply to the manufacture or import, subject to prescribed conditions, of small quantities of any drug for the purpose of clinical trial, examination, test, analysis or personal use.

Section 27 of the Drugs Act: *Penalties.-*

(1) Whoever himself or by any other person on his behalf:-

(a) exports, imports, manufactures for sale or sells any spurious drug or any drug which is not registered;

(b) manufactures for sale any drug without a licence; or

(c) imports without licence any drug for the import of which a licence is required;

shall be punishable with imprisonment for a term which shall not be less than three years or more than ten years and with fine which may extend to one lakh rupees:

Provided that the Drug Court may, for any special reasons to be recorded, award a sentence of imprisonment for a term of less than three years.

> ***Section 478 of the PPC:*** *Trade Mark.*
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> *A mark used for denoting that goods are the manufacture or merchandise of a particular person is called a trade mark, and for the purpose of this Code the expression "trade mark" includes any trade mark which is registered in the register of trademarks kept under the Trade Marks Act, 1940 (V of 1940).*
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> ***Section 480 of PPC:*** *Using a false Trade Mark.*
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> *Whoever marks any goods or any case, package or other receptacle containing goods, or uses any case, package or other receptacle with any mark thereon, in a manner reasonably calculated to cause it to be believed that the goods so marked, or any goods contained in any such receptacle so marked, are the manufacture or merchandise of a person whose manufacture or merchandise they are not, is said to use a false trade mark.*
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> ***Section 482 of PPC:*** *Punishment for using a false trade mark or property mark.*
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> *Whoever uses any false trade mark or any false property mark shall, unless he proves that he acted without intent to defraud, be punished with imprisonment of either description for a term which may extend to one year, or with fine, or with both.*
>
> ***Section 483 of PPC:*** *Counterfeiting a trade mark or property mark used by another.*
>
> *Whoever counterfeits any trade mark or property mark used by any other person shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both.*

10. The Trade Marks Ordinance was enacted to *"amend and consolidate the law relating to trademarks"* in Pakistan in terms of determining the rights of a trademark owner and infringement of a trademark. The Trade Marks Ordinance is a special law that will trump other laws in case of conflict when it comes to determination of trademark infringement or enforcement of the rights of a trademark owner. The history of enactment of the Trade Marks Ordinance was enumerated by the Division Bench of the Sindh High Court in ***Soneri Travel and Tours Ltd. vs. Soneri Bank Limited (2011 CLD 193)*** in the following terms:

> *"Along with the Marrakesh Agreement, the states party to the same (known as member states, and including Pakistan) also entered into a number of other agreements, one of the most important of which (and of particular relevance for present purposes) was the Agreement on Trade-related Aspects of Intellectual Property Rights (commonly known as TRIPS). As its name suggests, TRIPS relates to intellectual property rights including patents, trademarks and designs. Developed countries had to bring their national legislation in conformity with the WTO and other related agreements, including TRIPS, more or less immediately, but developing countries like Pakistan were given certain grace periods in this regard, which in the case of TRIPS extended up to 5 years."*

11. The provisions of the Trade Marks Ordinance give effect to the rights of registered trademark owners articulated in Articles 15 to 21 of the Agreement on Trade-Related Aspects of Intellectual Property Rights **("TRIPS")**. In the impugned order passed by the Drugs Appellate Board, it has misapplied itself to the origin of trademark rights protection and the evolution of intellectual property protection regime within the realm of international law as well as within Pakistan, by holding that the legislature sought to create no linkage between registration of drugs and intellectual property rights being *"cognizant of the hard-won victories by the developing world in the international regime of intellectual property laws."* Pakistan is a signatory to TRIPS and as underscored by the Sindh High Court in **Soneri Travel and Tours Ltd.** the provisions of the Trade Marks Ordinance are to be interpreted such that they give effect to provisions of TRIPS. Article 17 of TRIPS provides as an exception that, *"members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate*

interests of the owner of the trademark and third parties." The only occasion to conclude that trademark infringement would be of no consequence in the realm of drug registration would have arisen had the legislature provided for such exception by a clear statutory provision as contemplated by Article 17 of the TRIPS Agreement. Any such exception would also need to be narrowly tailored to protect the legitimate interests of owners of trademark, and also third parties, which in case of drug registration would be the consumers of drugs. No such exception has been provided under the Drugs Act or the DRAP Act. To the contrary, in terms of Section 3(f) of the Drugs Act that defines counterfeit drugs, together with Sections 23 and 27 of the Drugs Act, there is not just a clear prohibition against export, import or manufacture of a counterfeit drug, but doing so constitutes an offence punishable with imprisonment for up to seven years.

12. The definition of a counterfeit drug under the Drugs Act is meant to cover the same subject-matter that has been addressed by the definitions of "counterfeit trademark goods" and "deceptively similar" as defined under the Trade Marks Ordinance. A counterfeit drug under the Drugs Act is one that *"is an imitation of or resembles or so nearly resembles as to be calculated to deceive…"* The Trade Marks Ordinance also defines counterfeit trademark goods to include *"a trademark which is identical or deceptively similar to the trademark validly registered in respect of such goods…"* And deceptively similar is then defined as *"near resemblance between it and another trademark that is likely to deceive or cause confusion."* Notwithstanding the difference of language in the definitions, there is no conceptual difference in terms of the subject-matter

that the definitions seek to cover. It is therefore curious that the Drug Registration Board and the Drugs Appellate Board somehow came to the conclusion that the prohibition to export, import or manufacture a counterfeit drug was not reflective of the legislative intent to protect the property of a registered trademark owner in relation to a drug as well as the interests of consumers of such drug.

13. Let us restate a few principles of interpretation before moving further ahead. It is a settled principle of interpretation that special law overrides general law. For purposes of determining the rights of a trademark owner as well as trademark infringement, the Trade Marks Ordinance is the special law and not the Drugs Act. When a question arises whether a drug qualifies as a counterfeit drug for using a trademark or tradename that is identical or deceptively similar to a registered trademark or tradename of another drug, a determination made by a court under provisions of the Trade Marks Ordinance ought to prevail. For other matters related to the import, export, manufacture, storage, distribution and sale of drugs, there is no cavil with the proposition that the Drugs Act is the special law. There is no provision within the Drugs Act that gives it an overriding effect over the Trade Marks Ordinance, which was enacted later in time. The DRAP Act was enacted in 2012. Section 32 of the DRAP Act provides that its provisions are in addition to and not in derogation of provisions of the Drugs Act. Pursuant to Section 27 of the DRAP Act, Schedule-II prohibits the import, manufacture and sale of a counterfeit therapeutic good and Schedule-III provides that the import, manufacture or sale of a counterfeit therapeutic good attracts

imprisonment of up to seven years. In this regulatory scheme, it is evident that the legislature has penalized the import, manufacture or sale of a counterfeit drug in full view of the provisions of the Trade Marks Ordinance.

14. The other principle of interpretation that must be borne in mind is that no absurdity can be attributed to the legislature. It cannot be countenanced that on the one hand the legislature would declare the use of identical or deceptively similar trademarks to be an offence, and on the other hand it would allow the use of identical or deceptively similar trademarks for purposes of drug registration and use. Statutory provisions within municipal laws are to be interpreted such that they speak with one voice and add certainty with regard to the requirements they impose on citizens. It is not desirable to imagine conflicts between statutory provisions where none exist. It is to be assumed that the legislature while enacting a statute was aware of other statutory provisions and meant for the provisions of different statutes to co-exist without creating conflicts. It is from such perspective that provisions of different statutes are to be approached to provide harmonious interpretation to them, of course without doing any violence to the text of such provisions.

15. The manner in which provisions of the Drugs Act and the DRAP Act are to be interpreted came before the Lahore High Court in ***Dawakhana Hakim Ajmal Khan (Pvt.) Limited vs. Federation of Pakistan and others*** ***(PLD 2020 Lahore 899)***, in which it was held that, *"different regulatory regimes work for different regulatory objectives. The regulatory objective impacts the purpose of the regulator and its policy, therefore, each*

regulatory regime will work within its regulatory field and achieve its regulatory objective. The significant factor in this case is that each regulator works in furtherance of its own objective and in doing so there may be a situation when two or more regulatory regimes call for compliance over the same product. This suggests that there can be overlaps and even in some cases conflict between the regulatory regimes. However, neither the overlap nor the conflict can be interpreted to mean that different regulatory regimes cannot co-exist, or that a product or entity cannot be subjected to more than one regulatory regime. Regulatory overlap is possible because the legislature gives regulating authorities broad based delegation of authority to give them flexibility to respond to the changing regulatory environment. This does not make regulatory regimes incompatible or mutually exclusive. Any overlap or conflict will have to be seen on case to case basis, in the context of the facts and circumstances of the case and possibly call for better coordination and harmonization."

16. There appears to be no conflict between the manner in which provisions of the Trade Marks Ordinance and the Drugs Act/DRAP Act are to be given effect. Provisions of the Drugs Act and DRAP Act are not in conflict with provisions of the Trade Marks Ordinance. Under both sets of laws the import, manufacture and sale of counterfeit goods has been prohibited and declared to be an offence. Any reading of the provisions to the contrary would amount to imagining a conflict where none exists. The relevant part of Section 39 of the Trade Marks Ordinance and the rights conferred by the registration of a trademark has been reproduced above. Section 39(1) of the

Trade Marks Ordinance declares a registered trademark to be the personal property of the trademark owner. It cannot be imagined that the legislature, while enacting the Drugs Act or the DRAP Act, wished that the property rights of a person could be infringed without consequence when it came to the import, manufacture or sale of drugs. Articles 23 and 24 of the Constitution protect the property rights of citizens and to the extent that the legislature sought to provide an exception for purposes of import, manufacture or sale of drugs, it would have done so explicitly. In view of the constitutional protection afforded to property rights it cannot be assumed or concluded under some theory of interpretation that while enacting the Drugs Act and/or the DRAP Act the legislature wished to create a haven for drug manufacturers to usurp trademark rights of competitors.

17. Trademarks serve at least two purposes. One, they constitute the property rights of the holder enabling such holder to identify and distinguish his/her goods from that of another person. And two, they act as an aid to consumer protection by enabling a consumer to identify products and distinguish them from other products. It is therefore both the rights of the trademark holder and the rights of the consumer that the Trade Marks Ordinance seeks to protect by prohibiting use of identical or deceptively similar trademarks. And it is to prevent any deception or confusion within the realm of drugs that the Drugs Act prohibits the import, manufacture or sale of counterfeit drugs. There is nothing in the Drugs Act or the DRAP Act that leads one to the conclusion that the legislature did not wish to protect consumers of drugs from unfair competition and

consumer deception. It needs to be highlighted that confusion or deception within the market for drugs can have devastating and/or fatal consequences. The principle prohibiting manufacture, import or sale of identical or deceptively similar goods therefore needs to be strictly applied when it comes to drugs.

18. The Indian Supreme Court in ***Cadila Healthcare Ltd. vs. Cadila Pharmaceutical Ltd. (2001(5) SCC 73)*** held that the following factors were relevant when it came to the question of deceptive similarity:

a) The nature of the marks, i.e., whether the marks are word marks, label marks, composite marks.

b) The degree of resemblances between the marks, phonetically similar and hence similar in idea.

c) The nature of the goods in which they are used as trademarks.

d) The similarity in the nature, character, and performance of the goods of the rival traders.

e) The class of purchasers who are likely to buy the goods bearing the marks they require on their education and intelligence and a degree of care they are likely to exercise in purchasing and/or using the goods.

f) The mode of purchasing the goods or placing orders for the goods; and

g) Any other surrounding circumstances which may be relevant in the extent of dissimilarity between the competing marks.

It further held, in the facts and circumstances of the case before it that, *"the drugs have a marked difference in the compositions with completely different side effect, the test should be applied strictly as the possibility of harm resulting from any kind of*

confusion by the consumer can have unpleasant if not disastrous results... If the goods involved are medical products each with different effects and designed for even subtly different uses, confusion among the products caused by similar marks could have disastrous effects. For these reasons, it is proper to require a lesser quantum of proof of confusing similarity for drugs and medicinal preparations… A stricter approach should be adopted while applying the test to judge the possibility of confusion of one medicinal product for another by the consumer. While confusion in the case of non-medicinal products may only cause economic loss to the plaintiff, confusion between two medicinal products may have disastrous effects on health and in some cases life itself."

19. A key obligation of the regulator under the Drugs Act and the DRAP Act is to ensure that drugs are safe and their use is efficacious. Where a consumer is likely to be confused or deceived into using a drug produced by one manufacturer while he/she actually intended to use the drug produced by another manufacturer, the underlying issue becomes that of the safety and efficacy related to the use of such drug. It is not simply a question of intellectual property rights that can be brushed aside with complete disregard for the underlying consumer interest in being able to procure what he/she has been prescribed and/or what he/she intends to procure. In the instant case, the Drug Registration Board and the Drugs Appellate Board have concluded that the formulation of the drugs in question (i.e. FERIJET and FERINJECT) is not identical. The question before the drugs regulator was not whether respondent No.4 is to be authorized to produce FERIJET. The question was whether

respondent No.4 could be authorized to manufacture and sell FERIJET, which was found to be deceptively similar as a trade name/trademark to the petitioner's drug (i.e. FERINJECT). In concluding that the matter before the Drug Registration Board had nothing to do with the safety and efficacy of use of FERIJET, the Drug Registration Board and the Drugs Appellate Board have completely misapplied themselves to the issue before them. For purposes of import, manufacture and sale of drugs, the rule that the trademark or trade name of a drug must not be identical or deceptively similar to another is to be strictly applied and the threshold of proof is not as high as that in relation to other goods where a question of trademark infringement arises. This is due to the reason correctly identified by the Indian Supreme Court in **Cadila Healthcare Ltd.** (i.e. in case of any confusion over the use of a drug that has been mistaken for another drug, the consequences can be disastrous). Within the realm of trademark law, the protection being afforded to a trademark owner may have a greater focus on the property rights of such owner. But within the realm of regulation of manufacture, import or sale of drugs, the focus on preventing and prohibiting the use of counterfeit drugs is guided by the interests of the consumer of drugs.

20. The learned counsel for the DRAP relied on ***Bayer Corporation & ORS vs. UOI & ORS*** ***(ILR (2009) SUPP. 2 Delhi 145)*** for the proposition that there was no interface between patent law and drug registration, and such principle as laid down by the Delhi High Court was equally applicable to trademarks. **Bayer Corporation & ORS** does not help the case of the respondents. In the said matter, the Delhi High Court

went to a significant length to explain the distinction between patent protection and trademark and/or copyright protection. The Delhi High Court held in **Bayer Corporation & ORS** that, *"the Drugs Act is a public regulatory measure, prescribing standards of safety and good manufacture practices which are to be followed by every pharmaceutical industry, or which are to be satisfied by the importer of a drug, to assure that what are marketed are safe. The provisions of the Act manifest parliamentary concern with public health in ensuring standard practices and that people do not fall prey to adulterated or spurious drugs."* The Delhi High Court observed that it was the controller of patents that had the expertise to judge whether a product was patentable or not and that, "*such expertise does not necessarily exist in the case of officials under the Drugs Act, who are required to test the safety of the product, and ensure that it conforms to the therapeutic claim put forward. Whether it involves an inventive step, or is novel, is not within the domain of the Drugs Act authorities and officials."* It was in the context of one party seeking the prevention of registration of a drug on the allegation that it breached the patent of such party that the Delhi High Court ruled that without the establishment of patent infringement before a court of law established under the Patents Act, the drugs regulator could not assume that such infringement existed and could not deny registration on the basis of allegations alone. It further clarified that, *"Parliament never expressed any intention, significantly, to place patent superintendence, or policing powers, with drug agencies."*

21. In the instant case, it has been held by the Intellectual Property Tribunal that the drug FERIJET manufactured and sold

by respondent No.4 is deceptively similar to the drug FERINJECT manufactured by the petitioner, and the Intellectual Property Tribunal has prohibited respondent No.4 from manufacturing and selling its drug while also ordering the removal of FERIJET's existing stock from the market. This is not a case of the petitioner pre-empting the registration of the drug on the basis of an allegation that the trademark of the drug of respondent No.4 is deceptively similar to that of the petitioner's drug. This has been found by a court of competent jurisdiction established for purposes of determining trademark infringement. The legislature, indeed, did not intend to place trademark superintendence with the Drug Registration Board or DRAP. Consequently, the Drug Registration Board cannot sit in judgment over a determination duly made by the Intellectual Property Tribunal that the trademark or trade name being used by a certain drug manufacturer is deceptively similar to the registered trademark of another drug. Where such determination has been made, it is for the Drug Registration Board to simply give effect to such determination within the meaning of provisions of the Drugs Act and the DRAP Act.

22. It has been held by the Sindh High Court in multiple cases that the mere registration of a drug under the Drugs Act does not immunize a party against the claim of infringement of its intellectual property rights in relation to patents and designs (see ***Sandoz Limited and another vs. Pakistan Pharmaceutical Products Limited (1987 CLC 1571)***, ***Pfizer Limited Vs. Wilson's Pharmaceuticals (2002 CLD 1653)*** and ***Getz Pharma (Pvt.) Limited through Authorized Signatory vs. Servier Laboratories (France) and another***

(2016 CLD 2229)). It was similarly found by the Sindh High Court in **The Welcome Foundation Limited** that the registration of a product under the Drugs Act could not protect the manufacturer or importer of the drug from a claim of infringement under the Trade Marks Ordinance. Likewise, it was held by the Sindh High Court in **Novartis AG** that, *"while public health concerns (e.g. drug name mistakes) are not strictly relevant to the issue of trade mark registration, however courts and drug authorities around the globe agree that they may be seriously considered when assessing the issue of confusion between drug names. In Sanofi-Aventis v GlaxoSmithKline Biologicals SA ((2010) 89 CPR (4th) 378 (TMOB)) the Canadian Trade Marks Opposition Board considered the issue of medication errors as a surrounding circumstance contributing to the likelihood of confusion between the trademarks PACIRIX and PLAVIX. The Board found both the marks to be confusing even though they were associated with different pharmaceutical preparations and end-uses. One other aspect that we need to consider in case where a new entrant in the market-place adopts an already existed distinctive and established trade mark is to make a query as to why the latter entrant had chosen a trade mark deceptively similar with one that had existed long before. When we posed this question to the learned counsel for the respondents as to why his client chosen to use a similar six letter word for which only the first letter "L" was replaced with the letter "D" (LESCOL v. DESCOL), the learned counsel had no satisfactory answer."*

23. While passing the impugned order dated 29.07.2021, the Drug Registration Board sought to sit in judgment over the

determination made by the Intellectual Property Tribunal in its judgment dated 13.04.2018, wherein it found that FERIJET was deceptively similar to FERINJECT and had been dishonestly adopted in a manner that undermined the rights of the petitioner. A perusal of the impugned order reflects that the Drug Registration Board sought to interpret provisions of the Trade Marks Ordinance to reach a contrary conclusion when it is vested with no authority to superintend provisions of the Trade Marks Ordinance or reach a conclusion different from one reached by a court of competent jurisdiction established for purposes of determining trademark claims under the Trade Marks Ordinance. The Drug Registration Board asserted in the impugned order that was concerned primarily with therapeutic quality, safety and efficacy of drugs and that FERIJET being deceptively similar to FERINJECT did not impinge on such concerns. Such finding is obviously contrary to the prohibition against the export, import or manufacture and sale of a counterfeit drug under Section 23 of the Drugs Act, which is punishable under Section 27 of the Drugs Act.

24. The Drug Registration Board further misapplied itself to the requirements of cancellation of a registration under Section 7(11) of the Drugs Act by concluding that there neither existed any circumstance which would lead the Drug Registration Board to conclude that the drug ought not be registered nor was it necessary in public interest to cancel the registration of FERIJET registered by respondent No.4. Once the Intellectual Property Tribunal had determined that the drug FERIJET manufactured and sold by respondent No.4 was deceptively similar to the drug FERINJECT manufactured by the petitioner, there existed a

determination validly made that FERIJET was a counterfeit drug. And consequently, in terms of Section 7(11)(b) of the Drugs Act the circumstances in which the drug FERIJET was registered no longer existed, as in the event that at the time of such registration such declaration was already in the field, the drug would not have been registered.

25. Further, once it had been declared that FERIJET was deceptively similar to FERINJECT and the trade name had been deceptively adopted to pass it off as the drug manufactured by the petitioner, it was necessary in public interest to cancel the registration in terms of Section 7(11)(d) of the Drugs Act to guard against the possibility that a person intending to purchase the drug FERINJECT did not mistakenly purchase FERIJET. The Drugs Appellate Board somehow conceived its refusal to give effect to the rights protected under the Trade Marks Ordinance, as declared by the Intellectual Property Tribunal, as some valorous act promoting the interests of developing countries against developed countries. Notwithstanding the debate with regard to the protections afforded to intellectual property disparately affecting interests in the North versus interests in the South, the matter before the Drug Registration Board was to give effect to the provisions of the Drugs Act and not to fight an imaginary war to promote the interest of manufactures and sellers of drugs unfettered by intellectual property claims.

26. The Drug Registration Board as well as the Drugs Appellate Board misapplied themselves in concluding that as the Drug Registration Board was not a party in the suit decreed by the Intellectual Property Tribunal, it had no obligation to give

effect to its findings. The drugs regulator has no dog in the fight between rival parties claiming trademark rights in their drugs. The drugs regulator is also not a court of law that can record evidence and make determinations with regard to claims of trademark infringement under the Trade Marks Ordinance. The rights guaranteed under the Trade Marks Ordinance by virtue of issuance of trademark registration are however to be used as a proxy by the drugs regulator to determine whether or not a drug sought to be registered is a counterfeit drug likely to cause confusion or deception or not. Where such claim has been settled and a determination has been made by the Intellectual Property Tribunal competent to do so, it is not for the drugs regulator to sit in judgment or second-guess such determination. Any aggrieved party has a right to contest such determination made by the Intellectual Property Tribunal in appellate proceedings. But once such determination has attained finality, it is for the drugs regulator to give effect to it for purposes of the Drugs Act.

27. Once a determination had been made by the Intellectual Property Tribunal that FERIJET was deceptively similar to FERINJECT by judgment and decree dated 13.04.2018, such judgment and decree was dispositive for the question of whether or not FERIJET was a counterfeit drug. The only question for the Drug Registration Board was then to exercise its powers under Section 7(11) of the Trade Marks Ordinance in determining whether respondent No.4 was willing to change the name of the drug so that it no longer qualified as a counterfeit drug and register the drug with a changed name. Instead of exercising its regulatory powers as such, the Drug Registration

Board concluded that the drugs market was a zone wherein parties could function unconstrained by protections afforded under the Trade Marks Ordinance. In doing so, the Drug Registration Board and the Drugs Appellate Board misapplied themselves to the provisions of the Drugs Act and the DRAP Act and the manner in which they are to be read along with provisions of the Trade Marks Ordinance.

28. For the above reasons, the impugned orders dated 29.07.2021 and 18.07.2022 are not sustainable in the eyes of law and are ***set-aside***. The registration of the drug FERIJET with the Drug Registration Board is liable to be cancelled in terms of Section 7(11)(b) and (d) of the Drugs Act, and shall be so cancelled. The Drug Registration Board is at liberty to invite respondent No.4 to change the tradename and/or trademark used for the drug manufactured and sold by it to a different one, such that it no longer remains an infringing trademark to that of the petitioner.

29. The petition is **allowed** in the above terms with a cost of Rs.50,000 payable by Respondent No. 4 to the Petitioner within a period of 4 weeks.

(BABAR SATTAR)
JUDGE

Announced in the open Court on **27.12.2024**.

JUDGE

Approved for reporting

A. Rahman Abbasi.