IN THE HIGH COURT OF SINDH AT KARACHI

Present:
Mr. Justice Muhammad Shafi Siddiqui
Mr. Justice Omar Sial.

(1)
High Court Appeal No.117 of 2023

Uzair Saboor
Versus
Federation of Pakistan & others

(2)
High Court Appeal No.118 of 2023

M/s Abbott Laboratories (Pakistan) Limited
Versus
Federation of Pakistan & others

(3)
High Court Appeal No.119 of 2023

M/s Muller & Phipps Pakistan (Pvt.) Limited
Versus
Federation of Pakistan & others

(4)
High Court Appeal No.120 of 2023

M/s NutriCo Morinaga (Pvt.) Limited
Versus
Federation of Pakistan & others

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Dates of hearing: 17.01.2024, 24.01.2024 and 26.03.2024.

Mr. Muhammad Vawda, Advocate for Appellants in all appeals.

Syed Muhammad Ghazanfar along with Syed Jamil Ahmed, Advocates for Respondent No.2/DRAP.

Mr. Touqeer Ahmed along with Mr. Hafeezullah, Advocates for Respondent No.5/FBR.

Mr. Shah Nawaz M. Sahito, Advocate for Respondent No.6.

Mr. Kazi Abdul Hameed Siddiqui, Assistant Attorney General.

Mr. Abdul Jaleel Zubedi, Assistant Advocate General Sindh.

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J U D G M E N T

Muhammad Shafi Siddiqui, J.- Appellants/Plaintiffs have filed their respective suits for declaration and permanent injunction wherein the legislative competence of Parliament was challenged to bring baby milk/infant milk within the regulatory regime of the Drug Regulatory Authority of Pakistan Act, 2012 [DRAP ACT, 2012] and

consequently an SRO No.412(I)/2014 [Rules, 2014] and a letter of 23rd September, 2016 of the Drug Regulatory Authority of Pakistan [DRAP] issued to Model Customs Collectorate Appraisement brought to a challenge in the suits. The suits were contested by the Respondents and following legal issues were framed.

1. *Whether DRAP Law is ultra vires the Constitution of the Islamic Republic of Pakistan, 1973?*

2. *Whether the Impugned Notification (SRO-412/2014) is ultra vires the above statute; and even if not, applicable to the Subject Products, for its enlistment with Defendant No.2 (DRAP)?*

3. *Whether the Letter dated 23.09.2016 and in pursuance of Circular of 07.10.2016 (issued by Defendant No.2 and Defendant No.6- Collector of Customs) in pursuance of above Impugned Notification, are valid or not?*

4. *What should the Decree be?*

2. The DRAP law in pursuance of issue No.1 was declared to be intra vires to the Constitution of Pakistan, whereas, the two later issues, which dilated upon the SRO and the letter to customs referred above, were also held to be in line with the above Law, Rules and the statutory requirement of the Act.

FACTS

3. The appellants are the importers of baby milk of different brands which they claimed to be a food item and regulated by Sindh Food Authority Act, 2016 and the Sindh Protection and Promotion of Breast-Feeding and Child Nutrition Act, 2023 and the Pakistan Standard Quality Control Authority.

4. It is appellants' case that DRAP Act, 2012 contained no provision which mandates the baby milk products to be regulated, licensed and enlisted by DRAP. It further does not prohibit or restrict sale of the baby milk, as claimed, without license/ enlistment from

DRAP. Learned counsel in this regard has relied upon the Schedule-II of DRAP Act, 2012 and the description/definition of 'therapeutic' goods, as provided under Section-2(xxxvi) of ibid Act.

5. It is argued that under Section 4(1)(h) of the DRAP Act, 2012 there is a Director Health and OTC (over the counter) products (non-drugs) and it does not cite baby milk and thus the Director Health and OTC has no power and the jurisdiction regarding baby milk. It is argued that although baby milk is mentioned in Section-2(xv) of the DRAP Act, 2012 [Definition of health and OTC products (non-drugs)], the legislature has deliberately omitted baby milk from the powers given to Director Health and OTC under Section-4(1)(h).

6. It is thus urged that the impugned SRO that is Alternative Medicines and Health Products (Enlistment) Rules, 2014 to the extent whereby Rule-3(1) requires the appellant to enlist baby milk/ infant milk, is thus ultra vires the Drug Regulatory Authority of Pakistan Act, 2012 and accordingly is of no legal effect.

7. Mr. Ghazanfar has opposed the arguments in the light of observations and discussion in Judgments such as Azfar Laboratories case[1] and Dawakhana Hakim Ajmal case[2] which has concluded the issue in principle. In addition to above citations, he has also taken us to the entire scheme of DRAP Laws which describe the drugs and therapeutic goods/alternative medicines.

8. With this background of facts, we have heard learned counsel and perused the material available on record.

[1] PLD 2018 Sindh 448 [M/s Azfar Laboratories (Pvt.) Ltd. through Directors and others v. Federation of Pakistan through Ministry of Health Services and 4 others].
[2] PLD2020 Lahore 899 [Dawakhana Hakim Ajmal Khan (Pvt.) Ltd. v. Federation of Pakistan and others].

ANALYSIS

9. Prior to the Eighteenth Amendment to the Constitution of Islamic Republic of Pakistan, 1973, the matters related to the drugs and medicines were listed under Entry No.20 of the Concurrent Legislative List as contained in the Fourth Schedule to the Constitution. Drugs and Medicines related issues were administered under the Drugs Act, 1976, which was a federal legislation. Section-3(g) of the Drugs Act, 1976 in terms of its clause-(i) includes the following:-

> *"(i). any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of disease, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals……".*

10. The Eighteenth Amendment brought the DRAP Act, 2012 in aid of Drugs Act, 1976 when the Concurrent Legislative List was abolished from the Fourth Schedule to the Constitution. As the issue therein was dealt with under Entry No.20 of the Concurrent Legislative List, it then after Eighteenth Amendment devolved to the provinces, the Provincial Assembly passed a resolution under Article-144 of the Constitution on 15.02.2012 to the effect that the Parliament may enact a law regarding enactment of Drug Regulatory Authority of Pakistan. Understandably, as not disputed, the other provinces have also obliged. The Parliament then enacted the Drug Regulatory Authority of Pakistan Act, 2012, which also meant to regulate the broad field of therapeutic goods defined under Section-2(xxxvi) (Definition of Therapeutic goods). This notification caters for all identified products to be regulated by DRAP including drugs/

alternative medicines or other related drugs as may be notified by the Authority.

11. The appellants were unable to express as to how the Parliament lacked legislative competence in view of the delegations required in terms of Article-144 of the Constitution of Islamic Republic of Pakistan, 1973 to bring the baby milk/infant milk within the regulatory regime of the DRAP Act, 2012. The other question raised in the arguments, however, discussed below in detail as to they (subject rules), being ultra vires to the DRAP Act, 2012 and/or without lawful authority or otherwise.

12. The Act of 2012 provides a discretion to the authority to include any other product within its statutory regime, even though not specifically enumerated. The definition describing the 'drug' is available under Section 2(xii) read with Schedule-I of the DRAP Act, 2012; similarly, Section-2(xv) which constitute definition of health and OTC products (non-drugs) include probiotics and disinfectant nutritional products, food supplements, baby milk and foods, medicated cosmetics, medicated soaps and medicated shampoos. The Azfar Laboratories case *(supra)* has also dilated upon the definition clause in terms of its para-42. The term OTC (over the counter) has been defined under Section-2(xxi), non-prescription products. Cumulative effect given in the case of Dawakhana Hakim Ajmal Khan *(supra)* is that even the products marketed under therapeutic claims and dispensed for the requirement of prescription, falls within the definition of DRAP.

13. Therapeutic goods have been included in the rules (under challenge), by DRAP Authority, made in exercise of its powers under

the DRAP Act, 2012 and the arguments that Section-4(1)(h) purposely ignore baby/infant milk is thus misconceived.

14. The prime arguments of Mr. Vawda rests upon Section-4(1)(h) of the DRAP Act, 2012 which does not provide a space/room for the baby milk/infant milk. Section-4 actually provides composition of the authority with their designated job. Section-4(1)(h) provides that Director shall be incharge of division of Health and OTC products (non-drugs) which shall be responsible for the assessment, licensing and registration of "alternative medicines" (emphasis applied) such as Ayurvedic, Chinese, Unani and Homeopathy, enlistment or registration of nutritional products and food supplements for human beings, animals and to perform other functions connected therewith. The exhaustive cap thus cannot be applied to the goods/ products/ drugs etc, described therein.

15. The impugned SRO was enacted in exercise of the powers under Section-23 of the DRAP Act, 2012. The challenged Rules enabled the DRAP to exercise its powers under Section-2(xxxvi) for notifying/different therapeutic goods for regulatory control. Thus, Section-2(xxxvi) of the DRAP Act, 2012 is of much significance, as it may include products, as could be covered by definitions, within the regulatory framework of DRAP. It might not be specifically enumerated therein Section-4(1)(h), as the said provision is not exhaustive in terms of limiting products likely to be regulated, however it otherwise fall within their regime, while we read it down. DRAP Authority through a reasoned and rational order may notify a product within the rules challenged before us, as the products defined for regulatory frame is not exhaustive in the subject provision 4(1)(h), relied upon by appellants.

16. Section-2(xii) of the definition clause of DRAP Act, 2012 gives a comprehensive definition of drug yet is not exhaustive of all defined in Schedule-I including 2(a) and (e), besides other sub-paras of para-2. It is because in terms of definition of drug under para-2(f) of Schedule-1 the Federal Government may by notification in the official Gazette declare any "substance" to be a drug for the purposes of this Act. The Schedule-I, which is an extension of the definition of drug in terms of Section-2(xii) of Act. For the purposes of present controversy, precisely, para-2 of Schedule-I gives us a definition, which is as under:-

> *(a) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of disease, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, including substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoepathic, Chines or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed.*
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> *(b) .....*
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> *(c) .....*
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> *(d) .....*
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> *(e) any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States, whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, Homeopathic, Chines or Biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-clauses (a), (b) and (c); and*
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> *(f) any other substance which the Federal Government may by notification in the official Gazette, declare to be a drug for the purpose of this Act.*

With this definition provided by Act, the Rules (SRO No.412(I)/2014) cannot be considered ultra vires the DRAP Laws.

17. To regulate the products described in the DRAP Act, 2012, the respondent No.2 only wants that they may be enlisted with it so that they may regulate it as being an alternative medicine/therapeutic goods. While appellants would make an application for enlistment, it would certainly be without prejudice to above understanding and notwithstanding their stance, a proper scrutiny would still be undertaken by DRAP to adjudge it as a product/drug etc, to be enlisted within frame of law (act and rules), which order will then be conclusive, subject to a challenge within DRAP Act, 2012.

18. Appellant of one of the connected appeals that is M/s Abbott Laboratories in High Court Appeal No.118/2023 has already enlisted its products in question under Rules 2014. Their products claimed to have been made via synthetic vitamins and minerals which have been declared as 'Drug' by the Registration Board of DRAP in its meeting. Since the appellants of High Court Appeal No.118/2023 have already surrendered themselves before the DRAP authorities for their enlistment and chosen to have undergone a scrutiny process of their products by the DRAP authorities, they, by applying doctrine of election, could not maintain a suit otherwise, since they have availed a remedy under the DRAP Act, 2012 which also provides an appellate remedy.

19. We are thus of the view that no interference is required. The appeals are dismissed.

Dated: - 29.04.2024

JUDGE

JUDGE

Ayaz Gul