IN THE HIGH COURT OF SINDH, KARACHI

SUIT NO. 00 of 0000

ABC Pakistan Limited Versus Pakistan & Others

WRITTEN ARGUMENTS OF AAA,
ADVOCATE FOR THE PLAINTIFF

(For *His Lordship*, Honourable Mr. Justice S.S)

Factual Background

1. In year 2004 the Plaintiff, in the course of its business, applied to the then Ministry of Health ("MOH"), Government of Pakistan for the registration and price approval of its drug "Maboo". Maboo is the trade name for Ritoo, a genetically engineered chimeric monoclonal antibody approved by the United States' Food and Drugs Administration ("FDA") for treatment of non-Hodgkin's lymphoma. Vide Letter of Registration dated 00.00.2004, the MOH registered Maboo under section 7 of the Drugs Act, 1976 and Rule 30 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Vide letter dated 00.00.2013, the brand name of the Plaintiff's drug Maboo was changed to Roseo.

2. On 00.00.2011, the Defendant No. 4 submitted Applications for registration of its drugs Drugbo Injection 500mg/50mL and Drugbo Injection 100mg/10mL ("Drugbo") which it claims are Similar Biotherapeutic Products of Ritoo (Maboo/Roseo). Drugbo is manufactured by Dr. Planet's Laboratories Limited in India and the Defendant No. 4 has applied for its import from India and sale in Pakistan. Since the Defendant No. 4 claims Drugbo to be a Similar Biotherapeutic Product of Ritoo, it is under obligation to strictly comply with the WHO Guidelines and undertake the vigorous comparability exercise mandated therein.

3. Drugbo was recommended for registration by the Expert Committee on Biological Drugs ("ECBD") in its 00th Meeting held on 00.00.0012.

4. The registration of Drugbo was discussed again at the 000th Meeting of the Registration Board of the Defendant No. 2, of which the Defendant No. 3 is a member.

5. At the 000th Meeting of the Registration Board of the Defendant No. 2 held on 0-0.00.2016, the Defendant No. 4's case was deferred for expert opinion of Brig. (Retd.) HIJ, Brig. CDE and Dr. KLM.

6. At the 000th Meeting held on 00th to 00th June 2016, the experts above stated that the Defendant No. 4 had submitted biosimilarity studies and recommended Drugbo for registration despite the fact that robust biosimilarlity trials had not been conducted on Drugbo**.** Thus, the Registration Board of the Defendant No. 2 considered the expert opinions and approved Drugbo's registration.

7. Aggrieved by the expert's opinions and the Registration Board's decision, and acting in public interest, the Plaintiff wrote a Letter to the Chairman of Registration Board on 00.00.2016**.** It expressed concern regarding the biosimilarity, efficacy and safety data provided by, *inter alia*, the Defendant No. 4 for registration of Drugbo. The Plaintiff reminded the Chairman that a drug which did not meet the criteria laid down in the WHO Guidelines i.e. had not been demonstrated to be similar in respect of quality, non-clinical properties as well as clinical safety and efficacy in head-to-head studies, could not be called a bio-similar under law. The Plaintiff requested the Chairman of Registration Board to reconsider the approval granted by it to register Drugbo.

8. On 00.00.2016, the Plaintiff wrote another Letter to the Defendant No. 2, reminding it that there were no Ritoo biosimilars that had received approval from stringent/reference countries whose law was in compliance with the WHO Guidelines.

9. Fearing that its grievances were falling on deaf ears, the Plaintiff expressed its concerns to the Chief Minister, Government of Punjab vide Letter dated 00.00.2016**.** It apprised the Chief Minister that no Ritoo biosimilars have been approved by strict regulatory authorities such as the EMA or the US FDA whose licensing standards, like Pakistan, are in alignment with the WHO Guidelines.

10. However, the Plaintiff's efforts have been in vain and it has reliably learnt that the Defendant No. 2 shall soon issue Drugbo's Letter of Registration.

11. In light of the above, the Plaintiff filed the present suit in this Honourable Court seeking, *inter alia*, declaration that the expert's opinions and the Registration Board's decision to approve Drugbo for registration are erroneous, illegal and *ultra vires* the WHO Guidelines and the DRAP Act; and a permanent injunction prohibiting the Defendant No. 2 and 3 from issuing a Letter of Registration for Drugbo or from permitting the Defendant No. 4 to market and/or sell Drugbo and furthermore prohibit the Defendant No. 4 from marketing and/or selling the same.

Legal Background

1. The Drug Regulatory Authority of Pakistan (Defendant No. 2) was established pursuant to the provisions of Section 3 of the Drug Regulatory Authority of Pakistan Act, 2012 (**DRAP Act**) for effective coordination and enforcement of the Drugs Act, 1976 and to develop, issue, adopt and enforce standards and Guidelines to ensure quality, efficacy and safety of therapeutic goods.

2. Section 7(c)(ix) of the DRAP Act provides that the powers and functions of the Defendant No. 2 shall be to issue Guidelines and monitor, *inter alia,* the enforcement of internationally recognized standards such as good laboratory practices, good manufacturing and distribution practices, bioequivalence studies, stability studies, anti-spurious codes, clinical trials, biosimilar evaluations, and endorsement and systematic implementation of World Health Organization ("WHO"), International Conference on Harmonizations and Food and Drug Administration Guidelines etcetera.

3. The adoption and implementation of WHO Guidelines and standards to ensure quality, safety and efficacy of therapeutic goods permeate the DRAP Act and are, in fact, its core objective. This is specially so in the case of Biologicals, such as Roseo. "Biologicals" are defined in Schedule I to the DRAP Act and include: "*Biological drugs produced by biological systems and which require standardization by biological assays according to the relevant and updated recommendations of the World Health Organization published in Technical Report Series and Biological Standardization Report....".*

4. It is apparent from the above that the very definition of Biologicals under the DRAP Act necessitates that such drugs conform to recommendations of the WHO. Biologicals must be subjected to sustained scrutiny and testing before they are marketed and sold. Biological products represent the cutting-edge of bio-medical research and often provide the most effective means to treat a variety of medical illnesses and conditions that have no other treatments available.

5. Biologicals may be either Originator Biological Drugs or biosimilar biological drugs. An Originator Biological Drug, as defined at clause 1(6) of Schedule-I to the DRAP Act, means a biological drug which has been licensed by the national regulatory authorities on the basis of a full registration dossier, i.e. the approved indication(s) for use were granted on the basis of full quality, efficacy and safety data. The Plaintiff's drug, Roseo is an Originator Biological Drug. Originator Biological Drugs serve as Reference Biotherapeutic Products for biosimilar biological drugs. On the other hand, as defined in clause 1(6) (b) of Schedule-I to the DRAP Act, biosimilar biological drugs are Similar Biotherapeutic

Products which are similar in terms of quality, safety and efficacy to an already licensed Reference Biotherapeutic Product ("RBP").

6. The definitions above closely follow the WHO Guidelines on Evaluation of Similar Biotherapeutic Products ("SBP") adopted by the 00th meeting of the WHO Expert Committee on Biological Standardization, Geneva 19-23 Month, 2009 ("**WHO Guidelines**"). The WHO Guidelines were passed in the wake of a surge in the production of therapeutic products that claimed to be similar to licensed Originator Biological Drugs. The WHO Guidelines realize that the established approaches for demonstration of bioequivalence of generic medicine—chemical, small molecule medicinal products—are not suitable for development, evaluation and licensing of Similar Biotherapeutic Products, which consist of relatively large and complex proteins that are difficult to characterize. A more robust regime is, therefore, required for Similar Biotherapeutic Products to ensure that the standard of evidence required to license them guarantees their acceptable quality, efficacy and safety.

7. In keeping with the above, the WHO Guidelines set out the following requirements for licensing Similar Biotherapeutic Products:

> *"A SBP is intended to be similar to a licensed biotherapeutic product for which there is a substantial evidence of safety and efficacy. The ability for the SBP to be authorized based on reduced non-clinical and clinical data depends on proof of its similarity to an appropriate RBP through the comparability exercise.*
> *…*
> ***Studies must be comparative*** *in nature employing analytical strategies (methods) that are sensitive to detect potential differences between the SBP and the RBP.*
> *…*
>
> *The basis for licensing a product as SBP depends on its demonstrated similarity to a suitable RBP in quality, non-clinical, and clinical parameters. The decision to license a product as a SBP should be based on evaluation of the whole data package for each of these parameters."*

8. The "comparability exercise" referred to in the excerpts above is defined in the WHO Guidelines as "**head-to-head comparison** of a biotherapeutic product with a licensed originator product with the goal to establish similarity in quality, safety and efficacy. **Products should be compared in the same study using the same procedures.** The WHO Guidelines further define "Head-to-head comparison" as "direct comparison of the properties of the SBP with the RBP **in the same study.**" The WHO Guidelines, therefore, make the licensing of Similar Biotherapeutic Products conditional to comparability exercises consisting of head-to-head comparison of the properties of the Reference Biotherapeutic Product with those of the proposed Similar Biotherapeutic Product.

MERITS OF THE CASE

1. The comparability exercise requires head-to–head comparison of Drugbo with the Reference Biotherapeutic Product (Roseo) to establish Drugbo's quality, safety and efficacy. As per the WHO Guidelines, a head-to-head comparison is a direct comparison of the properties of the Similar Biotherapeutic Product with the Reference Biotherapeutic Product in the same study. It includes non-clinical and clinical trials (testing in humans). In order to demonstrate that the Similar Biotherapeutic Product is just as efficacious as the Reference Biotherapeutic Product, the WHO Guidelines require randomized and controlled clinical trials that are preferably double-blind, or at the very least, observer blind. Stated simply, the WHO Guidelines mandate that the Similar Biotherapeutic Product and Reference Biotherapeutic Product are studied simultaneously in clinical and non-clinical tests. This is only possible in a study where both drugs are administered under comparable conditions to separate (but similar) subjects and the results of each are directly compared. The WHO Guidelines further require the trials to be randomized so that the subjects are evenly sorted and the recipients of one drug are not in a better or worse condition than those of the other. In addition, the trial must be double-blind (or at least observer blind) to prevent the subject's or observer's perception of a drug from effecting the recording of its results. In the absence of any of the above, a host of errors and biases may distort the results and seriously prejudice the comparability exercise.

2. In effect, the WHO Guidelines mandate a double-arm study in which both drugs, the Similar Biotherapeutic Product and the Reference Biotherapeutic Product, are administered and studied correspondingly during the study period. Such a study is referred to as a prospective study. On the other hand, a single arm study, in which merely the Similar Biotherapeutic Product is administered and its results compared to existing literature on the Reference Biotherapeutic Product, does not fulfill the requirements of the WHO Guidelines. Such a study is, by its very nature, not randomized since the subjects that are administered for the Similar Biotherapeutic Product are not under comparable conditions and may be systematically better off or worse off than those who were given the Reference Biotherapeutic Product. In addition, such a study is not double-blind or even single blind since the identity of a drug administered to a particular subject is known. Most importantly, the Similar Biotherapeutic Product and the Reference Biotherapeutic Product are not compared directly in the same study. Instead, the pre-recorded and pre-established results of the Reference Biotherapeutic Product are compared with the results of the Similar Biotherapeutic Product obtained through the single-arm study. Similarly, a retrospective study, which compares existing literature in respect of a Reference Biotherapeutic Product with the observed results of a Similar Biotherapeutic Product does not fulfill the purposes of the WHO Guidelines.

3. In the light of the above, a retrospective study or a single-arm trial do not conduct a head-to-head comparison of the Similar Biotherapeutic Product with the Reference Biotherapeutic Product and, therefore, do not fulfill the requirements of the WHO Guidelines. Consequently, any data obtained as a result of such studies has not been obtained through the stringent tests prescribed under the WHO Guidelines and does not establish the subject drug's quality, safety and efficacy. As a corollary, the registration application for a Similar Biotherapeutic Product based on such data is liable to be dismissed.

4. The clinical trials submitted by the Defendant No. 4 as part of its application for registration of Drugbo are single arm and retrospective studies. While the Defendant No. 4 has stated that its Reference Biotherapeutic Product is Maboo/Roseo, it has not conducted any prospective and double-arm studies. Its application, therefore, lacks robust and reliable data in respect of Drugbo's quality, safety and efficacy. The Defendant No. 4's registration applications in respect of Drugbo do not fulfill the requirements of the WHO Guidelines and the DRAP Act and Drugbo is thus not fit to be registered as a Similar Biotherapeutic Product.

5. No clinical trials for proving biosimilarity of Drugbo have been conducted that conform to the WHO Guidelines and satisfy the conditions of the DRAP Act. In this regard, a recent study comparing the efficacy and safety of Maboo and Drugbo is attached as **ANNEX L.** This study has been submitted by a number of pharmaceutical companies for registration of their so-called biosimilars in various jurisdictions. However, even the above study, as its name suggests, is a retrospective analysis and is not in compliance with the prerequisites of the WHO Guidelines. Furthermore, a number of shortcomings mark the above study:

    (i) The objective response rate of the trial was studied in only 67 patients;

    (ii) Mandatory large head-to-head Phase III trials were not conducted to prove biosimilarity;

    (iii) No comparison was done to make sure the assay of Drugbo was similar to Maboo;

    (iv) The study is a single center, retrospective, observational study conducted on a small scale.

6. Despite the above serious shortcomings, Drugbo was recommended for registration by the Expert Committee on Biological Drugs ("ECBD") in its 00th Meeting held on 00.00.0002**.**

However, in the same Meeting, the ECBD strongly recommended and adopted the WHO Guidelines to ensure the efficacy, safety and quality of drugs and harmonization of the regulatory regime. The ECBD further decided that all applications shall be evaluated on the basis of the WHO Guidelines to harmonize the Defendant No. 2 with the National Regulatory Authorities of developing countries.

7. The registration of Drugbo was discussed again at the 000th Meeting of the Registration Board of the Defendant No. 2, of which the Defendant No. 3 is a member**.** The Registration Board observed that the biosimilarity of, *inter alia*, Drugbo still remained to be proved and that there was a need to frame and implement a stringent policy for importing Biologicals originating in countries that were not part of the Stringent Regulatory Authorities (non SRA). Non SRA include India, from where the Defendant No. 4 intends to import Drugbo.

8. At the 000th Meeting of the Registration Board of the Defendant No. 2 held on 3-4.00.0000, the Defendant No. 4's case was deferred for expert opinion of Mr. HIJ, Mr. CDE and Dr. KLM.

9. Despite the fact that robust biosimilarlity trials have not been conducted on Drugbo, at the 000th Meeting held 28th to 29th June 0000, the experts above stated that the Defendant No. 4 had submitted biosimilarity studies and recommended Drugbo for registration**.** Thus, the Registration Board of the Defendant No. 2 considered the expert opinions and approved Drugbo's registration.

10. Aggrieved by the expert's opinions and the Registration Board's decision, and acting in public interest, the Plaintiff wrote a Letter to the Chairman of Registration Board on 00.00.0000. It expressed concern regarding the biosimilarity, efficacy and safety data provided by, *inter alia*, the Defendant No. 4 for registration of Drugbo. The Plaintiff reminded the Chairman that a drug which did not meet the criteria laid down in the WHO Guidelines i.e. had not been demonstrated to be similar in respect of quality, non-clinical properties as well as clinical safety and efficacy in head-to-head studies, could not be called a bio-similar under law. Therefore, the Plaintiff requested the Chairman to revisit its approval of various cases, including that of the Defendant No. 4, which had not provided adequate head-to-head trials and quality, safety and efficacy data as per the WHO Guidelines and the DRAP Act nor provided a full registration dossier. On 00.00.0000, the Plaintiff wrote another Letter to the Defendant No. 2, reminding it that there were no Ritoo biosimilars that had received approval from stringent/reference countries whose law was in compliance with the WHO Guidelines**.**

11. Fearing that its grievances were falling on deaf ears, the Plaintiff expressed its concerns to the Chief Minister, Government of Punjab vide Letter dated 00.00.0000**.** It apprised the Chief Minister that no Ritoo biosimilars have been approved by strict regulatory authorities such as the EMA or the US FDA whose licensing standards, like Pakistan, are in alignment with the WHO Guidelines. The Plaintiff further referred to the decision of the Honourable Lahore High Court in W.P. No. 10045 of 2016 *M/s Alfalah Medicos and another v. Government of Punjab and others* ("*Alfalah Medicos case*") wherein the Learned Single Judge had held that one of the core functions of the DRAP Act is endorsement and systematic implementation of the WHO Guidelines. However, the Plaintiff's efforts have been in vain and it has reliably learnt that the Defendant No. 2 shall soon issue Drugbo's Letter of Registration.

12. The clinical trials submitted by the Defendant No. 4 are single arm and retrospective studies. These studies do not involve a head-to-head comparison of Drugbo with the Reference Biotherapeutic Product—Maboo/Roseo. The results of such studies are not based on stringent tests prescribed under the WHO Guidelines and, therefore, do not establish Drugbo's quality, safety and efficacy. The Defendant No. 4 has not fulfilled the requirements of the WHO Guidelines and the DRAP Act and its registration applications in respect of Drugbo are liable to be dismissed.

13. The single-arm, retrospective clinical trials submitted by the Defendant No. 4 in support of its registration applications are not randomized and do not involve any blinding. The above conditions would only have been met if the Defendant No. 4 had conducted a head-to-head trial of Drugbo and Maboo/Roseo in the same study, as mandated by the WHO Guidelines. This would have involved administering the two drugs to randomized groups of subjects under similar conditions and studying their results side by side. Instead, the Defendant No. 4 has submitted retrospective analyses of Drugbo which merely conduct a comparison of Drugbo's results with pre-recorded literature on Maboo/Roseo. It is evident that a host of errors and biases could have entered such a study. These include a difference in the external conditions under which the study was performed; the subjects to whom Drugbo was administered may be, as a group, better off or worse off than those who were treated with Maboo/Roseo; observer and subject biases etc. Any of the above factors may seriously prejudice the results of a study and render its credibility questionable. Therefore, Drugbo's quality, efficacy and safety as a Similar Biotherapeutic Product have not been established, and the Registration Board's decision to approve its registration despite the above is patently illegal.

14. It is well documented and universally acknowledged that sources of error and bias are more common in retrospective studies than in prospective studies. Special care must, therefore,

be taken to avoid any bias or inaccuracy in the case of retrospective studies. Consequently, retrospective studies do not yield robust results with regard to a drug's quality, safety and efficacy. These results are all the more unreliable and specious for the development, evaluation and licensing of Similar Biotherapeutic Products which consist of large and complex molecules. It was precisely with a view to establish necessary and stringent trials for Similar Biotherapeutic Products that the WHO Guidelines were passed and were incorporated in the DRAP Act.

15. It is evident from the comments of the experts that their appraisal of Drugbo is based on a hopelessly flawed understanding of the WHO Guidelines. For example, the experts state that the materials submitted by the Defendant No. 4 indicate that Drugbo is comparable to the published literature of the innovator Ritoo. The so-called experts have thus completely failed to understand that the WHO Guidelines mandate head-to-head comparisons which necessitate administration and direct comparison of the Similar Biotherapeutic Product with the Reference Biotherapeutic Product in the same study. Merely comparing the results of one study with the pre-recorded ones of another, without actually conducting trials on the two drugs simultaneously does not satisfy the requirements of the WHO Guidelines. The experts' opinion is, therefore, grievously flawed and should not be relied upon to approve Drugbo's registration.

16. The complete lack of any study proving the biosimilarity of Drugbo is evidenced by the fact that Drugbo is not registered as a Similar Biotherapeutic Product in any country belonging to the Stringent Regulatory Authorities. On the contrary, the manufacture and import of Drugbo has only been allowed in jurisdictions with lenient regulations that do not follow the WHO Guidelines in letter and spirit. This is not the case in Pakistan where ensuring compliance with WHO standards is one of the fundamental purposes of the DRAP Act and the WHO Guidelines enjoy statutory force.

17. Further, Drugbo has not been launched in the European Union despite the fact that the patent for Ritoo held by Xioxef Xdec, Inc. expired in 0000. The manufacturers of Drugbo are well aware that a jurisdiction following stringent Guidelines for Similar Biotherapeutic Products would not register a drug for which no head-to-head clinical trials have been conducted.

18. Drugbo has not been approved by the Food and Drugs Administration or the European Medicines Agency. In the absence of such approvals, its quality, safety and efficacy are unknown.

19. The lack of proper testing of Drugbo is further established by the fact that it has been banned in various jurisdictions for failure to comply with WHO's requirements. For example, the Constitutional Court of Ecuador resolved to ban the sale of Drugbo in Ecuador until it meets WHO's requirements for registration of biosimilars. A translated copy of the Resolution passed by Ecuador's National Agency of Regulation, Control and Sanitary Surveillance dated 00.00.0000 giving effect to the Constitutional Court's ban is attached as **ANNEX S.**

20. In light of the above, the expert's opinions and the Registration Board's decision to approve Drugbo for registration are erroneous, illegal and *ultra vires* the WHO Guidelines and the DRAP Act.

21. Hence, Drugbo should not be registered as a Similar Biotherapeutic Product and the Defendant No. 4 should not be allowed to import and sell a product whose impact on the health and safety of citizens is unknown.

CONTENTIONS RAISED BY THE DEFENDANTS IN THEIR WRITTEN STATEMENTS AND COUNTER AFFIDAVITS TO PLAINTIFF'S APPLICATION UNDER ORDER 39 RULE 1 & 2, CPC 1908

A. Section 39 of the Drugs Act, 1976 is an ouster clause which clearly bars jurisdiction of this Honourable Court from entertaining the present suit.

B. The Defendant No. 4 contended that the Plaintiff, though being aggrieved by the decision taken by the Drug Registration Board of the Defendant No. 2, has not filed any appeal under section 9 of the Drugs Act, 1976 before the Appellate Board within 60 days. According to the Defendant, the present suit is filed to circumvent such bar of limitation. Therefore, this present suit is not maintainable and is liable to be dismissed.

C. According to Defendant No. 4, the Plaintiff is clearly aggrieved by the decision of the Registration Board for granting registration to its drug Drugbo when it had allegedly failed to prove its quality, safety and efficacy according to the criteria laid down in WHO Guidelines. However, the Defendant No. 4 contends that the Plaintiff has not sought any declaration in relation to its own legal character and failed to disclose as to what legal right of the Plaintiff has been violated as a result of registration of Drugbo. Hence, the present suit is not maintainable.

D. It is contended by the Defendant No. 4 that the present suit has been instituted allegedly on behalf of the Plaintiff by one Mr. ZZ on the basis of a Special Power of Attorney and

General Power of Attorney. However, it has not been shown by the Plaintiff that these Power of Attorneys have been executed pursuant to a Board Resolution or Articles of Association of the Plaintiff through which the signatories of such Power of Attorneys were duly authorized. Hence, according to Defendant No. 4, the very institution of the suit is without authorization and the plaint is liable to be rejected.

E. It is contended by the Defendant No.s 1-3 that the territorial jurisdiction in the present matter lies with the Honourable High Court of Islamabad as the cause of action arose in Islamabad.

F. According to the Defendant No. 4, it is obvious and apparent that the institution of this present suit is a *mala fide* and belated afterthought and the Plaintiff has no locus standi to object to the registration of the Defendant No. 4's drug given that it remained silent throughout the registration process which continued for five years.

G. The Defendant No. 4 contends that nowhere in the DRAP Act is compliance with WHO Guidelines stated to be mandatory.

H. The Defendant No. 4 has contended that the judgment of the Honourable Lahore High Court in *Alfalah Medicos case* is inapplicable to the present case and has been *mala fidely* used by the Plaintiff to misguide this Honourable Court. According to Defendant No. 4, the said judgment is in relation to a challenge of a decision of the Grievance Committee in relation to a tender for Hepatitis medicines floated in Punjab. Further, the said judgment is contrary to the DRAP Act and the law.

PLAINTIFF'S REBUTTAL TO:

1. **CONTENTION A:** This Honourable Court has the powers of a Civil Court. It is settled law, as upheld by the Supreme Court of Pakistan on numerous occasions, that under Section 9 of the Code of Civil Procedure, Civil Courts are competent to try all suits of a civil nature except where their jurisdiction is barred either expressly or by necessary implication. Provisions that oust the jurisdiction of Civil Courts, such as Section 39 of the Drugs Act, 1976 ("Drugs Act") are to be construed very strictly. Unless a case falls within the letter and spirit of the ousting provision, the provision should not be given effect to. The Honourable Supreme Court has, therefore, laid down that where an authority acts in violation of the provisions of a statute which confer jurisdiction on it, an order made by the authority may be challenged before a Civil Court in spite of a provision in the statute

barring the jurisdiction of Civil Courts[1]. In the present case, the Registration Board and the experts have acted in violation of the WHO Guidelines and the DRAP Act. The experts' opinions and the Registration Board's decision to approve Drugbo for registration are erroneous, illegal and *ultra vires* the WHO Guidelines and the DRAP Act. Hence, this Honourable Court has jurisdiction to adjudicate upon the present matter.

2. **CONTENTION B:** It is specifically denied that the present suit has been filed because the Plaintiff did not file an appeal before the Appellate Board under Section 9 of the Drugs Act, 1976 or that it intends to circumvent the bar of limitation. The Plaintiff has approached this Honourable Court since its attempts to obtain relief from the Defendant Nos. 1-3 have been futile. The Plaintiff has previously complained to various officers of the Defendant No. 2, including the Chairman of the Defendant No. 2 and the Defendant No. 3 but has not received either attention or redress. It is obvious that the officers of the Defendant No. 2, the Registration Board and the experts have made up their mind to register Drugbo. An appeal under Section 9 of the Drugs Act is, therefore, an illusory remedy in the present circumstances.[2] Without prejudice, the Appellate Board has also not been formulated under Section 30(3) of DRAP Act. Hence, there are no statutory remedies available to the Plaintiff.[3]

3. **CONTENTION C:** The Plaintiff clearly mentioned in paragraph 28 of the plaint that it wrote the letters in public interest. The failure of Defendants to prove quality, efficacy and safety of Drugbo is a clear violation of the sanctity of public health. Moreover, the Defendants claim the drug Drugbo to be a Similar Biotherapeutic Product of Ritoo (Maboo/Roseo). This could entail serious adverse impact on the market share of Roseo if the Defendant's drug is not perceived to be of good quality, safe and efficacious. The fundamental right of the Plaintiff to market and sell Roseo will be violated. It has been held by the superior Courts that a civil suit can be filed where a fundamental/civil right

---

[1] *Abdul Rauf v. Abdul Hamid Khan PLD 1965 SC 671; M. Jamil Asghar v. The Improvement Trust PLD 1965 SC 698; Hamid Hussain v. Government of West Pakistan 1974 SCMR 356; Samiullah v. Fazle Malik PLD 1996 SC 827; Mirpurkhas Sugar Mills v. Consolidated Sugar Mills PLD 1987 Karachi 225; Hyderabad Municipal Corporation v. Fateh Jeans 1991 MLD 284; Syed Raunaq Raza v. Province of Sindh 1994 CLC 317; Usman Panjwani v. Government of Sindh 1996 CLC 311; K.G. Traders v. Deputy Collector of Customs PLD 1997 Karachi 541; Tri-Star Industries v. The Commissioner of Income Tax 1998 PTD 3923; Asia Petroleum Limited v. Federation of Pakistan 1999 PTD 1313; Malik M. Saeed v. Federation of Pakistan 2006 PTD 2167; Sanofi Aventis Pakistan Limited v. Province of Sindh PLD 2009 Karachi 69; Karachi Electric Supply Corporation v. Federal Board of Revenue 2013 PTD 851; Quetta Textiles Mills v. Province of Sindh PLD 2005 Karachi 55; Arif Builders and Developers v. Government of Pakistan PLD 1997 Karachi 627* and *M. Hussain v. Federation of Pakistan 2016 PTD 622*

[2] *Pak Land Cement Limited v Central Board of Revenue 2007 PTD 1524; Collector of Customs and others v S.M. Ahmad & Company (Pvt.) Limited 1999 SCMR 138; Haroon Brothers v Drugs Registration Board and another 1992 CLC 1017; Gulistan Textile Mills Ltd. v Pakistan – 1983 CLC 1474; GETZ Pharma (Pvt.) Ltd. v Province of Sindh PLD 2016 Sindh 479; ALM (Pvt.) Ltd. v. D.G. Excise & Taxation, Lahore 2000 CLC 1485; Baluchistan Textile Mills v. CBR 1984 CLC 2192*

[3] *Sarfaraz Saleem v. Federation of Pakistan PLD 2014 SC 232; Augere Pakistan Ltd. v. Province of Sindh 2015 PTD 1340; All Pakistan Textile Mills Association v. Federation of Pakistan PLD 2009 Lahore 494*

was being violated.[4] In any event, it is held in *Arif Majeed Malik v. Board of Governors, Karachi Grammar School* reported as *2004 CLC 1029* by a Division Bench of this Honourable Court that even if declaratory relief could not be granted under the law the prayer for injunction could be treated as independent relief and could always be granted. Further, this case widens the scope of section 42 of the Specific Relief Act, 1877 and holds that the provisions of section 42 were not exhaustive [5] and declaratory relief could always be granted by a Civil Court if the matter fell within the provisions of section 9 of Code of Civil Procedure, 1908 ("CPC"). It is also trite law that a civil court has jurisdiction to adjudicate upon an illegal act or an order passed in violation of law.[6] In the present matter, since the expert's opinions and the Registration Board's decision to approve Drugbo for registration are erroneous, illegal and *ultra vires* the WHO Guidelines and the DRAP Act, this Honourable Court clearly has jurisdiction.

4. **CONTENTION D:** First, the Special Power of Attorney dated 00.00.0000 and General Power of Attorney dated 00.00.0000 have been validly executed under Article 77 of the Plaintiff's Articles of Association and Circular Resolution of the Directors of the Plaintiff dated 00.00.0000. The very fact that the General Power of Attorney dated 00.00.0000 was drawn up establishes that the Directors of the Plaintiff had the power to appoint an attorney and confer such powers as they deem fit. Second, it is denied that filing the relevant Circular Resolution and Articles of Association at the present stage shall be belated. It is settled law that a resolution of the board of directors of a corporation may be filed at the time of evidence and that there is no mandatory provision for a corporation to submit a resolution of the board of directors at the time of filing of a suit.[7] In the present suit, the parties have not yet led evidence. Therefore, the Defendant No. 4's contentions in the above respect are groundless and *mala fide.* Furthermore, in keeping with the above principle, the Supreme Court of Pakistan has laid down that where it is necessary to refer to a corporation's Articles of Association in order to establish whether its directors were

---

[4] Arif Builders and Developers v Govt. of Pakistan - PLD 1997 Kar 627; Marriage Hall Association v Government of Sindh - 1999 YLR 1247; Mirpurkhas Sugar Mills v. Consolidated Sugar Mills PLD 1987 Karachi 225

[5] *Salim Ullah Beg v. Motia Begum PLD 1959 (W.P) Lahore 429; Veeramachanani v. Soma Pitchayya AIR 1920 Mad. 665; Vangipuram v. Sri Rajah AIR 1935 Mad. 964; Desu Reddiar v. Srinivasa Reddi AIR 1936 Mad. 605; Sri Krishna Chandra v. Mahabir Prasad AIR 1933 All 488*

[6] *Kali Khan v Bodlo - 2013 CLC 507; University of Punjab v Miss Wajiha Urooj - 2008 SCMR 1577; Islamic Republic of Pakistan v General Traders and Ammunition Manufacturers Ltd. - 2008 CLC 1462; Ahsan Ali through L.Rs v Province of Sindh - 2007 MLD 884; Federation of Pakistan v Messers Saman Diplomatic Bonded Warehouse - 2004 PTD 1189; Kanwar Qutubuddin Khan v Karachi Development Authority - 2002 CLC 634; Abbasia Coop. Bank v Muhammad Ghauss - PLD 1997 SC 3; Rehmatullah v Sher Muhammad - 1997 MLD 2905; Muhammad Ghaus v Province of Punjab - 1996 CLC 1382; Rafiuddin v Karachi Metropolitan Corporation - 1994 MLD 874; Mujeeb-Ur-Rehman Shami v Principal, Aitchison College, Lahore-3 - 1994 CLC 342; Mian Muhammad Latif v Province of West Pakistan through Deputy Commissioner, Khairpur - PLD 1970 SC 180; Rais Dil Murad Khan v. Ali Nawaz 1997 MLD 1309; Hazara Improvement Trust v. Qaisra Elahi 2005 SCMR 678; Province of Punjab v. Haji Yaqoob Khan 2007 SCMR 554*

[7] *Muhammad Siddiq Muhammad Umar v. The Australasia Bank Ltd – PLD 1966 SC 684; Pakistan National Shipping Corporation v. M.V. Le Cong – 2009 CLD 234; Al-Ahram Builders (Pvt) Ltd v. Pakistan Defence Officers Housing Authority – 2003 CLD 1497; Pak Turk Enterprises (Pvt) Ltd v. Turk Hava Yollari (Turkish Airlines Inc.) 2015 CLC 1; Emirates Bank International Ltd. v Super Drive-in Ltd. and 8 others 1990 MLD 538; Duncan Stratton & Co. vs N.S. Construction Co. 1992 CLC 1128; Trading Corporation of Pakistan (Pvt.) Ltd. v Merchant Agency – 2007 CLC 1811*

competent to delegate power, additional evidence in the form of such Articles may be recorded.

5. **CONTENTION E:** The Defendant Nos. 1 and 2 are ubiquitous throughout Pakistan, as mentioned in paragraph 41 of the Plaint, and may be sued at Karachi. It is settled law that the Federal Government, or any person performing functions in connection with the affairs of the Federation, enjoys ubiquitous presence everywhere across the country and may be sued anywhere in Pakistan, or in other words, within the territorial jurisdiction of every High Court in the country. Such omnipresence renders it immaterial where the office or residence of such person was located and in such a case it would be up to the aggrieved party to choose the High Court of his convenience. Furthermore, both the Plaintiff and the Defendant No. 4 have their registered offices at Karachi. Most importantly, entire cause of action has accrued to the Plaintiff at Karachi as it is at Karachi that its registered office is located, from where it conducts its business operations and where it shall be hurt by the actions of the Defendants. This Honourable Court, therefore, has territorial jurisdiction to adjudicate upon the present matter.

6. **CONTENTION F:** It is misleading and incorrect to suggest that the Plaintiff did not act at the appropriate time or that it complained of the various deficiencies in Drugbo much after its registration. The Registration Board recommended Drugbo for registration at its 000th Meeting held on 28-29 June, 0000. Before this, the Registration Board had merely observed that Drugbo's biosimilarity remained to be proved, that there was need to frame and implement stringent policies for importing Biologicals, and had referred Drugbo's case to experts. It is evident that if the experts had decided in accordance with the WHO Guidelines and the DRAP Act, as well as with the Registration Board's earlier observations, it would have decided against registering Drugbo. There was, therefore, no need to complain of any decision of the Registration Board. However, the expert's decision to register Drugbo at the Registration Board's 000th Meeting surprised the Plaintiff. Soon thereafter, on 00.00.0000, the Plaintiff wrote a Letter to the Chairman of the Registration Board, highlighting that the Defendant No. 4 had not carried out the necessary research and testing mandated by the WHO Guidelines and the DRAP Act. This Letter also categorically stated that the Plaintiff's actions arise out of concern for safety and well-being of patients in Pakistan. In light of the above, the Defendant No. 4's allegation that the present suit is an after-thought is frivolous. Second, it is important to highlight that the Defendant No. 2 has still not issued a Letter of Registration in respect of Drugbo. The registration process is, thus, not complete. Consequently, the Defendant No. 4's contention that the Plaintiff remained silent throughout the registration process is misleading and false. Third, while the Defendant No. 4 has called the Plaintiff's letters "disparaging", it has not denied their veracity. The Defendant No. 4 lacks a defensible

argument in respect of the biosimilarity of Drugbo. It has leveled various untrue and groundless allegations throughout in its Written Statement and Counter Affidavit in an attempt to evade the crux of the suit—that Drugbo does not comply with WHO Guidelines and the Registration Board's decision to register it is illegal.

7. **CONTENTION G:** The adoption and implementation of WHO Guidelines and standards to ensure quality, safety and efficacy of therapeutic goods permeate the DRAP Act and are, in fact, its core objective. This is specially so in the case of Biologicals, such as Roseo, defined in Schedule I to the DRAP Act. Further, the definitions of technical terms such as Originator Biological Drugs and Similar Biotherapeutic Product closely follow the WHO Guidelines on Evaluation of Similar Biotherapeutic Product adopted by the 00th meeting of the WHO Expert Committee on Biological Standardization, Geneva 19-23 Month, 0000. It is apparent that the very definition of Biologicals under the DRAP Act necessitates that such drugs conform to recommendations of the WHO. The necessity of fulfilling the requirements of the WHO Guidelines for ensuring the quality, efficacy and safety of Similar Biotherapeutic Products and for their licensing under the DRAP Act has been upheld by the Honourable Lahore High Court in *Alfalah Medicos case.* The WHO Guidelines have statutory importance and unless their requirements are fully complied with, a Similar Biotherapeutic Product may not be licensed under the DRAP Act.

   In the said case, the Lahore High Court held that as per the WHO Guidelines, which enjoy statutory force, full comparability exercises should be undertaken starting with a comprehensive assessment of the quality characteristics of Similar Biotherapeutic Products and Reference Biotherapeutic Products. This is a prerequisite for licensing and registration of Biologicals. In the present case, the Defendant No. 4 has evidently not complied with the WHO Guidelines. The findings of the Honourable Lahore High Court in *Alfalah Medicos case* in respect of the necessity of fulfillment of the WHO Guidelines for the purposes of licensing and registration are, therefore, fully applicable to the current circumstances. Secondly, and without prejudice to the above, in *Alfalah Medicos case*, the Honourable Lahore High Court simply upheld the manifest purpose of the DRAP Act: All applications for seeking authorization for manufacturing and marketing of biosimilar drugs in Pakistan are required to be evaluated on the basis of the standards set out in the WHO Guidelines regarding licensing of biosimilar drugs. Therefore, even if it is assumed *arguendo* that the decision of the Honourable Lahore High Court in *Alfalah Medicos case* does not apply to the present case, the Registration Board's contravention of the DRAP Act and the illegality of its decision to register Drugbo shall not be purged. Also, without prejudice, it is trite law that if application of any statute (DRAP Act in the present matter) involves the consideration of any International Law (WHO Guidelines in the present matter) then

attempt should be made to interpret the statute in consonance with the International Law.[8]

8. **CONTENTION H:** Firstly, the Defendant No. 4 has failed to establish how the Judgment of the Honourable Lahore High Court in *Alfalah Medicos case* is inapplicable to the present case. In *Alfalah Medicos case*, the Lahore High Court held that as per the WHO Guidelines, which enjoy statutory force, full comparability exercises should be undertaken starting with a comprehensive assessment of the quality characteristics of Similar Biotherapeutic Products and Reference Biotherapeutic Products. This is a prerequisite for licensing and registration of Biologicals. In the present case, the Defendant No. 4 has evidently not complied with the WHO Guidelines. The findings of the Honourable Lahore High Court in *Alfalah Medicos case* in respect of the necessity of fulfillment of the WHO Guidelines for the purposes of licensing and registration are, therefore, fully applicable to the current circumstances. Secondly, and without prejudice to the above, in *Alfalah Medicos case*, the Honourable Lahore High Court simply upheld the manifest purpose of the DRAP Act: All applications for seeking authorization for manufacturing and marketing of biosimilar drugs in Pakistan are required to be evaluated on the basis of the standards set out in the WHO Guidelines regarding licensing of biosimilar drugs. Therefore, even if it is assumed *arguendo* that the decision of the Honourable Lahore High Court in *Alfalah Medicos case* does not apply to the present case, the Registration Board's contravention of the DRAP Act and the illegality of its decision to register Drugbo shall not be purged. Thirdly, the Plaintiff has failed to elaborate how the above judgment is contrary to the DRAP Act and the law.

Karachi
Dated:

AAA
(Advocate High Court)

[8] *Hanover Fire Insurance Co. v. Muralidhar Banechand PLD 1958 SC 138; Marine Engineers' Association of Pakistan v. Shipping Master, Karachi 1989 CLC 588; Sadia Jabbar v. Federation of Pakistan PTCL 2014 CL 537; Imperial Tobacco Co. v. Commissioner of Income Tax, Karachi PLD 1958 SC 125*