Page 1883 - 1890 **DOI:** *https://doij.org/10.10000/IJLMH.113533*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 4

2022

Delineating Relevant Markets in the Pharmaceutical Industry: A Different Approach

MR. SACHIN MISHRA[1] AND MR. RAKESH KUMAR[2]

ABSTRACT

The pharmaceutical industry is a complex industry for competition law authorities around the globe as defining relevant market in the industry has been highly intricate. Traditionally to define the relevant market in the pharmaceutical industry competition authorities have employed therapeutic and chemical classification, which is a starting point for determining the relevant market. However, the use of this classification is not binding and has its own set of concerns. A civil court of Venice (Italy) has deployed a different approach other than the traditionally used therapeutic and chemical classification in defining the relevant market in abuse of dominant case against Glaxosmithkline SpA (GSK), a drug manufacturer in Italy. Present paper revolves around the competition law aspects of the judgment as it is of great interest in the field of pharmaceutical industry with respect to the principles of Competition law applied in the industry.

Keywords: *Anti-Trust, Relevant Market, Abuse of Dominance, Pharmaceutical Industry.*

I. INTRODUCTION

A civil court in Italy's Venice[3] has held GSK guilty for their violations of principles of good faith and proper performance of the contract and abuse of dominant position within the meaning of Article 102 of Treaty on the Functioning of the European Union (TFEU). This case generates interest as this case has previously been filed before the national competition authority which had rejected the request of the complainant (SFM) to delineate relevant market on factors other than the traditionally used ATC 3 classification. However, when SFM brought the same issue before the civil court in a suit for damages, the civil judge dived into the competition issues and handed a judgement in favour of SFM, which has pointed towards a fresh approach for assessing the relevant market for the pharmaceutical industry with respect to competition law.

[1] Author is a Young Professional (Law) at the Competition Commission of India.
[2] Author is an Adviser (Economics) at Competition Commission of India.
[3] https://www.concurrences.com/IMG/pdf/sentenza_antitrust.pdf?77794/a535ebb7fa49b65085d5c4daf147fab80d55b26a7076a7d245ad39c9e8acfdca

 [ISSN 2581-5369]

II. ALLEGATIONS

It was alleged by SFM, a wholesale distributor of pharmaceutical specialities that, GSK being a big pharma company that markets wide range of drugs in Italy had steadily, remarkably and single-handedly reduced the supply of *Avodart* a drug to treat *benign prostatic hyperplasia* and *Seretide* a drug to treat *asthma*, which violated the competition law (abuse of dominant position as within the meaning of Article 102 of TFEU and Article 3 of the Law of October 10, 1990 No. 287 (Italian Competition law on the safeguarding of competition and the market, and acts of unfair competition within the meaning of Article 2598 of the Italian Civil Code) along with other violations of principles of law. The complainant in the action for damages claimed for loss of turnover, loss of customers and loss of opportunity to make investments.

SFM also contended that GSK abused its dominant position by supplying the quantities 80-90% below demand, of the two medicines at issue.

III. OBSERVATIONS OF THE COURT

A) On the Definition of Relevant Market:

The judge first observed that prerequisite for the finding of an abuse of dominant position case is *definition of relevant market*. The court observed that geographical area to be taken into consideration is that relating to the entire territory of Italy, with complainant having warehouses spread throughout the national territory. Thereafter, court observed that in the pharmaceutical industry there exist following segments:

- Drug manufacturers such as GSK;
- The Wholesale trade, which includes distributors and sometimes producers both; and
- Retail trade in which includes pharmacies.

Further, after analysing the parameters to define relevant market as enucleated by the European Union and community jurisprudence that have been firmly accepted by national jurisprudence, and after considering the fact that how competition in the sector takes place, the court stated that the relevant market includes medicinal products that can be used for same therapeutic indications, as it will be clarified and corresponding to ATC 3 classification.

To explain the ATC 3 classification the court noted that in pharmaceutical industry, the legal substitutability of drug is traditionally established on the basis of the anatomical, therapeutic and chemical classification system (ATC) which defines groups of molecules according to their composition and therapeutic indications. This system is often the starting point of the method

used to delineate the relevant market both in terms of anti-competitive conduct and merger control.

The complainant assailed the use of ATC 3 classification. According to the complainant this system of drug classification is not capable of providing a correct definition of the market and it suggested to use a criterion which is more clinical and pharmacological. It was suggested by the complainant that it is the pharmacist who determines the market for the wholesaler's demand *vis-a-vis* manufacturer who does not have the right to change the doctor's prescription and therefore the relevant market is defined by the doctor's prescription based on therapeutic choice made by him.

The defendant, on the other hand, contended that the relevant market is determined by all comparable pharmaceutical specialties that the doctor considers when writing the prescription, which implies considering the perspective of the "patient-consumer" to whom the therapeutic need refers, the doctor is merely serving as a "technical mediator." The judge points out that the European Commission and the national competition authority have used ATC 3 (the third level indicates the therapeutic subgroup or pharmacological class), or even ATC 4 (this level corresponds to the chemical class that the drug belongs to or to the drug's mode of action), and believes that this approach is not exclusive because neither the competition authority nor the judicial authority are constrained by the sectoral law on pharmaceuticals.

In fact, antitrust intervention pursues goals that are separate and independent from the goal of protecting public health that is sought within the framework of marketing authorization (MA), the latter being unrelated to the market assessments necessary for the application of antitrust regulations. The ATC categorization is merely one instrument among several that the court believes can be used to determine the relevant competitive market. Additionally, in Aspen vs. AGCOM (Judgment of the Council of Status March 13, 2020 Aspen vs AGCOM) the Conseil d'Etat has previously said that while the intended therapeutic use of pharmaceuticals is the starting point of the competitive analysis, the primary drawback of using ATC 3 is that it ignores the clinical efficacy of the treatments and their tolerance level. The High Administrative Court ruled that the authorities in charge of enforcing competition laws must be permitted to take into consideration both the actual usage of the goods and the empirical research on prescribers' conduct, provided that these standards are more appropriate under the circumstances.

The Court of Venice rejected the pharmaceutical company's argument, stating that it was necessary to take into account the vertical structure of the market (the wholesale market) in this case, specifically the relationship between the wholesaler and his customer, the pharmacist, who

is also a competitor with other distributors of pharmaceutical specialties (supply market). This decision is "irreversible and not likely to be changed except with the generic medicine" once the doctor has written a prescription for a medication. On the one hand, pharmacists must give the patient-consumer the medication that the doctor has prescribed. On the other hand, wholesalers must provide the pharmacist with the medication that the doctor has prescribed, therefore they turn to the drug producers to fulfil this duty. Therefore, the judge delineated two distinct markets, first, there is a "prescription market" and second, there is "procurement market". The expert appointed by court has shown that it is improper to define the relevant market using ATC 3 in this situation in following manner:

Regarding *Avodart*- the expert noted that the drugs Alfuzosin, Tamsulosin, Terazosin, and Silodosin, although belonging to the same pharmacological therapeutic subgroup of Dutasteride (third level of the ATC classification, G04C), do not constitute actual substitutes for Dutasteride, as they are equipped with both a different mechanism of action (blockade of alpha-1 adrenergic receptors), and of distinct therapeutic effect (facilitation urination due to relaxation of the prostate tissue). From this point of view, these molecules are to be considered as *complementary rather than alternative remedies* to Dutasteride. The expert noted that only one alternative to *Avodart* was available at the time was *Proscar,* a specialty containing Finasteride, a drug with a similar action mechanism.

Thereafter, the judge noted that, in the case of pharmaceutical products, the choice of the drug is made by the doctor, while the consumption of the drug is done by the patient; to which the doctor is a technical mediator. In this context the question expressed by the patient, when approaching the pharmacy to purchase the drug, is a question Influenced and constrained by the physician's prior decision to which the patient sticks.

Therefore, the assessment of the degree of substitutability between pharmaceutical specialties must take into consideration the criteria used by the doctor to prescribe a medicine, with the latter being chosen due to the therapeutic use and not the expense of treatment. The Court noted that, the relevant market is decided by the disease and consequently by the prescription written by the physician, who bases his or her decision on the clinical effectiveness of a certain treatment and the tolerance to that drug in order to identify the best way to treat the disease.

Nonetheless, the judge in the present case observed that market segment constituted by the wholesaler pharmacist relationship as alleged, the damaging conduct of GSK would have hindered the competition in the relationship between pharmacists and wholesalers.

The judge further goes to note that the substitutability of a medicinal product is governed by a

 [ISSN 2581-5369]

National Convention according to which a drug can be replaced by the pharmacist in case of emergency with another drug, even if the same is manufactured by another manufacturer, is identical with the point of view of the active ingredient, of the composition, of the formulation and it does not cost the patient more than the drug which is being replaced. Further, if equivalent generic drugs marketed under the name of active ingredient are available in the market, the pharmacist can give such generic drugs subject to the consent of the patient.

The judge noted that the only alternative to Avodart that existed was Proscar, with different active ingredient Finasteride but with similar clinical efficacy. Therefore, the relevant market in relationship between wholesaler and pharmacist was only Avodart because it could not be replaced by the pharmacist on his own but only after a change in prescription from the doctor. GSK argued contrary to this point that as suggested by their experts Avodart's relevant market consisted of 8 active ingredients and a combination of drugs that are manufactured by over 50 pharmaceutical companies.

Regarding *Seretide*- the judge noted that active ingredients were Salmetarol Xinafoato and Fluticasone, has enjoyed patent coverage until 7.9.2013.

The judge therefore thought it necessary to distinguish two periods in a manner as: January 2012 - September 2013 in which the patent was active; October 2013 - February 2015 in which both drugs were placed on the market. In the first period the active ingredient of Seredite were also present in another drug i.e. Alifluss and in case of urgency Seredite was directly replaceable by pharmacist with Alifluss which was a therapeutically equivalent pharmaceutical speciality. In the second period Seretide was directly replaceable in case of free prescription with equivalent drugs such as Foster, Symbicort, Flutiformo and Leventair, who had different active ingredient but substantially similar clinical efficacy.

In conclusion, Avodart was not exchangeable since it cannot be substituted by generics for the whole three-year period under review owing to the uniqueness and irreplaceable character of the doctor's prescription, which determines the medication most fit for the patient's needs. Seretide was only interchangeable with Alifluss until September 2013, after that period it was also replaceable by other drugs.

B) On Abuse of Dominant Position:

To counter the allegation of abuse of dominant position by supplying the quantities 80-90% below demand, of the two medicines at issue, GSK stated that it identifies the maximum quantities of each drug that it deems fit to allocate for each member country through a system called European Allocation System (EAS), and to use this system, GSK uses the Trade

 [ISSN 2581-5369]

Dynamics Algorithm developed by a company called IMS Health (IMS). In order to determine the maximum allocable supplies of each drug to the warehouses of the various wholesalers, the system works through an alignment of supplies to the needs expressed in the individual areas by population.

It is the case of GSK that it is precluded from any anti-competitive, manipulative intervention because the data they feed to calculation algorithms which is developed exclusively by IMS cannot be modified by it, and the algorithms allows to operate an efficient distribution of drugs at the same time guarantees impartiality and non-discrimination in distribution of drugs at issue.

In the opinion of the expert appointed by the court the Trade Dynamics System in itself is not discriminatory, however, the final result of the estimates depend on the information entered and that the information transmitted by GSK to IMS is in itself suitable to determine the outcome of the same.

The court further noted that GSK provides with the data to IMS relating to *"sales to warehouses (ex-factory) for every single product relating to the last thirteen months."*

Therefore, if a warehouse had limited sales for a period, it will receive a reduced amount of drugs in the future. The court also observed that GSK objected to the expert gathering further data on the collaboration between GSK and the algorithm's creator IMS. According to the evidence acquired, it appears that the laboratory only allocated 10% of the quantity that the complainant had requested, without providing an explanation for this large decrease. On the other hand, there was no proof shown as to the unusualness of the orders the wholesale distributor placed. This means that other wholesale distributors benefited from the allocation of medicines produced by GSK, being able to respond more quickly to the demand of their customers, if the complainant experienced a sharp drop in the supply of the medicines ordered, while the needs of the Italian market were met for the period under consideration (the pharmacists). This has led to a distortion of the market for the wholesale of pharmaceutical specialities. The market for pharmaceutical specialties sold in wholesale has been distorted as a result. In fact, if a pharmacist is approached by a patient-consumer with a prescription and is unable to obtain the necessary medications on his own, he will turn to another wholesaler if he is unable to make an order with the complainant. The judge also underlined that, in accordance with sectoral legislation, the wholesale distributor of pharmaceutical specialties is subject to a number of requirements, including the need to list 90% of the products and supply to pharmacies within 12 hours after receiving an order. For his part, the pharmacist can use a computer system to find the distributors who have the desired medications; as a result, in the event of a stock

 [ISSN 2581-5369]

shortage, he will seek for a different source. These factors led the judge to conclude that GSK had abused its dominating position in order to injure a wholesaler client (SFM) with whom it had a long-standing and ongoing business agreement.

C) On the Maintainability of the action launched before the Civil Judge:

GSK alternatively argued that the present case concerns an action to ascertain the abuse of dominant position and that the same had already been decided by the National Competition Authority, which has rejected the request of SFM, adopting the same definition of relevant market as proposed by GSK.

The Civil Judge rejected these arguments on the grounds that, first the facts giving rise to the dispute predate the publication and entry into force of Directive (EU) No 2014/104. Admittedly, the action for damages brought before the national court is subsequent to the entry into force of the Directive but prior to the transposition period. Second, even prospectively, the judge is not bound by a closure decision issued by the national competition authority, since Article 9 of Directive (EU) 2014/104 and Article 7 of Decreto Legislativo 3/2017 that transposed it require a finding of infringement. Finally, it should not be forgotten that the objective litigation is still ongoing since the complainant has filed an appeal against the decision to close the case. No final decision confirming the market analysis conducted by the AGCM has been issued so far.

IV. CONCLUSION AS ARRIVED AT BY COURT OF VENICE

Finally, the judge concluded that "in the relationship between wholesalers and pharmacists, the pharmaceutical speciality that is the subject of a prescription is sufficient to constitute a relevant market, on which the manufacturers of medicines may potentially have a dominant position."

V. INDIAN EXPERIENCES IN PHARMACEUTICAL SECTOR

In India, the Competition Commission of India had also dealt with similar cases wherein the relevant market has been delineated on the basis of the ATC 3 and ATC 4 classification. In Combination Registration No. C-2019/03/654[4], wherein 'GSK' and Pfizer Inc., entered into a new incorporated entity, New JV Co, with GSK and Pfizer holding 68% and 32% shares in the New JV Co., respectively. Despite the high combined market shares, CCI allowed the Proposed Combination after considering the presence of multiple competitors having more or competing market, which ensured the presence of competitive restraint in all the relevant markets. CCI also noted that no vertical overlap existed between the business activities of the Parties.

[4] https://www.cci.gov.in/search-filter-details/1157

 [ISSN 2581-5369]

However, in Combination Registration No. C-2020/04/741[5] it was noted by the commission in paragraph 12 that "*For the purpose of defining markets in pharmaceutical cases, the Commission in the past had looked into the molecular details (ATC 4 level classification) with regard to prescription drugs. For instance, such is the approach in Sun/ Ranbaxy (C2014/05/170). As regards OTC products, the Commission in Novartis/ GlaxoSmithKline (C-2014/07/188) identified product markets based on formulation level as well as therapeutic indication (ATC 3 level classification). It is observed that the industrial classifications may guide the preliminary competition assessment. However, precise delineation of relevant market in a case would depend on the facts and circumstances including the dynamics of the given market."*

As a matter of fact, the Competition Commission of India, like the court of Venice, believes that while an industrial classification (ATC 3 and ATC 4) may be useful in assessing preliminary competition concerns, the proper delineation of the relevant market in a particular case will depend on the facts and circumstances of the given market. Therefore, it would of great interest to see if the delineation of relevant market as arrived at by the court of Venice will also be applied by the Commission in any future anti-trust, and merger cases.

*****

[5] https://www.cci.gov.in/search-filter-details/4408

 [ISSN 2581-5369]