Article 82 EC: How supply quota policies distort the pharmaceutical supply chain

*September 2005*
Table of content

A. INTRODUCTION AND EXECUTIVE SUMMARY ............................................................. 4

B. MAIN FEATURES AND CHARACTERISTICS OF THE PHARMACEUTICAL SUPPLY
CHAIN .............................................................................................................................. 6

C. ARTICLE 82 EC: ABUSE OF A DOMINANT POSITION PROHIBITED ......................... 10

I. Definition of the relevant market .............................................................................. 10
   1. Underlying principles ........................................................................................... 10
   2. The relevant product markets in the pharmaceutical sector .............................. 11
      2.1 Reference to the therapeutic use .................................................................. 11
      a. ATC .............................................................................................................. 12
      b. Individualising factors .................................................................................. 13
   2.2 Markets at pharmaceutical wholesale level ...................................................... 14
      a. Ordering system ........................................................................................... 16
      b. Public service obligation ............................................................................. 16
   3. The relevant geographic markets in the pharmaceutical sector ....................... 17
   4. Conclusion on market definition ......................................................................... 17

II. Assessment of dominance ....................................................................................... 18
   1. Single firm dominance ....................................................................................... 18
      1.1 Market share as an indicator of dominance .................................................... 19
      1.2 Dependence of customers based on additional factors ............................... 20
      a. High switching costs and limited number of suppliers ................................. 21
      b. Unavoidable trading partner ....................................................................... 21
      c. Barriers to entry and potential competition .................................................. 22
   2. Collective Dominance ......................................................................................... 23

III. Abusive conduct ..................................................................................................... 25
   1. Case law on abusive pattern of refusal to supply .............................................. 27
      1.1 Commercial Solvents ................................................................................. 28
      1.2 United Brands ............................................................................................ 28
      1.3 Hugin .......................................................................................................... 29
      1.4 Télémarketing .............................................................................................. 29
      1.5 Volvo .......................................................................................................... 29
      1.6 Magill ........................................................................................................... 30
      1.7 Ladbroke .................................................................................................... 30
      1.8 Bronner ....................................................................................................... 30
      1.9 IMS Health ................................................................................................. 31
   2. Impacts on pharmaceutical full-line wholesalers ................................................ 31
      2.1 Exploitative abuses and individualised impacts of refusal to supply ........... 31
      2.2 Impacts on competition ............................................................................... 33
      a. Arbitrary refusal as threat, punishment or inducement .................................. 33
      b. Market foreclosure and freezing of market shares ....................................... 34
      c. Discriminating pattern .................................................................................. 35
      d. Objective justification ................................................................................... 35
      aa. Product shortages ...................................................................................... 35
      bb. Significant supply shortages due to parallel trade ..................................... 36

IV. Conclusion and Summary ...................................................................................... 38

ANNEX: Examples of public service obligations fulfilled by pharmaceutical full-line wholesalers in Europe ................................. 40
   BELGIUM ............................................................................................................... 40
   FINLAND ............................................................................................................. 40
FRANCE......................................................................................................................... 40
GREECE......................................................................................................................... 41
ITALY.......................................................................................................................... 41
PORTUGAL....................................................................................................................... 42
AUSTRIA........................................................................................................................ 42
GERMANY........................................................................................................................ 42
A. Introduction and Executive Summary

Since 2001, a number of manufacturers of pharmaceutical products have unilaterally started to introduce supply quota systems for their sales to pharmaceutical full-line wholesalers throughout the European Union. The new policy consists of supplying wholesalers with only certain predetermined quantities of their products, within limited time periods. The quantities allocated by pharmaceutical manufacturers are often insufficient to meet the demands of the wholesalers. In many instances there is no possible way for a wholesaler to exceed the quantity of supply. In fact, this is the case even in circumstances where there is obviously a higher demand for the products from their usual customers and where the manufacturers clearly have the quantities available to meet the demands.

Pharmaceutical full-line wholesalers are not in a position to substitute products. This is due to the particularities of the pharmaceutical ordering system which excludes wholesalers from the purchase-decision making process and requires them to exactly deliver the ordered product. Due to factual and legal reasons, full-line wholesalers have no alternatives to supplying the pharmaceutical product, identified by product number, as ordered. They are legally not allowed to deliver alternatives. Even if identical, parallel imported products are due to legal restraints no substitutes from the wholesaler’s perspective. Technically, the order system does not provide for the possibility to offer alternatives in case the requested product is on stock. Moreover, wholesalers are in many Member States under a public service obligation to ensure supplies of pharmaceuticals and have minimum quantities of a range of pharmaceuticals on stock.

Consequently, from the perspective of pharmaceutical full-line wholesalers, each specific product as prescribed and ordered constitutes a separate market. In the light of the dependence described above, pharmaceutical manufacturers have to be considered dominant within the meaning of Article 82 EC on the relevant market.

Dominant firms are subject to a regime of special responsibility which requires them to abstain from using its market power against competitors, customers and end-consumers. The supply quota systems result in full-line wholesalers experiencing shortages of supply, lost sales and increased costs. These systems obstruct and distort competition and have exploitative and exclusionary effects. Operated arbitrarily and discriminatory, they lead to market exclusion and discrimination and are therefore abusive. Supply quotas make it impossible for new players to enter the market and facilitate that existing suppliers secure and extent their market power or expand regionally.
European Courts have ruled at various occasions that a dominant firm refusing to supply its customers without objective justification acts abusively. To date, pharmaceutical manufacturers have failed to offer any valid or legitimate explanations for the introduction of their new quota systems and have refused to engage in any dialogue with the full-line wholesalers concerning this matter. The motives behind the supply quota systems for national markets, in particular the prevention of parallel trade, cannot be regarded as legitimate on grounds of public health.

This paper will prove that the supply quota systems introduced by pharmaceutical manufactures constitute an abuse of their dominant position, which is contrary to Article 82 EC.
B. Main features and characteristics of the pharmaceutical supply chain

Pharmaceutical full-line wholesalers are the vital link between manufacturers on the one hand and retail pharmacies on the other. Pharmaceutical full-line wholesale consists of the distribution of the total range of medicines, including doctor prescription only medicines, over the counter medicines (OTC), generics and other health care products. Pharmaceutical full-line wholesalers offer a fast and frequent delivery service with up to six deliveries per day. Wholesale distribution of medicines is subject to strict rules, designed to guarantee the quality of medicinal products throughout the distribution chain. Moreover, EU legislation imposes jointly on holders of marketing authorisations as well as wholesalers the responsibility to ensure a stable and constant supply of pharmaceuticals. The amended Article 81 second paragraph of the Directive on the Community code relating to medical products for human use reads as follows:

“The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.”

The full range of medicinal products and the ability of continuous supply to pharmacies are core prerequisites of pharmaceutical full-line wholesalers. Consequently, the prompt supply of medicines to the patients throughout the European Union through public pharmacies relies on this function of pharmaceutical full-line wholesalers. Such obligations had before already been part of the national laws of many Member States. In Italy, France, Belgium, Greece, Spain and Portugal, full-line wholesalers are subject to additional “public service obligations” which require them to keep minimum quantities of stocks available. In some Member States the wholesaler must hold a stock of medicines with which he is able to supply the public pharmacies of his region on a normal and daily basis. The stock must be in accordance, for example, with at least two thirds of

---

1 See Directive 2001/83/EC on the Community code relating to medical products for human use (OJ 2001 L 311/67) as amended by Directive 2004/27/EC (OJ 2004 L 136/34). This amendment added a second paragraph to Article 81 of the Directive according to which the holder of a marketing authorisation, as well as the distributor are obliged to ensure a stable and continuous supply of the products sold.

2 National courts have defined the role of pharmaceutical wholesalers in various decisions. For Germany, see BGH, decision of 13 July 2004, KVR 2/03, page 3.

3 A survey and description of examples of these national obligations can be found in the Annex.

4 **Belgium**, council directive of 6 June 1960 concerning the manufacture, wholesale, distribution and the handling of medicines (as amended), Article 22 bis; **Finland**, Finnish Drug Act, Section 37; **France**, ...
pharmaceutical specialities, serums and vaccines. Pharmaceutical wholesalers are obliged to dispose of sufficient staff, sales- and execution services as well as means of transport in order to supply the public pharmacies daily provisioning of the territory.\textsuperscript{5} Other Member States impose the duty to hold a stock consisting in at least 90\% of the medicines used in that Member State.\textsuperscript{6} They have to deliver on-the-market-medicines, if the case arises, urgently or within 24 hours after the order.\textsuperscript{7}

Additional important items of the pharmaceutical distribution chain are the particularities of the ordering system. This leads to a legal inability of wholesalers to engage in any substitution of pharmaceuticals of any kind.

Typically prescribing physicians make decisions on behalf of their patients which pharmaceutical products have to be dispensed. Doctors take decisions on the therapeutic level and then decide between the different products on offer for the treatment in the specific anatomic or diagnostic area. Not even the pharmacist is fully aware of the diagnosis behind the prescription. They direct the dosage, the pharmaceutical form (e.g. pill, injection, etc), quantity (package size) and in all ways which exact product, identified by brand name,\textsuperscript{8} should be purchased. In special cases, especially when generics are available, the physician prescribes by using the substance name (i.e. INN), thus giving the choice between different manufacturers’ products with these ingredients to the pharmacist. In some countries the same choice is allowed if the physician prescribes using the brand name but adding the acronym “a.i.” for \textit{aut idem}. In any case the other criteria like dosage, quantity and form are defined by the physician.

\textsuperscript{5} Belgium, council directive of 6 June 1960 concerning the manufacture, wholesale, distribution and the handing of medicines (as amended), Article 22 bis. 
\textsuperscript{7} Belgium, council directive of 6 June 1960 concerning the manufacture, wholesale, distribution and the handing of medicines (as amended), Article 22 bis; France, decree D.98-79 of 11 February 1998, Article R 5115-13. 
\textsuperscript{8} The brand name defines a medicinal product with specific active substances and is, at the same time, part of the marketing authorisation. The authorities check that the name is not misleading and gives a clear definition of the product.
Generally pharmacists must follow the instructions of prescribing physicians. They must dispense exactly what is prescribed and are not entitled to offer alternatives. In some Member States, a substitution with a parallel traded product is permitted or after the patient protection has expired with a generic product. In Germany, for example, the pharmacist has to fulfil a fixed quota of parallel imported drugs dispensed on behalf of the “sickness funds” or to incur a financial penalty. As the parallel imported drug has usually a lower price and thus usually a lower margin for him, he will exactly control when he orders the parallel import and the original product. His decision is laid down in his order on the wholesaler, which defines the exact product (brand name, manufacturer/importer, dosage, form, pack size) by its ordering number.

Under certain circumstances the physician may delegate his power of decision to the pharmacists if he prescribes medicines generically, i.e. by using the substance name (INN) or by allowing aut idem surrogates. The pharmacist then has the choice between all medicinal products matching this prescription.

If the doctor uses the brand name of the product, in some countries and under special provisions the pharmacist is allowed to substitute the prescribed product by another generic product. This generic substitution is considered to be a qualified pharmaceutical decision only to be taken by or under the responsibility of a pharmacist. The pharmacist, like the physician, is subject to two legal regimes when taking his decision. However, under social security law, the pharmacist has to observe additional requirements if he wants to make a generic substitution. For instance, in Germany as of July 2002 the pharmacist is obliged, where it is possible according to the list mentioned above, to substitute the prescribed product by a generic product with a price located in the lowest third of the price range of all generics with the same characteristics. If the physician already has prescribed a product by its brand name (e.g. branded generic) with a price located in the lowest third of the price range, generic substitution by the pharmacist is forbidden. If the pharmacist does not substitute where it is both allowed and required, or if he substitutes where it is not allowed, he can be fined by the health authorities, the professional bodies and/or by the sickness funds. \(^9\) In any case the order once placed, with the wholesaler, cannot be changed.

Pharmacies place orders with wholesalers, usually electronically, by use of a detailed product numbering system. Within the product numbering system, every pack size of every product, sold by every manufacturer or importer has its own number. The wholesaler’s system will either

---

\(^9\) This may even lead to a change in the prescribing habits of physicians. In some Member States the pharmacist generally substitutes the prescribed medicine, unless the prescribing doctor has stated explicitly on the prescription that substitution is excluded. See opinion of 16 April 2003 for the German Federal Ministry of Health and Social Security, p. 17, available at http://www.bmgs.bund.de/downloads/GutachtenBMGS2705.pdf.
automatically confirm the availability of the product requested or it will indicate that it cannot meet that order.

Additionally, the wholesaler is not legally entitled to substitute the ordered medicine with an identical (e.g. parallel imported) product if the latter does not contain a matching product number. The exclusion of any commercial freedom with respect to product substitution is also a consequence of the special legal regime prescribing physicians and retail pharmacists are under. The choice of the correct medication is primarily part of physicians’ professional responsibility. They are in principle liable for their decisions. This includes side effects, unintended effects and interactions with other medicines. In addition, doctors’ prescription behaviour is controlled in most countries by cost containment measures such as budgets or formularies (positive or negative lists of products which doctors may prescribe and which the national government will pay for). If he exceeds his budget or prescribes products not on the reimbursement list, in many cases he has to pay compensation and/or fines. In a limited way, doctors can delegate, after prescribing the substance or a product of choice of the final medicinal product dispensed to the patient, to pharmacists. In those cases, also pharmacists are held liable for their decisions to the same extent doctors are liable for theirs.

For these reasons it is essential that the product issued to the patient corresponds to the prescription, once the physician or the pharmacist has taken his decision. Wholesalers only have the ability to respond to orders. They are therefore fully dependent on the manufacturers to supply the product ordered and identified by the product ordering number through the pharmacist. This, and its effects on competition, is about to be explained in detail.
C. Article 82 EC: Abuse of a dominant position prohibited

The EC Treaty establishes a system of undistorted competition, Article 3 (g) EC. This implies that the Community competition rules must also address anti-competitive practices based on unilateral conduct if these are carried out by firms which hold a certain amount of market power which may have a harmful effect on competition. To meet this aim, Article 82 EC prohibits any abuse by one or more undertakings with a dominant position within the common market or in a substantial part of it, as incompatible with the common market, in so far as it may affect trade between Member States. The degree of market power is determined by the concept of dominance. The conceptual framework of dominance control as set out by the EC Treaty refers to a dominant position only within a properly defined market. Dominance is not determined by the overall strength of an undertaking, but by its position on a specific market which, due to specific characteristic features of competition, can be distinguished from other markets.

I. Definition of the relevant market

As the definition of the relevant market is of paramount importance for dominance control, it is helpful to recall its conceptual framework as well as the relevant case law relating to the pharmaceutical industry to date. New guidance may follow from recent developments. In July 2005, the Commission found AstraZeneca to be abusing its dominant position on the proton pump inhibitor market and imposed a fine of € 60 million on this firm.10 This is one of the first cases on the application of Article 82 EC in the pharmaceutical sector.

1. Underlying principles

The purpose of market definition is to identify the boundaries of competition between firms. It is a systemic way of identifying the competitive constraints undertakings are facing in a specific field or area. In addition, market definition is closely related to the objectives pursued under Community competition policy.11 There are three basic criteria which constitute the test of market definition:

10 The decision is not yet published. Press release of case COMP/37.507 of 15 June 2005 available, see IP/ 05/737.
• demand substitutability;
• supply substitutability; and
• potential competition.

In general, market definition is based on evidence of demand-side substitution among the range of competing products. In order to assess the interchangeability of two products, the intended purpose of a product must be identified.\textsuperscript{12} All the products that are regarded as interchangeable in terms of intended use, price, availability and main product characteristics are considered as being part of the same product market. A tool to assess demand-side substitution is the extent to which price variations in one product market affect the demand of another. If as a result of a hypothetical small, but significant non-transitory increase in price ("SSNIP"-test, in the range of 5-10%) the acting firm would incur a loss of sales of such magnitude that the price increase would be unprofitable for the manufacturer, additional substitutes are included in the market.\textsuperscript{13}

2. **The relevant product markets in the pharmaceutical sector**

2.1 **Reference to the therapeutic use**

Pharmaceutical products are used for the treatment of human illnesses and diseases. The main product characteristics of pharmaceuticals relate to the therapeutic indication for which the drug is used. Due to the facts that pharmaceutical are typically patent protected (or covered by other IP rights), price competition is of less significant importance in pharmaceuticals. IP rights are obvious barriers to entry and make it impossible to find alternative products if prices were increased. Therefore the SSNIP-test does not lead to any meaningful results and is, from a methodology point of view, impossible to apply. As prices of pharmaceuticals are often subject to governmental control and reimbursement levels, the price setting freedom is limited. Therefore, other criteria were found to be more useful in the pharmaceutical industry. However, in any event the manufacturer is not obliged to place a product on the market in the case where he does not agree with the price he would get to for his product in a Member State.

\textsuperscript{13} Market Definition Notice, para 17.
In its previous decisions, the Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Classification" (ATC). The ATC system has been developed and maintained by the European Pharmaceutical Marketing Research Association (EphMRA). According to the Introduction of the 2005 ATC Guidelines:

“It is a subjective method of grouping certain pharmaceutical products and does not represent any particular market, as would be the case with any other classification system.”

This classification allows medicines to be grouped together by reference to their composition and their therapeutic properties. The ATC categorises pharmaceutical products into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

As a starting point, the Commission typically refers to the third level of the ATC, as this is supposed to reflect the generalised therapeutic use of pharmaceuticals. However, the Commission has also considered that the third level of the ATC is not in all cases an appropriate basis for the definition of product markets and that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceuticals. This would be the case where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease. It may also be appropriate to apply a narrower market definition where the pharmaceuticals forming part of a certain ATC-3 class have clearly differing indications. In certain cases, pharmaceuticals could also be split further into a prescription and a non-prescription segment. The Commission has also constituted separate

---


15 www.ephra.org.


17 The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed.

18 M.1403, Astra/Zeneca, para 7; M.737, Ciba-Geigy/ Sandoz, para 23; M.2922, Pfizer/ Pharmacia, para 16; M. 2517, Bristol Myers Squibb/ Du Pont, para 11.

19 M.737, Ciba Geigy/ Sandoz, para 17; M.495, Behringwerke AG/ Armour Pharma, para 14. M. 1397, Sanofi/ Synthelabo, para 23, 29 et seq.

20 M. 1397, Sanofi/ Synthelabo, para 23, 29 et seq.; M.2922, Pfizer/ Pharmacia, para 17, 37.

21 M.2922, Pfizer/ Pharmacia, para 17; M.3394, Johnson & Johnson/ MSD Europe, para 15; M.3544,
markets for immediate release and the slow-release segments of the same ATC-3 class, although the same active ingredients were used.\textsuperscript{22}

This illustrates that the ATC approach is only a very rough indication of which products should be allocated to the same product market. It is only a preliminary classification which requires case-specific adjustments. This holds in particular true for the supply chain between pharmaceutical manufacturers and full-line wholesalers. From the perspective of wholesalers, an approach according to ATC-3 classes is not meaningful. Rather, a wholesaler, to meet an order, is dependent on supplies of a specific drug from the manufacturer. This already indicates that dominance of pharmaceutical manufacturers has to be assessed on the basis of the “one product, one market” approach in relation to wholesalers.

b. \textbf{Individualising factors}

It is established case law\textsuperscript{23} that not only the product characteristics but also other factors have to be taken into account, which have a decisive influence on the purchase decision relating to pharmaceuticals. As set out above, one of the main features of the distribution of pharmaceuticals is neither the patient and the wholesaler typically have no influence as regards the choice of the product. It is the prescribing doctor who takes the decision, which products will be given to the patient and which accordingly are purchased by the wholesaler from the pharmaceutical manufacturers. Therefore, prescription habits of general practitioners\textsuperscript{24} as well as different methods of administration and pharmaceutical reimbursement have to be taken into account.\textsuperscript{25} This illustrates that market definitions in pharmaceuticals are very case-specific. It is not only the general product characteristics which influence this definition, but also the perspective and function of the individual undertaking involved in the pharmaceutical supply chain. This concept of an individualised assessment from the perspective of the undertaking concerned was also favoured by the ECJ. The Court ruled in \textit{Michelin}:

\begin{quote}
\textit{It must be noted that the determination of the relevant market is useful in assessing whether the undertaking concerned is in a position to prevent effective competition from being maintained and behave to an appreciable extent independently of its competitors and customers and consumers. For this purpose, therefore, an}
\end{quote}

\begin{flushleft}
\textit{Bayer Healthcare/ Roche, para 13; M.3751, Novartis/ Hexal, para 3.}
\end{flushleft}

\begin{flushleft}
\textit{M.1835, Monsanto/ Pharmacia & Upjohn, para 30.}
\end{flushleft}

\begin{flushleft}
\end{flushleft}

\begin{flushleft}
\textit{For instance cases M.737, Ciba-Geigy/ Sandoz, para 21; M.1403 Astra/ Zeneca, para 26.}
\end{flushleft}

\begin{flushleft}
\textit{For instance cases M.2922, Pfizer/ Pharmacia, para 17, 42; M.464, BMSC/ UPSA, para 11.}
\end{flushleft}
examination limited to the objective characteristics only of the relevant products cannot be sufficient: the competitive conditions and the structure of supply and demand on the market must also be taken into consideration.”26

As the ECJ stated, the structure of supply and demand have to be taken into account when determining the relevant product market.27 As detailed above, the different actors in the pharmaceutical supply chain have different functions and accordingly, different economic needs. As the ECJ has stated,

“If a product could be used for different purposes and if these different purposes are in accordance with economic needs, which are in themselves also different, there are good grounds for accepting that this product may, according to the circumstances, belong to separate markets which may present specific features which differ from the standpoint both of the structure and the conditions of competition..

The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned.”28

Similarly, also the Commission stressed an individual perspective while comparing the substitutability of products. This is of particular importance for undertakings being active in the pharmaceutical distribution chain. The Commission suggests that, while products may be very similar with respect to their physical characteristics, there can be more than one distinct product market where individual customer groups can be identified:

“The extent of the product market might be narrowed in the presence of distinct groups of customers. A distinct group of customers for the relevant product may constitute a narrower, distinct market when such group could be subject to price discrimination.”29

2.2 Markets at pharmaceutical wholesale level

Wholesalers operate under specific market conditions. The Commission has defined wholesale markets on various occasions concluding that there is a separate market for wholesale supply of
prescription pharmaceutical products.\textsuperscript{30} Clearly the wide ATC3-based market definition the Commission used in the cited merger cases is not appropriate when defining markets for the purpose of identifying illegal abusive practices within the meaning of Article 82 EC. Merger control relates to long-term structural changes whereas Article 82 EC, while limiting the commercial freedom of dominant firms, establishes a level playing field on the market concerned.

Because of the legal constraints described above, full-line wholesalers are not in a position to substitute the ordered products with alternatives. They are simply not allowed to deliver any other product than the prescribed and/or ordered drug. Supply side substitutability is not an option for wholesalers as they are not active at production level. Moreover, typically patents and other IP-rights exclude the possibility of sourcing from competitors at production level.

From the perspective of wholesalers, the ordered product as identified by its ordering number constitutes a separate product market. This will be explained in a greater level later on but to provide an initial summary it is correct that for pharmaceutical full-line wholesalers each product constitutes a separate market (“one product, one market”).

\textsuperscript{30} M.2573 A&C/ Grossfarma; M.2432 Angelini/ Phoenix/ JV; M.2193 Alliance Unichem/ Interpharm; M.1716 Gehe/ Herba; M.1243 Alliance Unichem Plc/ Safa Galenica SA; M.1201 DuPont/ Merck; M.1058 Unichem/ Alliance Sante; M.718 Phoenix/ Comifar; M.716 Gehe/ Lloyds Chemists; M.426 Rhone Poulenc / Cooper. All decision available at http://europa.eu.int/comm/competition/mergers/cases/.
a. **Ordering system**

Due to the particularities of the pharmaceutical ordering system as described above, wholesalers have no demand substitutability as it is practically impossible for them to offer their customers (e.g. retail pharmacies and hospitals) alternatives to the ordered products. Wholesalers have no alternatives to the products ordered by their customers and may only respond to an order of a specific product. Imported products even if identical to the prescribed medicine are no possible substitute as they are identified by a separate product number and sent back by the customers if delivered as non-fulfilment of the original order.

Once a physician has prescribed a particular pharmaceutical product by brand name and has been identified by the pharmacist by its product number, there is an unalterable distribution chain of that product. Wholesalers only respond to specific orders and find themselves in a “sandwich position” without direct access to production or patients. They have no role in shaping demand by, for example, suggesting alternatives or proposing imported products as substitutes for what is actually ordered.

Also wholesalers are not legally entitled to replace the ordered product with an identical product from parallel trade origin or with a similar product from a competitor used for the same indication. Wholesalers are responsible for the distribution of pharmaceuticals from source to retail and are not involved in the decision making progress. This is the professional responsibility of prescribing doctors and, to a limited extent, of pharmacies. Both must rely on that upstream distributors to execute their order as lodged as otherwise the prescribed medicines may not achieve its purpose. Member States do not allow wholesalers to interfere with the decision process for which doctors are primary responsible.

b. **Public service obligation**

Furthermore, wholesalers are required, often by law, by virtue of their public service obligations, to stock at least minimum quantities of a full range of pharmaceutical products. Not only does this mean that wholesalers may not decide to purchase alternative products from another manufacturer, but they may not even realistically decide not to buy the products manufactured by a specific manufacturer if its products constitute a “must store”.

The French *Conseil de la Concurrence* has considered that every product ordered can constitute a separate product market, provided that full-line wholesalers lose a substantial part of their

---

31 Decision 04-D-05, February 24, 2004, *Phoenix Pharma* (interim measures). The *Conseil de La Concurrence* found in this interim order that the existence of a market for each specific product was not excluded.
customers if they fail to deliver this specific pharmaceutical. In other words, if pharmacies switch to other full-line wholesalers just because their usual full-line wholesaler is not able to supply them with one specific pharmaceutical, this will not constitute product alternatives from the perspective of full-line wholesalers. Wholesalers are bound by pharmacists’ orders using the unique product number. As wholesalers have, from a legal perspective, no freedom to alter this order they depend on the matching medicine which constitutes a separate product market.

It should be pointed out that the concept of narrow markets is not unfamiliar in the pharmaceutical sector where IP-rights often constitute barriers to entry and lead to the conclusion that every patent protected product constitutes a separate product market. Moreover, also the concept of dominance control which relates to a “relative” market power, individualising the relationship between the manufacturer and the distributor, is well known in national competition laws. For instance, under the German Competition Act, a firm is also considered dominant if other undertakings depend on them “in such a way that sufficient and reasonable possibilities of resorting to other undertakings do not exist”.32 Vertical dependencies, particularly if these are based on outside circumstances, require a strict application of the competition rules as otherwise the dominant firm has the possibility of monopolising the market.

3. The relevant geographic markets in the pharmaceutical sector

Due to national particularities, relevant geographic markets in the pharmaceutical sector are no larger than national. Because of the specific regulatory framework in each Member State, the relevant geographic market for wholesale distribution of pharmaceuticals does not extend beyond the borders of Member States.33 At wholesale level, it is appropriate to define the activities of wholesalers as being geographically limited or regional because wholesalers have to be close to the pharmacies they supply.34 Their public supply and stockholding obligations require an immediate response which in turn is only feasible if the wholesaler is geographically proximate to their customers.35

4. Conclusion on market definition

As demonstrated above, depending on the specific circumstances, from a pharmaceutical full-line wholesaler’s perspective, there exist separate markets for each product prescribed and ordered (“one
product, one market”). Relevant product markets can be defined in line with the ordering number of the specific pharmaceutical as the wholesaler is legally not in a position to deviate from the specific pharmaceutical identified by its ordering number. In their geographical scope, the relevant markets are not larger than national markets.

II. Assessment of dominance

The existence of dominance is closely interlinked with the respective market definition. Where there is a monopoly there is by definition no competition and thus dominance. Where there is more than one product on the market it depends whether the firm alleged to be dominant has:

“... a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.”

1. Single firm dominance

Dominance relates to a position of economic power, with the ability to influence the competitive situation on the relevant market. This is obvious where there is one firm on the market having market power over its competitors and customers which allows it to act independently on the market.

The Commission has recently held in its AstraZeneca decision of 15 June 2005 that the pharmaceutical company AstraZeneca holds a dominant position on the proton pump inhibitor market for the purpose of Article 82 EC. Thus, it is beyond doubt that the Commission is willing to apply Article 82 EC to the pharmaceutical sector and that abusive practices vis-à-vis competitors or customers are now in the spotlight of the Commission’s investigation.


1.1 Market share as an indicator of dominance

In determining whether a firm has a dominant position on a defined market, market shares are perhaps the most important indicator. High market shares may be in themselves proof of dominance or create, shifting the burden of proof towards the company in question, a strong presumption for dominance. The ECJ concluded in *Hoffmann-La Roche* that:

“...the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position. An undertaking which has a very large market share and holds it for some time [...] is by virtue of that share in a position of strength.”39

This presumption rule was confirmed at several occasions, *inter alia*, in the *Hilti* case where the ECJ ruled:

“With particular reference to market shares, the Court of Justice has held (Hoffmann-La Roche judgement, [...] ) that very large shares are in themselves, and save in exceptional circumstances, evidence of a dominant position.

*In this case it is established that Hilti holds a share of between 70% and 80% in the relevant market. Such a share is, in itself, a clear indication of the existence of a dominant position in the relevant market (see the judgement of the Court of Justice in Case 62/86 AKZO Chemie BV v Commission [1991] ECR I-3359, paragraph 60).”40

In cases of very high market shares of around 90%, Advocate General Fennelly even spoke of “superdominance”, i.e. “overwhelming dominance verging on monopoly” that could give rise to “particularly onerous special obligations”41. The Courts and the Commission seem to sympathise with this idea, without expressly referring to it.42

---

In *AKZO*, the ECJ ruled that market shares above 50% lead to a (rebuttable) presumption of dominance:

> “With regard to market shares the Court has held that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position (judgement in Case 85/76 Hoffman-La Roche v Commission [1979] ECR 461, paragraph 41). That is the situation where there is a market share of 50% such as that found to exist in this case.”

In these cases, the burden of proof lies with the undertaking to demonstrate that it is not dominant.\(^4^3\) It has to demonstrate that, despite their market power as expressed in market shares, there is no position of economic strength which allows it to act independently of competitive constraints.

It depends on the individual case under assessment as to whether and to what extent market shares are considered as proof or indicator of dominance. However, on narrowly defined markets, there is a very strong likelihood that the firm in question is to be found dominant. Demand side substitutability as decisive factor for market definitions and dominance are closely linked to each other as the absence of alternatives at upstream supply level indicates, particularly in the pharmaceutical industry, market dominance. It is therefore a question of establishing the concrete level of market shares; if it is above 50% it can be used as evidence in itself for dominance. Below that level, dominance has to be based on additional factors which prove that the dominant firm is not disciplined by competitive pressure. Examples of these additional factors conferring market dominance are explained in the following.

Pharmaceutical manufacturers often hold a 100% market share vis-à-vis full-line wholesalers and therefore have a legal monopoly. This is in particular true if one applies the “one product, one market” approach. It is obvious that these firms enjoy an economic strength which is not sufficiently controlled by effective competition. There is hence sufficient proof coming from the market share test for the assumption that pharmaceutical manufacturers are dominant within the meaning of Article 82 EC.

1.2 Dependence of customers based on additional factors

Dominance can also be found where customers, or a specific group of customers are dependent on an undertaking and market shares do not accurately reflect the real level of competitive


interdependence on the market. Such dependence might occur where one or more of the following factors are present.

a. High switching costs and limited number of suppliers

It is well settled that high switching costs may prevent a customer from sourcing from a different supplier.\(^45\) The degree of dependency is higher where there are virtually no alternatives due to the particularities of the ordering and supply systems as well as state interventions by means of public service obligations. Further, existing IP rights may block customers from purchasing from alternative suppliers.

b. Unavoidable trading partner

It is established case law that dominance can also be established where a firm is “substantially dependent” on its supplier of goods or services. This supplier is regarded as an unavoidable or obligatory trading partner and therefore is considered dominant.\(^46\) As explained above, this applies particularly to pharmaceutical full-line wholesalers as they are legally obliged to execute orders as lodged by pharmacies. Ultimately, in case of prescription medicine, it is the doctor who decides which specific drug a patient should take, and which is ordered accordingly. The “unavoidable trading partner” test as shaped in the jurisprudence of the European Courts is a further proof of dominance of pharmaceutical manufacturers.


c. **Barriers to entry and potential competition**

Dominance may also be due to the fact that there is no potential competition, or that barriers to entry for new market participants are high. Barriers to entry and barriers to expansion are some obstacles which an undertaking capable and willing to enter a market or to expand would face. Barriers to entry or expansion are, above all, ownership of intellectual property rights\(^{47}\), other regulatory systems and legal provisions, other essential facilities, and generally any substantial sunk costs linked to market entry or expansion.\(^{48}\) Moreover, access to capital, economies of scale, breadth of product portfolio, as well as vertical integration or well-developed distribution systems may as well constitute a barrier to entry or expansion. Similarly, the absence of potential competition\(^{49}\) is likely to influence the finding of dominance.\(^{50}\) This factor applies more to the upstream production level but can also be used as an indicator of dominance vis-à-vis wholesalers where alternative pharmaceuticals are not available in the mid to long run.

Moreover, generics are not competing supply alternatives as long as patent protection lasts. The currently dominant undertaking may exploit its situation as long as potential competition has not become a “real threat” to business. Only with actual market launch of a generic product after IP protection has expired, pharmaceutical manufacturers may feel the urge to give up a behaviour which they were unrestrained to exercise without the presence of the new competitors. Even after expiration of patent protection, the market launch of generics quite often does not offset the dominating market position of formerly patent protected and well-branded products.\(^{51}\)

---

\(^{47}\) See, for example, M.3544, *Bayer Healthcare/Roche*, para 55. The Commission regarded the sunk costs of building a new brand as a significant barrier to entry.

\(^{48}\) The Court has consistently held that the need for large-scale capital investment constituted a barrier to entry, see ECJ, Case C-27/76, [1978] ECR 207 *United Brands v Commission*, para. 122; Case 85/76, [1979] ECR 461 *Hoffmann-La Roche vs. Commission*, para 49.

\(^{49}\) This holds in particular true for “perceived” potential competition which causes the incumbent firm to act competitively to an extent which prevents market entry by outsiders.


\(^{51}\) See, for example, M.2922, *Pfizer/Pharmacia*, para. 73; M.1846, *Glaxo Wellcome/Smithkline Beecham*, para. 90.
2. Collective Dominance

Even if one does not follow the “one product, one market” approach, one arrives at the conclusion that pharmaceutical manufacturers are dominant. Article 82 EC refers to any “abuse by one or more undertakings of a dominant position” and thereby envisages the possibility that two or more undertakings jointly hold a dominant position. This has been confirmed by the European Courts. Whilst, on the one hand, the concept of collective dominance within Article 82 EC is well established, on the other hand, the criteria in which a collective dominant position exists have not been fully clarified. While early case-law required an “economic link” for undertaking to exercise collective dominance, recent case-law acknowledges that oligopolistic interdependence is sufficient to establish collective dominance. Oligopolistic interdependence refers to a situation where the undertakings active on the market have not co-ordinated their behaviour by way of an anti-competitive agreement or concerted practice (which qualifies as collusion and is prohibited under Article 81 EC) but are able to foresee each others’ behaviour due to their interdependence in the framework of repeated interaction. The latter is also referred to as “tacit co-ordination”.

The case law on collective dominance refers predominantly to merger control. Arguably the test for collective dominance within the framework of behavioural control is less strict and refers to a lesser extent to structural elements because merger cases require a long-term forward assessment whilst Article 82 EC reflects a situation currently envisaged on the market.


As to the test of collective dominance in merger cases, the CFI holds that a collective dominant position may arise where:

“in view of the actual characteristics of the relevant market and the alteration in its structure that the transaction [i.e. a concentration] would entail, the latter would make each member of the dominant oligopoly, as it becomes aware of common interests, consider it possible, economically rational, and hence preferable, to adopt on a lasting basis a common policy on the market with the aim of selling at above competitive prices, without having to enter into an agreement or resort to a concerted practice within the meaning of Article 81 EC.”

In order to form a collective entity, the undertakings must (i) be active on a transparent market, (ii) have an incentive not to depart from the parallel behaviour (“retaliatory mechanism”) (iii) be free of absence of reaction by a current or potential competitor as well as customers. Even if the parties which jointly hold a dominant position compete with each other, it is possible to be jointly dominant (however, it is unclear which degree of competition is allowed within an entity which is jointly dominant).

Given the facts at hand, there are strong indications that several pharmaceutical manufacturers on wider defined markets collectively hold a dominant position. Almost all manufacturers operate or have installed, with slight variations, supply quota systems limiting the requested order volume of wholesalers. These manufacturers include Pfizer, Sanofi-Synthelabo, GlaxoSmithKline and Boehringer which introduced supply quota systems in 2001 and 2002.

As to the structural elements of the dominance test, the market seems at least sufficiently transparent, which is one of the preconditions for collective dominance. Moreover, pharmaceutical manufacturers all have an incentive not to “break out” of these new quota systems. The deviating manufacturer will, in the long run, suffer losses due to increased parallel trade if he deviates from the tacit co-ordination. This is as such a deterrent mechanism to make him stick to the parallel conduct. Wholesalers have no countervailing buyer power and depend on supplies of the collectively dominant manufacturers due to the particularities of the ordering system and the public services obligations as described above.

58 See, for example, the facts of the case in the decision of the French Conseil de la Concurrence, decision no. 04-D-05 of February 24, 2004 – Phoenix Pharma, paras. 11-19.
For the reasons of the above, there are strong arguments for the conclusion of a collective dominant position at wider markets if one were to negate the finding of single dominance on a narrowly defined market.

III. Abusive conduct

The governing principle of behaviour control as set out by Article 82 EC is that conduct by a dominant firm which seriously and unjustifiably distorts competition within a properly defined relevant market will be prohibited in so far as it affects trade between Member States.\textsuperscript{59} From this conceptual starting point, the European Courts have developed the test of abusing a dominant position as an objective concept imposing specified behavioural duties serving the superior goal of undistorted competition within the community market. In \textit{Hoffman/ La Roche}, the European Court of Justice set out the parameters of this test to be applied in practice:\textsuperscript{60}

\textit{“The concept of abuse is an objective concept to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.”}

Emphasis added

As the concept of dominance is an object test referring to the mere presence of a dominant firm in the marketplace and the effects on competition resulting from the mere presence of that firm, business practices which may be considered permissible in a normal competitive situation may amount to an abuse if carried out by a dominant firm. This is justified as dominant firms carry a “special responsibility” for the existence of the remaining competition in the market on account of the prejudice that their activities may cause to the interest of competitors, suppliers, customers and consumers.\textsuperscript{61}

\textsuperscript{59} Bellamy/ Child, 5\textsuperscript{th} edition, § 9-066.
\textsuperscript{60} ECJ, case 85/76, [1979] ECR 461, \textit{Hoffmann-La Roche}, para 91.
“Dominant undertakings have a special responsibility not to allow their conduct to impair genuine undistorted competition on a market where competition is already restricted by the fact of their dominant position.”

It therefore follows from the nature of this special responsibility that dominant firms are deprived of the right to adopt a course of commercial conduct or take measures which are not in themselves “abusive” (within a moral sense of the word). It suffices that they result in a serious distortion of competition depending on the amount of market power the acting firms possess.

Examples of commercial conduct being considered abusive are manifold. The scale encompasses conduct which is unfair towards customers who have no alternative source of supply (such as excessive and predatory pricing). It also covers conduct which seems favourable for the customer, but has the effect of further reducing or impeding effective competition in the market (such as tying, exclusionary conduct or fidelity rebates). Between these two categories falls a situation in which the dominant undertaking reduces its supplies unilaterally. This is harmful to the customer because, due to the market presence of the dominant firm, the negotiating equilibrium is overbalanced and the customer has nowhere to go, but to accept the reduced amounts offered by the dominating undertaking.

Equally, this also distorts competition as a dominant undertaking is likely to supply favourably those customers which agree to exclusionary practices, i.e. give their consent to source exclusively from that firm or take other measures which strengthen or ensure the dominant position of the acting firm. This leads to serious market distortions such as foreclosure, barriers to entry as well as barriers to expansion and to a freeze of competitive market structures.

---

1. Case law on abusive pattern of refusal to supply

Due to their “special responsibility”, dominant firms are limited in their commercial freedom to enter into contractual relations with whom they want.

It is established case law that a refusal to deal may constitute an abuse of dominance. While the precise boundaries of the circumstances in which a refusal to deal infringes the competition rules are yet to be determined there is no doubt that an arbitrary refusal to supply qualifies as such an abuse of dominance.63 An offer to supply only on terms that the supplier knows to be unacceptable is also considered to be a constructive refusal to supply.64 Since Commercial Solvents, it is clear that the operation of a scheme of supply quotas where customers receive only a limited amount of product requests also falls within the category.65

“[Commercial Solvents] had decided to limit, if not completely to cease, the supply of nitropropane and aminobutanol [raw materials for specialty drugs] to certain parties in order to facilitate its own access to the market.”65

The ECJ ruled that the dominant firm Commercial Solvents had to meet the customer’s requirements for raw material. The Commission found a similar pattern abusive in the case Polaroid/SSI Europe.66 Polaroid refused to supply a customer with a larger order of instant film.

For a comprehensive legal assessment, it is helpful to recapitulate more generally the case law dealing with the question under which circumstances a refusal to enter into contractual relations infringes Article 82 EC.

64 See Commission, OJ 1999 L 95/1, TACA.
1.1 Commercial Solvents

In the case Commercial Solvents the Court clarified that an undertaking which has a dominant position in the market for raw materials and which refuses to supply a downstream competitor is abusing its dominant position if this refusal may eliminate all competition on the part of this customer.67

1.2 United Brands

In United Brands,68 the ECJ found the practice of a dominant firm that discontinued supplying green bananas to one national distributor abusive. The discontinuance of supplies was considered a “serious interference” with the independence of the distributor in its commercial relations with the dominant supplier. The reasoning of the Court also included the economic strength of the undertakings facing each other. As the distributor was depending on supplies from this particular supplier, the discontinuance was disproportionate and could not be justified with the commercial freedom of undertakings to choose freely the companies they want to do business with. Even more interesting than the Court’s findings is the reasoning of the case, which clarified the underlying principles of dominance control as set out by the EC Treaty:69

“... an undertaking in a dominant position for the purpose of marketing a product – which cashes in on the reputation of a brand name known to and valued by the customer – cannot stop supplying a long standing customer who abides by regular commercial practice, if the orders placed by that customer are in no way out of the ordinary. Such conduct is inconsistent with the objectives laid down in Article 3 (g) of the Treaty which are set out in detail in Article [82], especially in paragraphs (b) and (c), since refusal to sell would limit markets to the prejudice of consumers and would amount to discrimination which might in the end eliminate a trading party from the relevant market.”

69 ECJ, case 27/76, [1978] ECR 207, United Brands, para 182 et seq.
1.3 Hugin

The Commission found in the case *Hugin* the refusal by a manufacturer to continue supplying spare parts to its former distributor as infringing Article 82 EC. The Commission found that this behaviour qualified as an abuse of Hugin’s dominant position in its own spare parts, particularly since the distributor had been a customer for 12 years and had built up a substantial business in the supply of spare parts.

1.4 Télémarketing

In the *Télémarketing* judgement the Court found an abuse where a dominant firm in the television broadcasting market refused without objective justification, to supply its services to any “telemarketing” undertaking other than a member of its own group. A dominant firm must not reserve to itself an ancillary activity that might be carried out by another undertaking as part of its activities upon a neighbouring but separate market with the possibility of eliminating all competition from such undertaking.

1.5 Volvo

In the *Volvo* case the Court considered it abusive that an IP right was used to prevent third parties from manufacturing and selling automotive spare parts incorporating the protected design. The Court found several additional abusive elements such as the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level and the strategy of no longer producing spare parts for a particular model even though many cars of that model were still in circulation.

---

70 Commission, OJ 1978 L 22/23, *Hugin Kassaregister*; see also ECJ, case 22/78, [1979] ECR 1869, *Hugin Kassaregister*. The ECJ annulled the Commission’s decision on grounds of absence of effects on trade between Member States. However, the Commission’s findings on the question of abusive behaviour were not contested.


1.6 **Magill**

In the *Magill* judgement the Court ruled that television broadcasters had abused their dominant position on the market for their television programme listings by invoking their copyright over such listings in order to prevent third parties from publishing complete weekly guides to the programmes of the various broadcasters. *Magill* intended to be the first provider of a weekly television guide covering all channels. At that time only weekly guides for each station were available. The copyright protected listings were indispensable essential facilities material for compiling a weekly television guide as intended by *Magill*. The Court ruled that the prevention of a new product, a comprehensive weekly guide to television programmes, for which there was a potential consumer demand was abusive.\(^{74}\)

1.7 **Ladbroke**

In *Ladbroke*, the CFI found that French racetracks did not infringe Article 82 EC by refusing to supply Belgian *Ladbroke* with pictures and sound of French races for use in Ladbrokes betting shops. Only if the refusal concerned a product or a service that was either essential for the existence of competition or if the emergence of a new product was prevented the refusal might be abusive.\(^{75}\)

The CFI ruled that the relevant market was Belgium alone and since the French racetracks were not present on the Belgian market they could not be discriminating as between operators on the Belgian market. The pictures and sound of French races were not indispensable for the betting activities in question carried out in Belgium.

1.8 **Bronner**

In *Bronner*, an owner of a nation-wide home-delivery scheme for newspaper denied access to the scheme sought by a publisher of a rival daily newspaper. The court ruled that a refusal to grant access to the home delivery services is only abusive if this refusal is likely to eliminate all competition on the part of potential customers in the daily newspaper market. This would be the case were the service in itself indispensable without actual or potential substitutes for competing on the newspaper market.\(^{76}\)

---


1.9 **IMS Health**

In the case *IMS Health*,\textsuperscript{77} the ECJ found the refusal to grant access to a copyright protected structure abusive if (1) the refusal is preventing the emergence of a new product for which there is a potential consumer demand; (2) it is unjustified; and (3) the refusal is to exclude any competition on a secondary market.

2. **Impacts on pharmaceutical full-line wholesalers**

Analysing these cases, there are various common features, which have a particular meaning for pharmaceutical wholesalers. One distinct feature is that it has always been the intention of the European Courts to find the right balance between the legitimate commercial interests of a dominant firm and its obligations under the regime of “special responsibility” for the remaining competition in the market. It is also evident that the Courts intend to protect customers of the dominant firm from exploitative abuses. This covers taking undue advantages of consumers by using market power.

2.1 **Exploitative abuses and individualised impacts of refusal to supply**

As the early case law such as *United Brands* shows, the abusive test, where it relates to exploitative abuses, has to take into account the individual interests of the excluded undertaking and the circumstances under which it operates.

In *United Bands*, it was the fact that the excluded distributor was a long standing client and due to its reputation and brand name, the dominant firm had become an indispensable trading partner for the undertakings active on the relevant market.\textsuperscript{78} Similarly, the Commission found in the case *BBI/Boosey & Hawkes* the that immediate termination of a long standing supply agreement adds a special abusive element.\textsuperscript{79} A dominant firm might be entitled to seek to protect its legitimate business interests but in doing so it must be fair and proportionate. Again, this results from the balance of interest taking into account the conceptual principle of special responsibility which is imposed on dominant firms.


\textsuperscript{79} Commission, OJ 1987 L 286/36, *BBI/Boosey & Hawkes*. 
Pharmaceutical wholesalers are legally dependent on pharmaceutical manufacturers and can therefore be exposed to commercial harm if an upstream supplier regulates deliveries. In many countries pharmaceutical wholesalers are subject to a regime of public service obligations which ensure a stable and continuous supply of medications.\textsuperscript{80} Unlike manufacturers which can comply with this obligation by means of adjusting their production facilities (i.e. increasing output if they face a shortfall) distributors fully depend on upstream manufacturers. If a manufacturer decides to reduce its supplies towards a distributor, the latter cannot deliver at all to certain customers and has no alternatives but to fail its public service duties.

Pharmaceutical full-line wholesalers also face the economic disadvantage of legally not having influence on the ordering process. When a physician prescribes a medication and the prescription is presented to a pharmacist, it describes to the pharmacist exactly what is to be dispensed. Pharmacists themselves have almost no ability to suggest to the patient to try an alternative to the product prescribed. This already puts tight limitations on the flexibility of demand. At wholesale level, however, there is no flexibility at all. Pharmacists place orders with wholesalers by electronic means for specifically described products employing a detailed numbering system. Within this numbering system, every pack size of every product sold by every manufacturer of the product has its own number. The system even distinguishes between the products directly marketed by the manufacturer themselves in a particular country and identical products, which are re-imported or parallel imported. Moreover, wholesalers are not allowed to deliver alternatives to orders placed by pharmacies. This stresses the high dependence of full-line wholesalers on pharmaceutical manufacturers and leads to the conclusion that the degree of special responsibility which dominant firms in the pharmaceutical supply chain have towards wholesalers counts extremely high in the appreciation of countervailing interests.

\textsuperscript{80} See Article 81(2) Directive 2001/83/EC, OJ 2001 L 311/67 on the Community code relating to medical products for human use as amended by Directive 2004/27/EC, OJ 2004 L 136/34. See also the various laws of Member States which contain various stockholding obligations for wholesalers.
2.2 Impacts on competition

Further, the cited case law also contains a detailed analysis of the impact limited or refused supplies have on competition. Refusal to supply limits markets to the prejudice of consumers and can even amount to discrimination which might in the end eliminate a trading party from the market.\footnote{ECJ, Case 27/76, [1978] ECR 207 United Brands para 183.} In addition, it hinders the entrance of new players on the market and generally results in a freeze of market shares.

a. Arbitrary refusal as threat, punishment or inducement

Any refusal to supply can produce anti-competitive effects where the refusal is in reality a threat or punishment or inducement designed to make a customer adopt a particular course of action.\footnote{ECJ, Case 27/76, [1978] ECR 207 United Brands; also Commission, OJ 1987 L 286/ 36, BBI/ Boosey & Hawkes.} Most obviously this is the case where the dominant undertaking stops supplying its distributor because the latter starts to stock competing products. A dominant firm is likely to rely on its privileged market position as a bargaining tool to induce customers to accept trading terms and conditions it would not have accepted from non-dominant firms. Such conducts are exclusionary practices which lead to market foreclosure as competitors at producing level are deprived access to the dominant firm’s distributors. These practices also restrict and distort competition at distribution level because the producer sets the parameters for delivery in a discretionary way.

The exclusionary effects are particularly prominent in the pharmaceutical supply chain where pharmaceutical manufacturers have imposed supply quotas. Pharmaceutical full-line wholesalers are regularly not able to acquire new customers if the supply from the distributors is limited to an amount which is only sufficient to serve existing customers. This leads to static market shares in the supplies to pharmacies with the respective product. In this context it has to be considered, that due to legal restrictions, the possibilities for competition by product substitution at the wholesale-level are not existing. Wholesalers compete with a better distribution system and the ability to supply pharmacies faster, i.e. to provide for an increased added value service, but not by substituted products.
b. Market foreclosure and freezing of market shares

Any quota system bears the risk that the current market situation, in particular the current market shares, is frozen, that wholesalers cannot react to a sudden increase in demand and that no new market participants can enter the market. This results in serious anti-competitive effects also at upstream manufacturing level as a frozen market structure facilitates collusion, blocks the entrance of innovative newcomers or enables manufacturers to act in a concerted way.

This holds also true for supply quota schemes which allocate quotas according to former sales or former supplies. In particular if there are similar quota systems by different manufacturers, the wholesalers already active on the market are forced to keep their current market position and are not in a position to enlarge their market shares. Moreover, new players capable and willing to enter the market cannot do so since no quotas are foreseen for them. The status quo would be frozen, with no chance for the wholesalers to compete effectively for market shares.

This risk was addressed in a recent decision of the French Conseil de la Concurrence. If supply quotas are allocated in accordance to preceding purchases or sales, a wholesaler will never be in a position to enlarge its business activities and new competitors could never enter the market. Rather, the firms active on a market and their market shares would stay the same, and competition would effectively come to a halt.

Therefore, it is of paramount importance that quota systems provide for enough flexibility to respond to changes in the market situation as well as security margins and reserves for firms capable and willing to expand as well as for new market entrants. Against the background that allocation systems are very different (allocation base, reference period etc.), it has to be decided on a case-by-case basis whether a given quota system is sufficiently flexible to allow wholesalers to grow, to respond to suddenly increased demand or to allow for new market entries. Accordingly, the French Conseil de la Concurrence has held in its Phoenix interim order that quota systems of certain pharmaceutical laboratories may be anti-competitive.

However, even with flexible quota systems operated arbitrarily, any growth plans and business decisions of wholesalers would, in the end, depend on the willingness of the manufacturers to actually grant bigger supply quotas. They therefore likely to be considered abusive per se, particularly if the carry discriminatory elements.

83 Decision 04-D-05, February 24, 2004, Phoenix Pharma (interim measures), paras 37-54.
85 Decision 04-D-05, February 24, 2004, Phoenix Pharma (interim measures), para. 54.
c. **Discriminating pattern**

Moreover, the dominant firm has a duty **not to discriminate** under Article 82(c) EC by “applying dissimilar conditions to equivalent trading parties, thereby placing them at a competitive disadvantage.”86 It is clear that a dominant manufacturer of pharmaceuticals must treat similar customers in the same way in similar transactions and is not entitled to deduct from the quantities supplied without objective justification.

d. **Objective justification**

There may be objective circumstances which limit the supply to customers. Community case law as cited above provides dominant undertakings with the possibility of demonstrating objective justifications for their conduct if Article 82 should not apply. However, the standards for reasons provided by dominant firms to meet this test are very high taking into account the identified anti-competitive impacts of arbitrary refusals to supply.

   aa. **Product shortages**

This is most obvious in times of product shortages where it is impossible for dominant firms to fulfil every order. In these cases, the dominant firms have to lay down criteria for the priority in which orders are met, but such criteria must be objectively justifiable and non-discriminatory in any way.87 The dominant firm is not entitled to make a selection and serve those customers first which “loyally” source the majority of its demand from the dominant firm.88 Such criterion resulted in the provision of equivalent services on unequal terms and was both discriminatory and exclusionary in effect. In order to preserve undistorted competition, a very strict standard has to be applied. In *BPB Industries*, the CFI found that the abusive nature of the loyalty-priority system could not be justified by the fact that the refusal to supply non-priority customers was not absolute but temporary: normally the delays in supplying other customers did not exceed one day. The Court found the priority of supply an important parameter of competition which also encompasses timely deliveries. Priority lists have to be set up based on objective criteria which exclude any form of unlike treatment of like customers.

The case law on supply shortages gives some guidance on the question of how limitations of supply could be justified. However, these principles cannot be fully applied to supply quota policies

88 See also the ban of royalty rebates under EC competition law which serves the similar goal of preventing any exclusionary effects.
because these, unlike shortages, lack at the outset an objective justification why certain deliveries cannot be fulfilled. It is incompatible with the framework of special responsibility imposed on dominant firms to allow dominant firms to manipulate the supply of customers arbitrary. This applies particularly to pharmaceutical wholesalers which are dependent on upstream supply of pharmaceuticals as they typically have no other sources of supply.

Nevertheless, it would be disproportionate if one was to consider this obligation to supply absolute. There may be legitimate grounds for a refusal to supply. For instance, a dominant firm may be justified in refusing to supply further goods to a customer if it itself suffers capacity restraints. In doing so, it must however be non-discriminatory. However, in the course of a balanced commercial relationship as between pharmaceutical manufacturers and pharmaceutical full-line wholesalers there is very little room for a manufacturer to justify a limitation or significant reduction in supply.

bb. Significant supply shortages due to parallel trade

It is currently being discussed whether supply quota policies with the intention of restricting parallel trade are a proportionate measure for pharmaceutical manufacturers to ensure continuous supply in low price countries. Advocate General Francis G. Jacobs recently delivered his opinion concluding that there might be circumstances under which supply quotas, even if aiming at preventing parallel trade, were justifiable.89

At the outset, it has to be noted that these finding were very case specific with respect to the supply situation in Greece and the pharmaceuticals in questions. AG Jacobs highlighted that his conclusion was:

“highly dependent on the specific economic and regulatory context in which the case arises”.90

Secondly, these findings are of no relevance to full-line wholesalers. In order to qualify for a justification, dominant manufactures have to give evidence that the individual supply quota is indispensable to achieve the wider aim of supply security. As security of supply is an aim which has to be pursued jointly by manufacturers and by wholesalers, it appears obvious that firms subject to these public service obligations would not, and are not legally entitled to do so, shift their supply to high-price countries.

Third, as the findings of AG Jacobs were obviously of no relevance to the case under review,91 they have no general impact on the assessment of supply quota policies. In particular, AG Jacobs’

90  Case C-53/03, [2005] ECR Syfait, para 68.
conclusions should not be misinterpreted as pleading for a general permissibility of arbitrary limitations of supply. The reasons why such refusal might not be abusive were not analysed in detail, but summarised in catch phrases only. Also the assumption that supply obligations might act as a disincentive to pharmaceutical companies to innovate is by far too general and misleading to be considered as a justification for supply quota restrictions. Whilst it is presumably correct that pharmaceutical markets are characterised by high R&D spending and often uncertain return on investment it was unable to establish in the case at hand any causal relationship between parallel trade and R&D expenditure. As the Commission set out in more detail in a decision regarding Glaxo Wellcome in Spain an undertaking can react to a decline in profits by reducing other cost-intensive items. Abstract R&D spending should not be considered as justifying parallel trade interference and other restrictions of competition resulting from supply quota policies.

In more general terms one has also to ask the question whether supply quotas are an eligible measure to serve the superior good of continuous and stable pharmaceutical supply. It is in no way a guarantee that the wholesaler concentrates on the domestic market if its orders were not executed in full and where it only obtains the quantities required for the domestic market. The issue of supply shortages is addressed by public service obligations; supply quotas are of no help in ensuring stable supplies to the domestic patients because, in the absence of public service obligations, the distributor is likely to export any quantities he receives in order to generate higher margins. Hence the likely effects would be that the distributor would withdraw fully from the low priced market which is in obvious contradiction to the aims the Treaty intends to achieve. Consequently, also in the case at issue, there is no verifiable evidence that parallel trade is preventing companies from fulfilling their supply obligations in the public interest in the export or import state. According to the decision of the referring Greek competition commission in the case at hand, it was not possible to prove that shortages had occurred on the Greek market as a result of drug exports. On the contrary, the competition commission had indications that supply problems arose only after the pharmaceutical manufacturer stopped supplies to Greek wholesalers.

Fifthly, the approach taken by Advocate General Jacobs does not fully take into account the weight of the overriding aim of market integration which is one of the elementary aims of the Treaty. In that respect, Article 82 EC has to be applied in the light of the purposes intended by the general freedom of Article 28 EC. While the basic freedoms prohibit restrictions on market integration by

---

91 GA Jacobs had already denied the question whether the Greek competition authority was entitled to refer the case to the ECJ.
95 Koenig/ Engelmann, Parallel trade restrictions in the pharmaceutical sector on the test stand, ECLR 2005, p. 338.
Member States, the competition rules (of which Article 82 EC is part) are aimed at preventing corporate measures of market partitioning which could have the effect of replacing the falling trade barriers originally set by Member States through barriers set by undertakings. The fact that parallel trade on the pharmaceuticals markets is due mainly to price differences between the Member States resulting from divergent price regulations in the individual states does not alter the fact of an abuse due to supply restrictions by market dominating pharmaceutical companies aimed at combating parallel trade.\textsuperscript{96}

In its parallel trade jurisprudence on Article 28 EC, the ECJ has repeatedly established that even where the imposition of price controls actually constitutes a situation which, under certain conditions, could distort competition between the Member States, this situation could not justify an exception to the basic principle of free movement of goods.\textsuperscript{97} Rather, distortions to competition due to different national price regulations should be addressed by measures of EU authorities and not by other Member States or undertakings. It is very doubtful whether the principle of market integration which was found to be superior over the commercial interests of companies in various cases judged by the European Courts and is indispensable for the realisation of the single market should be restricted to the benefit of an uncertain outcome.

For the reasons of the above, AG Jacobs opinion is of no relevance for the case at hand dealing with supply quota schemes vis-à-vis pharmaceutical full-line wholesalers. While Jacobs’ conclusions with respect to parallel trade restrictions and his single sided interpretation of the Treaty to the disadvantage of parallel traders remain highly doubtful, there is no general justification of supply restrictions in Jacobs’ findings. Dominant firms have to provide a convincing objective reasoning if they refuse to deal with customers or operate a scheme of supply quotas.

**IV. Conclusion and Summary**

In conclusion, supply quota policies come within the scope of the prohibition of abusing a dominant position pursuant to Article 82 EC. When a dominant undertaking places medicines on a market and refuses to supply wholesalers the quantities ordered such refusal might qualify as an abuse of a dominant position.

Pharmaceutical manufacturers often have dominant positions on accurately defined product markets. The exercise of defining markets is a systemic method of identifying competitive

\textsuperscript{96} Koenig/ Engelmann, Parallel trade restrictions in the pharmaceutical sector on the test stand, ECLR 2005, p. 338 (341).

interrelations and constraints undertakings are facing in a specific field or area. Within the supply chain of pharmaceuticals, demand side substitutability has to be established from the perspective of the purchasing entities which are in this case full-line wholesalers. Due to legal constraints, full-line wholesalers have no alternatives to supplying the pharmaceutical product, identified by product number, as ordered. This is due to the particularities of the pharmaceutical ordering system which leave wholesalers no discretion in executing exactly the product orders as lodged. Legally pharmaceutical full-line wholesalers are not allowed to deliver alternative products with diverging ordering numbers even if these are identical with the ordered products.

Moreover, public service obligations imposed by EU and national legislators oblige wholesalers to carry at least minimum quantities of an adequate range of products and additionally to keep a stock of identified pharmaceuticals for immediate delivery. This further reduces supply side substitutability. In summary, while this has to be established on the specific facts of the case, there are strong arguments that for full-line wholesalers each individual product in each form of delivery constitutes a separate market (“one product, one market”).

Given the dependence of pharmaceutical wholesalers on supplies from upstream manufactures there is little doubt that those manufactures will be found dominant within the meaning of Article 82 EC on these individually defined markets.

Supply quota systems are abusive where they are operated arbitrarily, in a discriminatory way or without an objective justification. While for the determination of abusive practices the legitimate commercial interests of manufactures to do business with whom they want also have to be taken into account, this freedom is per se limited according to the regime of “special responsibility” as developed by the European Courts. This responsibility hinders dominant firms from allowing their conduct to impair undistorted competition on a market where competition is already restricted by the fact of their dominant position. As a consequence, any refusal to supply is abusive where it is in reality a threat, punishment or inducement designed to make a customer adopt a particular course of business. This leads to exclusionary practices and causes a significant, considering the market power of the dominant firm, impediment to competition. Also discriminatory supply schemes are abusive which is explicitly prohibited by Article 82(2)(c) EC. In particular, supply quotas involve the risk that there is a freeze of the current market situation, leaving no room for expansion, new market entries or responses to suddenly increased demand.

However, there might be objective circumstances, such as product shortages, where a manufacturer cannot fulfil all quantities ordered. In these cases the dominant firm has to lay down objective, non-discriminatory and proportional criteria for the priority and quantities in which orders are met. Any deviation from these criteria is likely to result in the respective supply quota policy being considered abusive and in violation of Article 82 EC.
ANNEX: Examples of public service obligations fulfilled by pharmaceutical full-line wholesalers in Europe

BELGIUM


Article 22bis: The wholesale distributor must:

Continually hold a stock of medicines, with which he is able to supply the public pharmacies of his region on a normal and daily basis. The stock must be in accordance, on one hand, with at least two thirds of the pharmaceutical specialties, sera and vaccines, and, on the other hand, with the average value of one month’s turnover of the past year;

Dispose of sufficient staff, sales- and execution services, as well as means of transport in order to supply the public pharmacies daily provisioning of his territory

Make the necessary arrangements to supply the on-the-market-medicines, if the case arises, in urgency, or else within 24 hours after the order

Make the necessary arrangements to provide, if necessary, a replacement for him, by another wholesaler-distributor of the same guard-duty. When he is on guard-duty, constantly be available at his address to deliver medicines to all public pharmacies, organize at least one delivery within his territory to hospital pharmacists and to on-call public pharmacists if they request it.

FINLAND

Wholesalers are obliged to have enough stock for the whole population:
Finnish Drugs Act § 37: Drug wholesalers must strive to make sure that they keep a sufficient stock of drugs.

FRANCE

The decree D. 98-79 of 11 February 1998 specified and strengthened the 1962 regulation concerning the distribution of medicinal products. Article R 5106 defines and distinguishes the “manufacturers”, “market authorization holder”, the “stock holder” and the “wholesaler”.

Article R. 5115-13 defines the public service obligations for wholesalers. The wholesale distributor must:

Communicate the territory that each of its companies covers to the French Agency for the sanitary security of health products (AFSAPS). Every district where the company usually sells products to one or more pharmacies is included in this territory,
Hold a stock consisting in at least 90% of the medicines used in France,
Have a two weeks supply capacity for their usual clients,
Be able to deliver within 24 hours.
These obligations concern all medicinal products, reimbursed or not.
When no other source of supply is available, the Director General of the AFSAPS can exceptionally impose to a wholesaler to deliver to a pharmacy located outside the wholesaler’s territory.

GREECE

In the Greek Competition Committee decision there is a reference to Presidential Decree 194 of 25.5/6.6.95 (in compliance with Council Directive 92/25/EEC of 31 March 1992) on the wholesale distribution of medicinal products for human use. According to Article 3, paragraph 2: Public service obligation is the obligation imposed on wholesalers concerned to permanently supply a diversified range of pharmaceutical products sufficient to cover the demands within a geographically defined area and to ensure the delivery of the necessary supplies within a very short period of time throughout the territory specified. There are no further details in this Decree on minimum stock levels or on time limits for delivery, which may have been set by subsequent legislation.

ITALY

Decree with the force of law regarding the wholesale distribution of medicines for human use - Minimum quantity of medicines and supply of the products

1. The owner of the authorized wholesale distribution is obliged to detain at least:
   the products stated in table 2 attached to the Official Pharmacopoeia of the Italian Republic.
   90% of the specialized medicines in the market.
   At least one pre-packaged medicine produced by each formulation stated in the national formulary in the market.

2. To supply the medicine to the interested parties, which is provided to the distributor with the utmost urgency and, within 12 hours of the original request, within the territory established in the declaration of art. 5, comma 2, etc.

The wholesale distributor must have an Emergency Plan with ensure effective implementation of any recall from the market ordered by the competent authorities of carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned.

According a recent self-discipline agreement between wholesalers association (ADF) and Trade Unions, even in case of strike, the wholesaler is obliged to deliver the most important medicines.

3. For all transactions, the wholesale distributor must deliver the receiver a document, which demonstrates in addition to the name and address:
The date
The trade name and the pharmaceutical formula of the medicine
The amount supplied to the receiver
The name and address of the receiver
PORTUGAL

Translation concerning the Article 12, nº1 b) of the Portuguese Law (Dec.- Law nº 135/95 of the 9th of June) which rules the wholesaler Activity in Portugal: Article 12 (Obligations of the wholesaler): nº1 b)- (The wholesaler must have)..."Permanent availability of Drugs which may be deemed sufficient in quantity and variety terms, to promptly address the needs of a certain geographic area"

SPAIN

Article 16.
1. Pharmaceutical wholesalers have to dispose at all times of a sufficient assortment of medicines and medical substances and other pharmaceutical products that are sufficient for delivering to the pharmacies which they usually provide to.

2. Pharmaceutical wholesalers should constantly guarantee the provision of sufficient medicines in order to respond to the needs of the territory they provide to, as well as the delivery of the requested provisions in function of the type of concerned medicine. Therefore, pharmaceutical wholesalers should dispose of a minimum amount of medicines, conform article 79.1 b) of law 25/1990 on medicines of 20 December. The Autonomous Communes have the task to elaborate a list of medicines that they consider necessary to treat the particular needs of their territory.

3. Pharmaceutical distributors will organize control services for every locality, proportionally to the correct provision to the market, in order to answer all needs at public holidays, at least in case of emergencies.

AUSTRIA

Minimum stock levels are not laid down in the Austrian national legislation. In two Bundesländer there are provisions regarding obligatory stocks of certain products for emergencies.

GERMANY

Public Service Obligations for pharmaceutical wholesalers can be implemented in emergency situations by order of the competent authority according to the German regulation on wholesale distribution of medicinal products (§ 8 Betriebsverordnung für Arzneimittelgroßhandelsbetriebe). Pharmacies must hold a stock sufficient for the supply of the public covering the average demand of two weeks according to pharmacy operation regulation (§ 15 Apothekebetriebsordnung). The Federal Civil Court (Bundesgerichtshof) ruled that public pharmacies depend on full-line wholesalers to fulfil their public service obligations (BGH 21/02/1995, KVR 11/94). General public service obligations for wholesalers, however, are not yet implemented.