CHAPTER 17
Restrictions on Parallel Trade of Pharmaceutical Products and EU Competition Law

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§17.01 INTRODUCTION

Restrictions on parallel trade of pharmaceutical products in the EU is an issue that has attracted more than once the gimlet eye of the European Commission (the Commission). On 24 May 2012, the Commission launched a new probe into this issue.1 We wait to see if this new probe will provide additional guidance on the legality under EU competition law of drug makers’ efforts to block parallel trade of their pharmaceutical products. In the meantime, this article provides an overview of the legal principles applying to the most common types of restrictions on parallel trade of pharmaceuticals,2 namely:

- dual pricing;
- supply quota restrictions; and
- product life cycle management strategies.

1. Aoife White, European Union Opens Probe of Parallel Drug Trade, http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2012/05/22/BU7T1OLPFC.DTL.
§17.02 BACKGROUND

Parallel trade consists of buying pharmaceutical products in one Member State and selling them in another at a higher price, thus making a profit from the price difference between the export country and the import country.

Member States intervene to limit the prices payable for medicinal products within their territories. The aim of such intervention is to protect the budgets of the social health insurance funds, which are the primary purchasers of pharmaceutical products. EU Member States adopt different approaches in their attempts to fix or influence the price of pharmaceutical products. As a consequence, the price of pharmaceutical products in some Member States is typically much higher than in others. It is the price differentials between Member States which create the opportunities for parallel trade.

In a recent Communication, published prior to the most recent enlargement of the European Union, the Commission predicted that enlargement would further increase such differentials, with a resulting increase of parallel trade of pharmaceutical products. On the one hand, this parallel trade is a multi-billion euro business opportunity for those wholesalers who engage in it. On the other, it is a threat to the returns, and the research and development (R&D) spending ability, of pharmaceutical companies: schematically, for each unit sold at a price of 100 in the country of origin there is a corresponding unsold unit at a price of 100 + n in the country of destination.

As is to be expected, the perspectives of parallel traders and pharmaceutical companies inevitably clash: parallel traders use EU competition law as a ‘sword’ to attack attempts to restrict parallel trade and pharmaceutical companies use it as a ‘shield’ to protect their business by devising strategies aimed at restricting parallel trade of pharmaceutical products. A similar clash exists between the perspectives on this issue of the Commission and of the EU Courts. These two institutions have adopted often diverging approaches on how to assess restrictions on parallel trade under EU competition law.

3. Some States are prepared to allow pharmaceutical products to sell at a higher price than others. This may be in recognition, explicit or implicit, of the need to allow pharmaceuticals originator companies a sufficient return to provide an incentive for the research and development (R&D) of new pharmaceutical products.
6. The turnover of parallel traders is approximately € 3.5 billion–5 billion in Europe, which is between 2% and 3% of the overall market. There are approximately 100 companies engaged in parallel trade in the EU employing in total between 10,000 and 15,000 people. With few exceptions, parallel traders fall within the definition of SMEs. Source: DG Competition Staff Working Paper – Pharmaceutical Sector Inquiry Preliminary Report, ¶ 95.
7. Case T-168/01, GSK, ¶ 258.
§17.03 THE COMMISSION’S PERSPECTIVE

The Commission considers restrictions on parallel trade of pharmaceutical products to be among the most serious violations of EU competition law. The Commission’s approach is predicated by two principles:

1. the Single Market in pharmaceuticals requires the unhindered free movement of products – private companies cannot erect barriers to undermine this without distorting intra-brand competition; and
2. the efficiency claims advanced by the research-based pharmaceutical industry is unsubstantiated – i.e., there is no evidence that partitioning the common market would spur on global investment in inter-brand innovation.

§17.04 THE EU COURTS’ PERSPECTIVE

Whereas, the EU courts have developed a more nuanced approach and have accepted that in certain circumstances restricting parallel trade of pharmaceutical products can be justified, having regard to the applicable legal framework and the specific features of the relevant markets.

§17.05 LEGAL FRAMEWORK

Two provisions of the Treaty on the Functioning of the EU (TFEU) are relevant for the competitive assessment of restrictions on parallel trade of pharmaceutical products, namely:

- Article 101(1), which prohibits agreements and concerted practices that are restrictive of competition, unless their efficiencies outweigh their anti-competitive effects pursuant to Article 101(3); and
- Article 102, which prohibits abuses of dominant position, unless objectively justified.

In applying these provisions to cases regarding restrictions on parallel trade, the Commission and the EU Courts have been guided by the so-called ‘single market imperative’, which provides that a clause designed to prevent a buyer from reselling or exporting goods he has bought is liable to partition the markets within the EU and

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8. Memo/08/567: Commission welcomes Court decision on parallel trade in the pharmaceutical sector.
10. Joined cases C-486/06 and 478/06, Syfatt II, ¶ 78; and Joined cases C-501, 513, 519/06P, GSK, ¶ 103.
consequently to violate EU competition law. This principle has also been reaffirmed by the Court of Justice specifically in relation to restrictions on parallel trade of pharmaceuticals. However, the Court has also stated that the pharmaceutical markets are characterized by specific features that ought to be taken into account when applying EU competition law to restrictions on parallel trade of pharmaceutical products.

§17.06 SPECIFIC FEATURES OF THE PHARMACEUTICAL SECTOR

Certain features of the pharmaceutical sector set it apart from all other industries engaged in the production of readily traded goods, including in particular the pervasive and diverse regulation to which pharmaceutical products are subject both at national and EU levels, including price and distribution regulations, as well as the importance of innovation and very costly R&D in this sector. As a result, competition in the pharmaceutical sector is not simply the interplay of supply and demand, as is the case in other industries.

These specific features have important consequences for the definition of the relevant markets, both from a product and a geographic point of view.

§17.07 RELEVANT PRODUCT MARKET

The relevant product market definition of pharmaceutical products under EU competition law is based on the Anatomical Therapeutic Classification (ATC) system developed by the European Pharmaceutical Market Research Association (EPhMRA). The ATC system classifies pharmaceutical products into groups, according to the organs or systems on which they act and their chemical, pharmacological and therapeutic properties, and divides them into five different levels. The third ATC level groups pharmaceutical products according to their therapeutic indications. The fourth ATC level normally takes into consideration the mode of action and the fifth level defines the narrowest classes, including active substances taken individually. The analysis generally starts from the third level of the ATC system. However, other ATC levels are also taken into consideration where it appears that sufficiently strong competitive constraints operate at other ATC levels and, consequently, the third ATC level does not seem to allow a correct market definition.

12. Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GSK, ¶ 60.
13. Ibid., ¶ 103.
15. Case T-168/01, GSK, ¶ 264.
This principle has been applied by the Commission in numerous merger decisions in the pharmaceutical sector to date. According to this consistent line of decisions, the interchangeability of pharmaceutical products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by established medical practitioners. The prescription practices of medical practitioners are regularly influenced by the objective scientific knowledge available to them concerning the active properties and similarities of medicines. In the case of medicines available on prescription only, therefore, the market definition cannot be based simply on whether different medicines are prescribed for the same illness (i.e., in the same indication group). The criterion is whether prescription is based on fundamentally the same medical grounds. For such prescription practice, account can be taken of whether the medicines correspond to each other, for example, in terms of active principle, tolerance, toxicity, and side effects.

However, parallel trade cases are concerned with competition in relation to the same pharmaceutical product (so-called intra-brand competition) that is being bought in one Member State and sold into another. They are not concerned with competition between different substitutable pharmaceutical products (so-called inter-brand competition). Therefore, the General Court found that it is not manifestly incorrect to accept that all the medicines which are capable of being subject to parallel trade in a given Member State constitute a relevant product market.

§17.08 RELEVANT GEOGRAPHIC MARKET

It is settled case law that the relevant geographic market is national, owing, in particular, to the existence in the Member States of different price and reimbursement regulations, different brand and packing strategies, different distribution systems, and different prescribing habits. However, the peculiarity of the distribution network of pharmaceutical products has sometimes led competition authorities to limit the relevant geographic market so as to coincide with the regional territory.

Having defined the relevant framework of analysis, the most common types of restrictions of parallel trade and the way in which they have been assessed under EU competition law by the Commission and by the European Courts respectively are summarized below.

20. Case T-168/01, GSK, ¶ 159.
21. Ibid., ¶ 150.
22. AGCM no. 14227 in C6974 Comifar Distribuzione v. Farmaceutica Bolognese: wholesalers’ distribution networks are sometimes organized at a regional level and their warehouses are located so as to enable them to make their deliveries to the pharmacies within the region or in the neighbouring regions.
§17.09 DUAL PRICING

Dual pricing consists of an agreement between a pharmaceutical manufacturer and its wholesalers whereby different prices are applied depending on where the wholesalers ultimately sell the pharmaceutical products concerned:

- lower prices for domestic sales; and
- higher prices for exports into other Member States.

Dual pricing was the focus of the GSK case. In the GSK case, the Commission found that dual pricing clearly impeded parallel trade by obliging wholesalers to purchase the drugs at prices which were higher than the maximum industrial price for domestic sales and it was thus a violation of Article 101(1).23 GSK challenged the Commission’s decision before the General Court. The General Court quashed the Commission’s decision and found that dual pricing was not a restriction of competition by object – therefore an assessment of its effects would always be required for a finding of a violation of Article 101(1).24 The Commission appealed the General Court’s judgment to the Court of Justice. In deciding the appeal, the Court of Justice disagreed with the General Court and reinstated the single market imperative, according to which an agreement aimed at limiting parallel trade is a restriction by object, without the need to assess its effects. However, the Court of Justice upheld the General Court’s finding that dual pricing may in principle benefit from an exemption under Article 101(3), if its efficiencies outweigh its anti-competitive effects.25 Crucially, the Court of Justice held that such an examination requires the nature and specific features of the sector to be taken into account as those specific features are decisive for the outcome of the analysis.26 In applying this test, the General Court found that parallel trade:

- entails a material27 loss in efficiency;28
- does not benefit consumers, because most, although not all, of the financial benefit accrues to the parallel trader rather than to the health care system or the patient;29 and
- impacts negatively on technical progress30 by reducing the capabilities for financing R&D.31

25. Ibid., ¶ 233.
26. Ibid., ¶ 264; and Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P GSK, ¶ 103.
27. Case T-168/01, GSK, ¶ 292.
28. Ibid., ¶ 258.
29. Ibid., ¶ 135.
30. Ibid., ¶¶ 269–280.
31. Ibid., ¶ 258.
By eliminating the inefficiencies inherent to parallel trade, dual pricing contributes to the promotion of technical progress,\(^\text{32}\) without eliminating competition for a substantial part of the relevant markets.\(^\text{33}\) It follows from this case law that dual pricing is a restriction of competition by object in violation of Article 101(1), which may nevertheless benefit from an exemption under Article 101(3), having regard to the specific features of the pharmaceutical sector.

Although the GSK case concerned only the application of Article 101, the General Court provided some guidance also on the application of Article 102 to dual pricing. First the General Court recalled that Article 102 does not preclude a company in a dominant position from setting different prices in the various Member States where they are applied on separate geographic markets, characterized by insufficiently homogeneous conditions of competition, regard being had in particular to the relevant regulatory framework.\(^\text{34}\) It then went on to say that these considerations are particularly relevant to the pharmaceutical sector, insofar as the relevant geographic markets are national owing, in particular, to the differences in the national regulations on the prices and the reimbursement of the medicines in question.\(^\text{35}\) According to the General Court, it follows that the finding of a dual pricing system based on different prices is not sufficient to support the conclusion that there is abusive discrimination in violation of Article 102, even assuming a dominant position.\(^\text{36}\)

§17.10 SUPPLY QUOTA SYSTEM BY A NON-DOMINANT COMPANY

A supply quota system consists of a supplier either ceasing to meet orders from wholesalers or, more usually, reducing the supply quota so as to provide the wholesalers with only enough products to cover domestic sales, e.g., there is no excess product with which to engage in parallel trade.\(^\text{37}\) The analysis under EU competition law of such a strategy depends on whether the supplier is in a dominant position or not. The situation in which the supplier who is not in a dominant position ceases to supply parallel traders was considered in the Adalat case.

In the Adalat case, the Commission found that such a strategy amounted to an agreement between Bayer and its wholesalers containing an export ban in violation of Article 101, which could be deduced from the following factors:

- a system for detecting exporting wholesalers; and  
- successive reductions in the amounts supplied where wholesalers exported all or some of the products concerned.\(^\text{38}\)

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32. \cite{ibid}, ¶¶ 259–308.  
33. \cite{ibid}, ¶ 313.  
34. \cite{ibid}, ¶ 177.  
35. \cite{ibid}, ¶ 178.  
36. \cite{ibid}, ¶ 179.  
37. The situation only concerns orders from existing customers. There is no obligation under EU competition law to supply new customers.  
Bayer appealed against the Commission’s decision. On appeal, both the General Court and the Court of Justice rejected the Commission’s inference of an agreement. For the Courts, it is necessary that the manifestation of the wish of one of the contracting parties to achieve an anti-competitive goal constitutes an invitation to the other party, whether express or implied, to fulfil that goal jointly and that applies all the more where, as in this case, such an agreement would not be at first sight in the interests of the other party, namely, the wholesalers.39

It follows from this case law that, provided he does so without abusing a dominant position, and there is no concurrence of wills between him and his wholesalers, a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States.40

§17.11 SUPPLY QUOTA SYSTEM BY A DOMINANT COMPANY

The situation in which the supplier who is in a dominant position ceases to supply parallel traders was considered in the Syfait I and II cases. These two cases stem from direct references to the Court of Justice for preliminary rulings.

The question referred to the Court in both cases was whether there is an abuse of a dominant position contrary to Article 102 if a pharmaceuticals company occupying such a position on the national market for certain medicinal products refuses to meet orders sent to it by wholesalers on account of the fact that those wholesalers are involved in parallel exports of those products to other Member States.41

In Syfait I, Advocate General Jacobs found that such a refusal is capable of objective justification, and thus of not constituting an abuse, given the complex nature and the actual development of the pharmaceutical sector.42 However, the Court of Justice declined to decide on the merits on grounds of lack of jurisdiction.43

In Syfait II, the Court of Justice found it had jurisdiction and, this time, it had to examine the merits of the question referred to it. However, the Court did not follow the Opinion given by Advocate General Jacobs in Syfait I. Instead, it found that:

an undertaking occupying a dominant position on the relevant market for medicinal products which, in order to put a stop to parallel exports carried out by certain wholesalers from one Member State to other Member States, refuses to meet ordinary orders from those wholesalers, is abusing its dominant position. It is for the national court to ascertain whether the orders are ordinary in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned. (emphasis added)

40. Case T-41/96, Adalat, ¶ 176.
41. Joined Cases C-468/06 to C-478/06, Syfait II, ¶ 28.
42. Case C-53/03, Syfait I, Opinion of Advocate General Jacobs, ¶ 105.
43. Case C-53/03, Syfait I, ¶ 39.
44. Joined cases C-486 e 478/06, Syfait II, ¶ 78.
The flip side of the Court’s ruling is that a dominant pharmaceutical company may legitimately refuse to supply orders that are out of the ordinary, having regard to:

- the size of those orders; and
- the previous business relations with the wholesalers concerned.

§17.12 PRODUCT LIFE CYCLE MANAGEMENT STRATEGIES

The Commission’s Pharmaceutical Sector Inquiry Report identified a number of product life cycle management strategies that are at risk of violating EU competition law. The use of such strategies to limit parallel trade was assessed under EU competition law in the *AstraZeneca* case.

In the *AstraZeneca* case, the Commission found that *AstraZeneca* had abused its dominant position in relation to its blockbuster drug Losec by selectively deregistering the market authorizations for Losec capsules in three Member States; withdrawing Losec capsules from the market; and launching Losec tablets in those same Member States. According to the Commission, those steps were capable of resulting in parallel importers losing their parallel import licenses in the three Member States in question.45

*AstraZeneca* appealed against the Commission’s decision in the General Court. In its appeal, *AstraZeneca* contended that, in withdrawing its marketing authorization, it exercised a fundamental EU right. This right had been recognized by the Court of Justice in *Rhône-Poulenc*46 as well as by the Commission itself in its written observations in *Rhône-Poulenc*. In particular, in those submissions, the Commission said:

- the withdrawal of an authorization is a fundamental EU legal principle;
- the applicant is master of the application procedures;
- after an authorization is granted, the holder of the authorization may equally demand that the authorization should be withdrawn at any point in time without being obliged to give any reasons; and
- the concept of compulsory licensing is unknown in any EU pharmaceutical legislation.

In addition, in *Paranova*, the Court of Justice held that the withdrawal of marketing authorizations for reasons other than public health does not justify the automatic cessation of the parallel import license.47

How then is it possible that the Commission found the exercise by *AstraZeneca* of a fundamental EU right was an abuse in violation of Article 102? The Commission and the General Court are in some disagreement on this. On the Commission’s case, the abuse comprised three ingredients:

- first, the launch of the Losec tablets on to the market;

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47. Case C-15/01 *Paranova* ¶¶ 25–28 and ¶ 33.
second, the withdrawal of Losec capsules from the market; and
third, the withdrawal of the marketing authorization for the Losec capsule.

By contrast, the General Court found that there was nothing abusive in the launch of a
new formulation of Losec and the withdrawal of Losec capsules. In its view, it was only
the withdrawal of the marketing authorization that amounted to an abuse. The
relevant test – for the General Court – is whether parallel import licenses have
traditionally relied on the existing marketing authorizations of a certain proprietary
medicinal product. If they have, then the deregistration of the marketing authorization
for a particular product may be presumed to be capable of inducing the national
medical product authority to withdraw the parallel imports licenses for such product.
This is the case even if the practice of the national medical product authority would be
wrong in law, having regard to the legal principles set out by the Court of Justice in
Paranova.

In applying this legal test to the facts of the AstraZeneca case, the General Court
quashed the Commission’s decision in relation to two of the Member States concerned,
where the Commission had failed to establish to the requisite legal standard that
deregistration of Losec capsules was capable of inducing the national medical product
authority to withdraw import licenses. As regards the other country in question, the
General Court found that it was not disputed that the medical product authority of that
country considered (albeit wrongly) that parallel import licenses could be granted only
if valid marketing authorizations were in place. It is unambiguously clear from this –
for the General Court – that the deregistration of the marketing authorizations for Losec
was such as to impede parallel imports in that country. In addition, the General Court
found that:

– subjective intent did not need to be shown;
– actual effects on the market did not need to be shown;
– the fact that parallel importers did not lose their import license and would have
  other means to enter the market did not matter; and
– the cost of maintaining the authorization – in terms of pharmacovigilance
  obligations on the authorization holder – was not a valid justification.

It follows from the General Court’s reasoning that, when there is no other documented
explanation for the withdrawal of a marketing authorization, this may be assumed to
have the sole purpose of restricting parallel trade and is therefore abusive. Accordingly,
a dominant company comes under a positive obligation to ensure that its marketing
authorizations are maintained so that it is easier for parallel imports to continue,
regardless of any subjective intent, commercial interests, and related pharmacovigi-
lance obligations. The legal issues here go beyond the facts of this case. As a result of
this ruling, many other product life cycle management strategies identified in the

49. Ibid., ¶ 810.
50. Ibid., ¶ 861.
51. Ibid., ¶ 862.
Pharmaceutical Sector Inquiry Report are at risk of falling foul of EU competition law, namely, marketing authorization switches, launch of follow-on products, OTC or follow-on products switches, etc. This is despite the fact that such strategies would be totally legitimate under intellectual property and pharmaceutical law.

AstraZeneca appealed the General Court’s judgment to the Court of Justice. In its appeal, AstraZeneca argued that, for a finding of abuse of dominant position, the Commission should at least be required to prove that the exercise of a validly held right (in this case, the right to withdraw a marketing authorization) tends to eliminate any effective competition. This would be similar to the conditions necessary for a finding of abuse in cases concerning compulsory licensing. However, the Court of Justice rejected the appeal and upheld General Court’s ruling.

§17.13 CONCLUSION

Despite the uncertainty created by the AstraZeneca judgment, what can be taken away from the jurisprudence of the Courts is that they are seeking to balance a broader range of concerns against the Commission’s view that restrictions on parallel trade segregate the single market and so are per se anti-competitive.

In such circumstances, pharmaceutical companies have to tread carefully in order to make sure that they are legitimately protecting their commercial interests without crossing the line and engaging in anti-competitive conduct. In spite of the Commission’s intransigent position, the Courts have been far more receptive to the potential dangers that parallel trade poses in the pharmaceutical sector. Following the Modernization Regulation, the role of the national courts is likely to prove decisive, and the interpretative role imposed upon them will determine Europe’s future approach to parallel trade in this sector.

52. Appeal C-457/10 P.
53. C-457/10 p AstraZeneca, not yet reported in ECR, para. 155, see also, Advocate General Mazak’s Opinion, paras 78–80.