

# Recent challenges to parallel trade

In the first article in this series, Cathal Gallagher and Richard O'Neil discussed the genesis of the law governing parallel imports. In this article they examine recent challenges to the legality of the parallel trade and measures designed to reduce or prevent it.

The legal arguments for and against the parallel trade in medicines have, on the whole, been fought between two camps: parallel traders and the pharmaceutical industry. Those engaged in parallel trade generally contend that their activities promote competition, thereby reducing prices to the benefit of patients and the health service. Those in the pharmaceutical industry say that parallel trading does not benefit consumers because prices are set by EU member states and are not determined by supply and demand. Pharmaceutical companies also say that parallel trading cuts into their profits, leaving less money to invest in research and development.

Most recent cases involving parallel trading have either been initiated by pharmaceutical companies challenging its legality, or by parallel traders challenging restrictions imposed by the pharmaceutical industry in an attempt to reduce the profitability of the trade. This article will examine the more prominent of these cases and assess their outcomes.

## Repackaging

National labelling regulations on medicines can mean that products have to be repackaged in the EU member state of importation. In the UK the standard labelling requirements for containers and packages for medicinal products for human use are set out in Regulation 4A of the Medicines (Labelling) Amendment Regulations 1992 (as amended). The way in which some products have been repackaged has led to legal disputes and challenges by the owners of the trade marks.

A series of cases at the European Court of Justice (ECJ) have established the extent to which a trademark owner is allowed to invoke trademark rights to prevent parallel importation between member states, where products have been repackaged to meet the legal or practical commercial requirements in the member state of importation.

The legal cases concern the interpretation of Article 7(2) of Council Directive 89/104/EEC (commonly referred to as the EC trade marks directive), which provides that the rights in a trademark will not be exhausted where the proprietor has legitimate reasons to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.



Oleksandr Svitlovskyi/Dreamstime.com

Repackaging of pharmaceutical products has typically been achieved by putting an information sticker in the language of the importing member state over the original packaging and replacing the original patient information leaflet with the version appropriate to the importing member state. Many of the legal disputes have centred on whether overlabelling impairs or changes the condition of parallel imports.

The leading case — *Bristol-Myers Squibb v Paranova A/S* — looked at whether the repackaging of medicines intended for parallel importation infringed on “rights conferred by a trademark” in three disputes between, on the one hand, Bristol-Myers Squibb and other pharmaceutical manufacturers and, on the other hand, Paranova A/S, which imports into Denmark products manufactured by those companies. The ECJ stated that a trademark owner could rely on his trademark to prevent the marketing of repackaged products unless:

- Repackaging does not affect the condition of the product, or
- Repackaging is not liable to damage the reputation of the trademark, or
- The new repackaging clearly states the identity of the original manufacturer and the repackager.

Overlabelling does not affect the condition of the package or container, or the product, and parallel importers invariably include the identity of the manufacturer on the new label, and so it does not infringe on trademarks. Notwithstanding this, the Medicines and Healthcare products Regulatory Agency always serves notice on the trademark owner of the intended marketing of the repackaged product and can provide a sample on request. This gives the trademark owner an opportunity to object if there is a fault with the packaging.

Recently, the ECJ gave a ruling in a group of cases about parallel importation of trademarked products referred from the English courts.<sup>2,3</sup> In these cases, Boehringer Ingelheim, Glaxo and Eli Lilly took action

- Reliance on the trademark contributes to artificial partitioning of the market, or

Cathal Gallagher, LL.M, MRPharmS, is senior lecturer, University of Hertfordshire (e-mail c.t.gallagher@herts.ac.uk), and Richard O'Neil, LL.M, MRPharmS, is associate head of the school of pharmacy

against parallel importers who had engaged in various types of repackaging, including re-boxing and the removal of the manufacturer's trademark and the importer's trademarks, or the addition of the importer's trademark. In its ruling, the ECJ stated the following:

- It is not necessary for a trademark owner to demonstrate damage to the specific subject matter of his trademark to oppose parallel imports.
- The legitimate interests of the trademark owner must be respected, which means that repackaging must not affect the original condition of the product or "harm the reputation" of the trademark.
- Repackaging, as opposed to relabelling, is objectively necessary if, without such repackaging, effective access to the market, or a substantial part of it, would be hindered as a result of strong resistance from a significant proportion of consumers to the relabelled product. However, resistance to the relabelled products does not always constitute an impediment to effective market access. It is for the national court to determine whether effective market access exists.
- A parallel importer must give reasonable prior notice to the trademark owner of his intention to repackage, failing which the trademark owner may oppose the marketing of the repackaged product.

The judgment states that parallel importation could be resisted if there is evidence that the reputation of the trademark would be damaged by the importation of the repackaged products. It also allows for purely commercial factors, in particular the likelihood of consumer resistance to relabelled products, to be taken into account in determining whether full repackaging, rather than relabelling, is necessary.

Following the ECJ judgment, the Court of Appeal upheld the earlier High Court judgment against Boehringer Ingelheim, Glaxo Group, SmithKline Beecham and Eli Lilly.<sup>4</sup> In his summation, Lord Justice Jacob stated: "Parallel importers are entitled to do more than just render the packaging lawful for UK marketing... [t]hey are entitled to replace the packaging if that is what is necessary to overcome a strong resistance in the market to relabelled boxes." He rejected the argument that pharmacists could overcome patient hostility to original packs that are covered with stickers with further explanation: "Poorly people want their pills, not explanations. Pharmacists have better things to do than explain things to concerned patients."

Lord Justice Jacob ruled that replacing the brand name on the box with the non-proprietary name while the brand name still appears on the actual product or its immediate packaging does not amount to passing off.<sup>5</sup> He said that there was no evidence that

a pharmacist or patient had ever been deceived. He added that replacement packaging that bears the originator's brand name and the parallel importer's mark caused no damage to the claimants' reputation and exclusivity. Relabelling or repackaging a parallel-imported medicine using a UK trademark name owned by the manufacturer, or a group of companies that includes the manufacturer, does not in itself infringe on the manufacturer's trademark rights.

### Spain

On 6 March 1998, Glaxo Wellcome SA notified its wholesalers in Spain of new sales conditions. The new arrangements incorporated a dual pricing system, which resulted in Spanish wholesalers being charged a higher price for drugs resold in other member states than for those resold in Spain. A number of wholesalers and associations lodged complaints with the European Commission arguing that Glaxo's sales conditions infringe Article 81 of the EC Treaty.

Article 81 bans activities or undertakings that "may affect trade between member states and that have as their object or effect the prevention, restriction or distortion of competition". It refers to activities that directly or indirectly fix purchase or selling prices or apply dissimilar conditions to equivalent transactions. Glaxo claimed an exemption under Article 81(3), which allows such agree-

Advertisement

ments where they “contribute to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit” and do not impose certain conditions or strive to eliminate competition.

On 8 May 2001, the commission ruled that Glaxo had infringed Article 81(1) by entering into an agreement with Spanish wholesalers that discriminated between those operating within Spanish borders and those that engaged in EU-wide trade. Glaxo’s request for an exemption, pursuant to Article 81(3), was rejected and it was ordered to bring the infringement to an end immediately.

Glaxo petitioned the Court of First Instance (CFI) to have the commission’s decision annulled. On 27 September 2006, the CFI ruled that the commission’s main conclusion — that Glaxo’s sales conditions had as their object the restriction of competition because they made provision for differentiated prices that sought to limit parallel trade — was incorrect.<sup>6</sup>

The court noted that the commission had not examined the specific and essential characteristic of the pharmaceuticals sector, in which the prices of medicines in individual member states are set or controlled by national regulations. According to the CFI, it could not be presumed that parallel trade tended to reduce prices and thus increase the welfare of final consumers. However, an examination of the sector suggested that parallel trade permitted a limited but real reduction in the cost of medicines. The CFI said Glaxo’s sales conditions diminished the welfare of final consumers in so far as they prevented that advantage from being produced.

The commission was found not to have carried out an adequate examination of Glaxo’s request for an exemption. The CFI annulled the decision to reject Glaxo’s request for an exemption, essentially returning all parties to their respective situations on the date of Glaxo’s original request for an exemption. The decision meant the commission would have to reconsider that request.

Each of the three main parties — Glaxo, Aseprofar: Asociación de Exportadores Españoles de Productos Farmacéuticos (Spanish Pharmaceutical Products

Exporters’ Association) and the European Commission — have appealed against the decision. The commission and Aseprofar contend that the CFI erred in law, while Glaxo argues that the court did not address its concerns adequately. The commission cited “errors of law and distortions in the interpretation and application [of the law]” as well as “many distortions, errors of law, and inadequacies or contradictions in the reasoning [of the CFI]”.<sup>7</sup> Aseprofar’s appeal centres on the contention that dual pricing and export bans are anticompetitive.<sup>8</sup> Glaxo’s lawyers contend that the CFI was wrong in reaching the conclusion that the general sales conditions produce appreciable anticompetitive effects and thus violate Article 81(1). Under these circumstances, they argue, the court’s annulment should have been complete, rather than partial.<sup>9</sup> Each appeal is, to date, unresolved.

### Greece

Glaxo was also involved in an attempt to foil the parallel trade in three of its products, Imigran, Lamictal and Serevent, via Greece. Until November 2000, Glaxo met orders that it received from Greek wholesalers in full. A substantial proportion of the orders were subsequently exported to other member states through parallel channels, so Glaxo withdrew the supplies to the wholesalers, resolving to supply hospitals and pharmacies direct.

Glaxo justified this by alleging that exports by wholesalers were leading to significant shortages on the Greek market. After intervention by the Greek competition commission (Epitropi Antagonismou), Glaxo reinstated supplies in February 2001, but determined to supply the domestic market in Greece with quantities equal to current prescription levels plus an additional 25 per cent to cover emergencies and changes of circumstance. This complies with the circular adopted on 27 November 2001 by the National Organisation for Medicines (Ethnikos Organismos Farmakon), which provides that all participants in the distribution of prescribed medicines provide at least 125 per cent of current demand.

The competition commission was uncertain as to whether Glaxo’s refusal to meet its

orders in full should be considered an abuse of its dominant position in the market within the meaning of Article 82 of the EC Treaty. It referred the matter to the ECJ for clarification.

In October 2004, as part of the ECJ’s deliberations, Advocate General Jacobs said that a refusal to supply by a dominant pharmaceutical company to limit parallel trade was capable of justification as a reasonable and proportionate measure in defence of that undertaking’s commercial interests.<sup>10</sup> Such a refusal could be justified where price differentials between member states were the result of state intervention, which fixed the price at an artificially low level.

Ultimately, however, the ECJ declared that the application by the Greek competition commission was inadmissible because it is not a court or tribunal of a member state and did not have the right to refer questions to the ECJ.<sup>11</sup> In effect, the case was thrown out on procedural grounds and, to date, it remains unresolved as a matter of EU law.

Parallel importers claimed the ECJ’s refusal to rule on the case was a victory.<sup>12</sup> But the “victory” was short-lived, because on 5 September 2006, the Greek competition commission decided that Glaxo had not abused its dominant position in restricting supplies to Greek wholesalers to prevent goods being parallel traded outside Greece.

It said that Glaxo had abused its dominant position for a limited period from November 2000 to February 2001 but, thereafter, the supply restrictions had not infringed Greek competition law. Furthermore, it suspended its ruling on whether Glaxo’s quota system infringed competition law. It seems likely that there will continue to be uncertainty for dominant companies implementing quotas for the supply of pharmaceutical products, or applying price restrictions, until there is a European Commission, CFI or ECJ decision on the matter.

In the final article of this series, we will examine the common pitfalls associated with application for a PL(P), and with dispensing parallel imports, with a view to minimising their occurrence and preventing pharmacists from falling foul of the Royal Pharmaceutical Society’s fitness-to-practise machinery.

### References

1. Bristol-Myers Squibb and Others v. Paranova A/S (Joined Cases C-427, C-429 and C-436/93), [2002] 3 WLR 1746.
2. SmithKline Beecham Plc and others v Dowelhurst Ltd; Boehringer Ingelheim KG and Another v Swingward Ltd; SmithKline Beecham Plc and others v Dowelhurst Ltd; Boehringer Ingelheim KG and Another v Swingward Ltd; Glaxo Group Ltd and Another v Dowelhurst Ltd and Another. Court of Appeal (Civil Division), 2000 WL 191253.
3. Boehringer Ingelheim KG v Swingward Ltd (C143/00); Boehringer Ingelheim KG v Dowelhurst Ltd (C143/00); Eli Lilly & Co v Dowelhurst Ltd (C143/00); Glaxo Group Ltd v Dowelhurst Ltd (C143/00); Glaxo Group Ltd v Swingward Ltd (C143/00); SmithKline Beecham Plc v Dowelhurst Ltd (C143/00). European Court of Justice, 23 April 2002. [2002] 2 CMLR 26.
4. Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co KG v Swingward Limited; Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co KG, Boehringer Ingelheim Limited v Dowelhurst Limited; Glaxo Group Limited v Swingward Limited; Glaxo Group Limited v Dowelhurst Limited; SmithKline Beecham plc, Beecham Group plc, SmithKline and French Laboratories Limited v Dowelhurst Limited; Eli Lilly and Company v. Dowelhurst Ltd. Court of Appeal (Civil Division), [2004] EWCA Civ 757.
5. The Pharmaceutical Journal 2004;272:344.
6. Case T-168/01, Glaxo Wellcome Plc v. Commission of the European Communities (2006)
7. Case C-513/06, Appeal brought on 18 December 2006 by Commission of the European Communities against the Court of First Instance judgment (Fourth Chamber, Extended Composition) delivered on 27 September 2006 in Case T-168/01: GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome Plc v Commission of the European Communities.
8. Case C-519/06, Appeal brought on 20 December 2006 by Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) against the judgment of the Court of First Instance (Fourth Chamber, Extended Composition) delivered on 27 September 2006 in Case T-168/01: GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome Plc v Commission of the European Communities.
9. Case C-501/06, Appeal brought on 11 December 2006 by GlaxoSmithKline Services Unlimited (GSK) against the judgment of the Court of First Instance (Fourth Chamber, Extended Composition) delivered on 27 September 2006 in Case T-168/01: GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome Plc v Commission of the European Communities.
10. Case 27/76, United Brands v. Commission of the European Community, [1978] ECR 207.
11. Case C-53/03, Syfait & others v. GlaxoSmithKline AEEV (2005).
12. The Pharmaceutical Journal 2005;274:668.