Flynn Pharma

A unique parallel import case?

Michael Silverleaf QC

Competition Law Association

Arnold & Porter 7 July 2017

Parallel importation: the rules

- CJEU has long developed jurisprudence to promote free movement of goods between member states under TFEU Art 34 and the interaction with the enforcement of intellectual property rights under Art 36.
- Parallel importer may relabel or repackage goods in order to have effective access to the market in the state of importation. This is particularly important in the case of pharmaceuticals where labelling is normally required to use the local langauge.
- Basic rule of exhaustion of rights now incorporated in Art 7 of the Trade Marks Directive:
  (1) The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under the trade mark by the proprietor or with his consent.
  (2) Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor 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.
- CJEU in BMS v Paranova laid down the conditions to be met in order to avoid the application of Art 7(2) where goods are repackaged.

The BMS conditions

- The repackaging is necessary in order to have effective access to the market (which means the whole market) in the state of importation
- The repackaging does not affect the condition of the goods
- The new packaging clearly identifies the person responsible for the repackaging
- The packaging is neither defective nor of a poor quality so as to damage the trade mark owner's reputation
- The importer gives the trade mark proprietor notice of his intention to repackage and market in the importing state before the repackaged product is put on sale

Repackaging with a different trade mark

- In *Pharmacia and Upjohn v Paranova* the CJEU allowed repackaging under a different trade mark used by the proprietor in the importing state
- So, where the trade mark proprietor uses one mark in the exporting state and another in the importing state the parallel importer may wish to replace the mark in the exporting state with that used in the importing state
- This is permissible "where the repackaging with reaffixing or the replacement of the trade mark is necessary in order to enable the products to be marketed by the parallel importer in the importing Member State"
- This is because to reach the opposite conclusion would necessarily lead to artificial partitioning of the market between the member states
- It is not necessary to show that it was the trade mark proprietor's intention to partition the market in order to be entitled to replace the mark used on the imported product

Flynn: the key facts for trade mark purposes

- Phenytoin sodium made and sold by Pfizer in capsules as a branded drug called EPANUTIN
- Operation of the PPRS had reduced the price to a level at which Pfizer found it essentially uneconomic to continue to market it
- Pfizer agreed to divest the product in the UK to Flynn who proposed to market it as a generic so that it was no longer within the PPRS and to sell it at a market driven price (apparently slightly lower than that of the tablets sold by Teva)
- Pfizer and Flynn entered into an exclusive supply arrangement under which Pfizer continued to make the capsules and supply them to Flynn for Flynn to market in the UK
- The capsules continued to have the brand stamped into the body of the capsule but Flynn not otherwise permitted to use the trade mark EPANUTIN
- Flynn sought marketing authorisation under the generic name.
- However:

Flynn: the key facts (2)

- MHRA refused to licence product as a pure generic because of its narrow therapeutic index which had led to guidance that patients should be maintained on the same source of product to avoid changes in therapeutic effect
- So MHRA required product to be authorised and marketed as Phenytoin sodium Flynn
- This made it effectively a branded product
- But the MHRA agreed to treat it for price regulation purposes as a generic
- Thus, Flynn was able to raise the price to a level determined by the competing tablets from Teva (leading to an approximately 20-fold price increase)
- The increased price made parallel importing attractive because the price of Epanutin sold by Pfizer elsewhere (in particular Spain and Ireland) was now considerably less
- DrugsRUs/Tenelol Merck sought to import and repackage Epunatin from Pfizer as Phenytoin sodium Flynn

Flynn: the key facts (3)

- The product sold by Flynn and DrugsRUs was the same, down to the stamped name EPANUTIN embedded in the capsule. All made and packed on the same production line by Pfizer
- Whilst the number of branded prescriptions for Phenytoin sodium Flynn was a relatively small proportion of the total (about 7%), Flynn had 40% of the market so a true generic product was excluded de jure from the branded prescription market and de facto from much more
- The court found that it was therefore necessary for DrugsRUs to mark the product as Phenytoin sodium Flynn in order to have effective access to the market in the UK
- Flynn and Pfizer are economically independent and the Flynn trade mark is not connected or associated in any way with Pfizer
- Because of the operation of the suite of agreements between Pfizer and Flynn and the regulatory regime in the UK in practice Pfizer controls the nature and quality of the product placed on the market by it elsewhere in the EU and by Flynn in the UK

The trade mark infringement dispute

- Flynn said they were an independent supplier to the UK market who controlled their own product and that there was therefore no parallel importation of a product first put on the market with the consent of the trade mark owner
- DrugRUs said that they needed to mark the product as phenytoin sodium Flynn as that was the authorised name of the product in the UK and that prescriptions for that product could only be filled with a product sold under that name
- DrugsRUs argued that Flynn was therefore not being used as a trade mark: rejected at first instance and barely pursued on appeal
- DrugsRUs then argued that parallel importation rules entitling them to access to the market apply whether or not product first placed on the market with the trade mark proprietor's consent: rejected at first instance and on appeal
- Finally DrugsRUs argued that use was necessary to indicate the type or characteristics of the goods and therefore protected by section 11(2)(b) of Trade marks Act: rejected

Analysis of the trade mark issues (1)

- The facts of this case are unique in many respects
- It follows that the outcome is not a likely predictor of the outcome in other cases
- The unusual trade mark position arises from the strange operation of the pricing and marketing regulation regimes in the very unusual circumstances of this case with the result that a branded product was regulated as a generic
- The argument that the use of the Flynn name was not trade mark was based upon the CJEU decision in *Adam Opel v Autec* which was concerned with use of the Opel logo on a model car
- Argument received short shrift from first instance judge (and was basically not run on appeal where there was an experienced trade mark judge on the panel)

Analysis of the trade mark issues (2)

- DrugsRUs argued that there was artificial partitioning of the market and that the requirements of TFEU Art 36 apply irrespective of whether the product had originally been placed on the market under the trade mark with the consent of the trade mark proprietor
- The argument was rejected at both levels, it being held that what is required for the requirement of free movement to prevent trade mark enforcement is either (a) control by the trade mark proprietor of the marketing of the goods in the exporting state or (b) that the links between the original marketer (in this case Pfizer) and the trade mark proprietor (in this case Flynn) are such that the mark in issue should be regarded as being under the unitary control of the original marketer (Pfizer)
- The court rejected the proposition that control of the nature and quality of the product being in the hands of the original marketer was itself sufficient to give rise to effective exhaustion of the rights of the trade mark proprietor

Analysis of the trade mark issues (3)

- The secondary argument by DrugsRUs that the use of the Flynn branding was protected by section 11(2)(b) of the Trade Marks Act was also rejected

- Section 11(2) provides that:

  > A registered trade mark is not infringed by … (b) the use of indications concerning the kind, quality, intended purpose, value, geographical origin, the time of production of goods or of rendering of services, or other characteristics of goods or services.

- The argument was rejected at both levels. Both courts held that the designation Flynn was not a reference to any characteristic of the goods, even though Flynn's marketing had begun with an education campaign to the medical and pharmaceutical professions to explain to them that Phenytoin sodium Flynn is the same product made on the same production line as the previously marketed Epanutin

Discussion

- There is as a result of the arrangements entered into between Pfizer and Flynn partitioning of the market between the exporting state and the importing state: the product being sold in the exporting state cannot be imported into the importing state and sold under the name used for that product by the original marketer in that state

- In effect, the court has held that this partitioning is not artificial and that it is therefore not caught by TFEU Art 36

- In practical terms, the court has treated the CJEU's reasoning in cases of complete divestment of a business carried on under a trade mark to a third party in one member state (*Ideal Standard*) as applying to cases where the third party nevertheless ties itself to the divester as the source of its product

- Do you agree with the court's approach?