

EU Customs Detention in the pharmaceutical sector

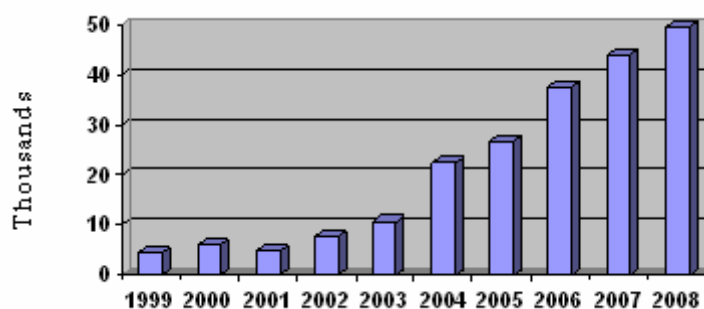
This note is intended to supplement our note entitled “*Customs Detention: A cost effective method of enforcing intellectual property in Europe*” and provides specific guidance on the use of EU Customs detention in the pharmaceutical industry.

As set out in the note, Regulation (EC) 1383/2003 (the Regulation) provides a powerful tool for national Customs authorities to prevent shipments from entering the EU market that are suspected of infringing intellectual property rights (“IPR”) such as trade marks and patents.

Statistics

In 2009, the European Commission Taxation and Customs Union reported on national Customs activities within the EU, relating to IPR during the previous year. The figures show a continuing increase in the overall number of Customs detention cases, showing a 13% rise in the total number of detentions since 2007. The number of total articles detained by Customs rose to almost 179 million for 2008 alone.

Number of registered cases 1999 – 2008



Number of cases	
1999	4.694
2000	6.253
2001	5.056
2002	7.553
2003	10.709
2004	22.311
2005	26.704
2006	37.334
2007	43.671
2008	49.381

Source: Report on European Commission Taxation and Customs Union. EU Customs Enforcement of Intellectual Property Rights: Results at the European Border – 2008.

Of the entire Customs intervention cases in 2008, 6.5% related to pharmaceutical products, which were 4.9% of the total number of articles seized by Customs. Although pharmaceuticals are not the highest detained category of goods, the seizure

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of medicines by Customs authorities was up 118% when compared with 2007 and was the third largest product category of intercepted articles.

The main originating country for pharmaceutical IPR infringing products was India, with 51.6% of the goods detained by Customs originating there. The second source was Syria, making up 36.4% and the third source was the United Arab Emirates, consisting of 8.66%. Most pharmaceutical products were discovered by Customs in air transport (more than 50%) and sea transport represented 36% (although this was distorted by one very large case).

An explanation for the rise in pharmaceutical detentions by Customs authorities is considered to be the direct impact of the European Commission initiated “Medi-Fake” action in 2008. On the basis of a risk profile carried out by the Commission, Customs authorities from the 27 Member States coordinated to prevent counterfeit pharmaceuticals from entering the EU and detained them at national borders. The action led to over 32 million pharmaceutical products being stopped by national Customs authorities, of which more than 15% were suspected of infringing IPR. Among the seized products were: antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines, as well as painkillers, Viagra and drug precursors.

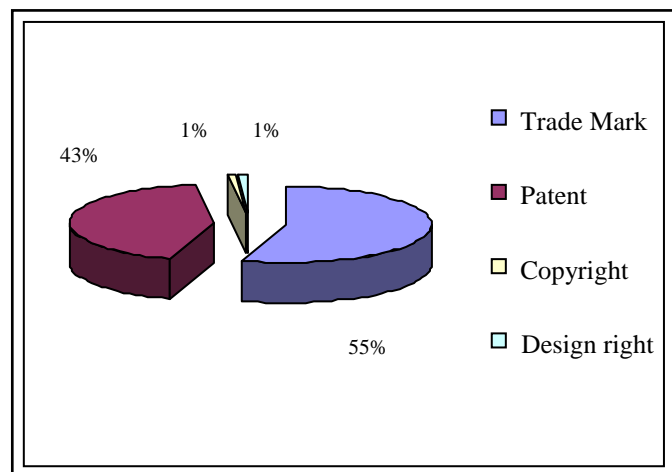
Over the course of 2008, there were reported some of the largest pharmaceutical seizures by national Customs authorities. Customs at Brussels airport registered the biggest seizure of illegal medicines ever recorded in Europe: 2,200,000 counterfeit medicine tablets were seized, of which 1,600,000 were painkillers and 600,000 were anti-malaria pills.

Despite this, the main category of pharmaceuticals detained is “life style drugs” (such as weight loss drugs).

Categories of Rights

The below chart shows the breakdown of Customs detained articles by type of infringed right across all product categories.

Breakdown by type of infringed right per detained articles



Articles	
Trade mark	54,92%
Patent	42,50%
Copyright/related right	1,25%
Design and model right	1,24%
Plant variety right	0,08%
Unknown	0,01%
Protected designation of origin	0,00%
Protected geographical indication	0,00%

Source: Report on European Commission Taxation and Customs Union. EU Customs Enforcement of Intellectual Property Rights: Results at the European Border – 2008.

Detention on the basis of Trade Mark infringement

According to the 2008 figures, more than 93% of all pharmaceutical products were intercepted by Customs authorities on the suspicion of a trade mark infringement. Trade mark infringement continues to be the IPR on which the most Customs detentions are based. The pharmaceutical industry is considered to be at high risk from trade mark infringement.

More than half of the articles suspected of trade mark infringements were detained in an import procedure, a quarter in transit procedures and the rest were detained during re-export procedures or were discovered in customs warehouses. (However, EU trade mark law requires the release of goods that are in transit to a non-EU country, even if they are obviously counterfeit – see below.)

Detention on the basis of Patent infringement

In contrast with the position in relation to trade marks, Customs authorities will not usually be on the “look out” for suspected patent infringements unless they have been asked to do so by rights holders, as it involves a technical assessment and is difficult to spot by a lay person.

There was a stark increase in 2008 in Customs detentions relating to patents compared with 2007, but this is thought to be attributable to the consumer electronics industry, being the main category of products involved.

According to the 2008 figures, 6% of all pharmaceutical products were intercepted by Customs authorities on suspicion of patent infringement. Almost all were intercepted in re-export procedures.

Pharmaceutical goods and “goods in transit”

There has been a line of European and English case law surrounding the legal implications of goods seized whilst in transit under a customs procedure and whether this constitutes trade mark infringement. The extent to which the same reasoning is applicable to the infringement of other intellectual property rights, such as patents, however, remains to be considered in depth by the courts.

The European Court of Justice (ECJ) decided in *Class International v Colgate-Palmolive* (C-405/03) and *Montex v Diesel* (C-281/05) that if goods come into the European Economic Area (EEA) under an external transit procedure, they will not infringe the trade mark owner’s rights in the EEA as they do not become “Community Goods” until they are placed on the market. The exception is where there is a proven risk that the goods will “leak” back onto the EU market.

In March 2008, the English Court of Appeal applied this reasoning in *Eli Lilly v 8PM Chemist*¹. The action concerned Lilly’s application for an interim injunction against 8PM Chemist. 8PM’s trade concerned pharmaceuticals ordered by patients in the US

¹ (1) *Eli Lilly and Company (2) Lilly Icos LLC v 8PM Chemist Ltd* [2008] EWCA Civ 24, in which Fasken Martineau acted.

from Canadian internet pharmacies, which came to Lilly's attention when a consignment sent from Turkey was detained by UK customs in transit, on suspicion of containing counterfeits. It did not in fact contain any counterfeits but Lilly, whose branded products were included in the consignment, sued 8PM for trade mark infringement. The High Court granted the interim injunction but the Court of Appeal applied *Class* and *Montex* and ordered the release of the goods. Accordingly, Lilly's action was dismissed, the injunction discharged and an inquiry into damages caused to 8PM by the injunction was ordered. In June 2009, the High Court awarded substantial damages to 8PM, as a result of the wrongly granted injunction.

In the recent case of *Nokia Corporation v Revenue & Customs*², Nokia sought judicial review in the English High Court of a decision by Customs to release a consignment of goods bearing Nokia's trade marks, which were counterfeit. The Court agreed with Customs that they were not empowered or obliged to detain allegedly counterfeit goods that were in transit through the EU, and rejected Nokia's application for judicial review, even though the Judge expressed regret at this outcome.

That decision was appealed by Nokia and, whilst the Court of Appeal considered the High Court Judge's reasoning to be persuasive, on 9 November 2009 they decided to refer questions to the ECJ, having regard in particular to a reference on a similar point in a copyright and designs case by the Belgian court on 4 November 2009³, and because a highly respected judge in the Dutch Court had come to a view effectively contrary to the position adopted by the English High Court. The English Court of Appeal also indicated that it will write to the President of the ECJ to suggest that the English and Belgian references be joined.

The precise form of the questions is still to be confirmed⁴, but they will essentially address whether non-Community goods in transit from one non-Member State to another non-Member State are capable of constituting "counterfeit goods" within the meaning of Article 2(1)(a) of the Regulation if there is no evidence that they will be released into free circulation in the EU or be illicitly diverted onto the EU market.

It seems possible that the ECJ might find a way to authorise detention of obvious counterfeits, such as those in the Nokia case, whilst maintaining the status quo in disputed cases. Whether the ECJ chooses to take this course or not, one thing is clear – the ECJ's response will be of significant commercial impact for holders of intellectual property rights and importers of goods, including pharmaceuticals, worldwide.

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² *Nokia Corporation v Revenue & Customs* [2009] EWHC 1903 (Ch)

³ *NV Koninklijke Philips Electronics v Far East Sourcing Limited* AR No 02/7600/A

⁴ At the time of writing, the form of questions has been agreed by the parties and is being considered by the Court of Appeal.

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