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A coping mechanism

Christopher Stothers and **Lincoln Tsang** explore how pharmaceutical manufacturers can protect their products from parallel importers from new members of the EU

Czechoslovakia first allowed patent protection for pharmaceutical products on 1 January 1991[1]. Over the next four and a half years, various countries in Central and Eastern Europe (CEE) followed suit, with Hungary permitting such protection from 1 July 1994. Protection in the form of supplementary protection certificates (SPCs) followed later, and a full table of the relevant dates is provided below.

Almost a decade later, on 1 May 2004, the first eight CEE countries acceded to the European Union (EU) and the European Economic Area (EEA), with a further two following on 1 January 2007.

Under the rules on the free movement of goods in the EU[2] and the EEA[3], the owners of intellectual property rights cannot exercise those rights to object to the resale within the EEA of pharmaceutical products which had previously been put on the market in any EEA country by them or with their consent. Such rights are "exhausted" in this way even if the owners had no IP rights in the exporting country and so its product was competing there with low price unauthorised products[4].

However, the total length of IP protection for pharmaceutical products can range from 20 years (patent protection only) to 25.5 years (products which qualify for a full SPC with paediatric extension). Therefore, for a significant time there will be pharmaceutical products that do not have IP protection in the CEE countries, but would normally be subject to the free movement rules. At the extreme, a pharmaceutical patent which was filed on 30 June 1994, the day before product protection was made available in Hungary, could potentially be protected until 30 December 2019 in other EU countries.

Pharmaceutical manufacturers were therefore rightly concerned that the accession of the CEE countries to the EU and EEA could lead to a floor of cheap parallel imported pharmaceuticals into the existing Member States, causing shortages in the CEE countries as well as reduced profits overall. The suggestion of the Court of Justice of the European Union that the manufacturer can simply choose whether to sell in countries where patent protection is unavailable, but must accept parallel trade if he does,[5] is not remotely commercial. As a consequence, and as with previous accessions to the EU, transitional provisions were introduced in the following terms:[6]

> **Specific mechanism**
> With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia [or Bulgaria or Romania], the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.
>
> Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.

Table of Dates When Protection Became Available[7]

Country	Product Patents	SPC	SPC only available where
Bulgaria	1 June 1993	1 January 2007	MA obtained after 1 January 2000
Czech Republic	1 January 1991	10 May 2000	MA obtained - after 10 November 1999 in CZ - after 1 November 2003 in EU
Estonia	23 May 1994	1 January 2000	
Hungary	1 July 1994	1 May 2004	MA obtained after 1 January 2000
Latvia	31 March 1993	20 April 1995 *	
Lithuania	1 February 1994	1 January 2002 *	Patent filed after 1 February 1994
Poland	16 April 1993	1 May 2004	MA obtained after 1 January 2000
Romania	21 January 1992	1 January 2007	MA obtained after 1 January 2000
Slovenia	4 April 1992	7 December 2001 *	
Slovakia	1 January 1991	1 July 2002	MA obtained after 1 January 2000

SPC = supplementary protection certification; MA = marketing authorisation
* = possibility to apply for an SPC re-opened upon accession to EU

Analysis

The rules appear to be clear cut. The key dates should be identifiable for any given product and country. Either patent protection (or SPC protection) was available in the exporting country on the date of filing in the importing country or it was not. If not, any importation will infringe the patent or SPC. There has been very little litigation in relation to the Specific Mechanism since May 2004, and consequently limited commentary.

However, this does not mean that patentees can safely ignore the Specific Mechanism.

For instance, it is unlikely that the lack of litigation is due to diligent observation of the rules by parallel importers. In practice, some parallel importers appear to be using the requirement of prior notification as a test of the willingness of patentees to enforce their rights under the Specific Mechanism. Depending on the response they receive, the parallel importer may decide to take a calculated risk to import (despite likely patent infringement if they are sued) or instead to wait until expiry of the patent or SPC rights in the intended country of importation.

In addition, as with SPC protection itself, it is likely that there will

be a gradual growth in litigation as the value at stake increases and interested parties decide to test the limits of protection. For instance, parallel importers may try to argue:

(a) that the pipeline or transitional patent protection made available in some of the CEE countries is sufficient to exclude the Specific Mechanism, even though it was not available on the relevant date of filing;

(b) that the effective scope of granted patents in the exporting country are of sufficient scope that they should be regarded as "such protection" for the purposes of the Specific Mechanism;[8] or

(c) that the Specific Mechanism does not apply because SPC protection was available in the exporting country when the SPC application was filed in the importing country, even in cases where an SPC was not available for the product in question due to non-availability of product patent protection in the exporting country at an earlier date.

There are serious flaws in all of these lines of argument. However, where the potential profit is sufficient, some parallel importers will take the risk that the manufacturer will not successfully pursue them for injunctive relief or damages.

Practical implications

Most pharmaceutical manufacturers are by now used to dealing with frequent parallel import notifications in relation to proposed repackaging of their products. However, Specific Mechanism notifications will be rarer, will arrive earlier and may be dealt with by a different department. Therefore, some guidance on dealing with Specific Mechanism notifications (or potential breach of the Specific Mechanism) may be helpful.

First, a brief but robust response to the notification is advisable, even where there is a general policy of not responding to repackaging notifications, unless it is absolutely plain that the importation would fall outside the Specific Mechanism. Bear in mind that a notification will normally only be made by a parallel importer who perceives a risk that the Specific Mechanism does apply. Given this, such notifications are often speculative and seek to identify which companies are willing to defend their position. There is no need to enter into great detail. An appropriate response may simply confirm that the Specific Mechanism applies and ask the parallel importer for confirmation that the patent and SPC rights will be respected and no authorisation sought (or an explanation of why he says the Specific Mechanism does not apply).

Second, remember that the Specific Mechanism only provides a requirement of notification. If a parallel importer provides evidence that a notification has been made, the regulatory authorities may not seek to rule on the Specific Mechanism, but may proceed to grant the requested authorisation. Therefore, if the importer does not provide the confirmation requested above, ensure that those monitoring parallel import authorisations are aware of the specific risk and will highlight any authorisation immediately to the relevant person so that action under the Specific Mechanism can be taken if necessary.

Third, even if an authorisation is obtained, the repackaging rules still apply. The notification to the patent owner required under the Specific Mechanism does not replace the notification and provision of a sample to the trademark owner required under the repackaging rules. The requirement for notification and a sample should be confirmed to the parallel importer, as the repackaging notification will provide a better indication of whether importation in breach of the Specific Mechanism is truly imminent, allowing the possibility to focus resources on the most serious threats.

Finally, if parallel importation in breach of the Specific Mechanism appears likely, it is important to identify possible arguments by the parallel importer before taking enforcement action. As well as previous correspondence, this is likely to involve considering the detailed timeline, the actual protection held in the exporting country and some or all of the potential arguments outlined above. There may be difficulty or delays in obtaining this information, depending on the strength of internal record-keeping for activities in the CEE countries in the early 1990s. However, early identification is crucial as these factors will form important inputs for the cost-benefit analysis not only of taking action but of seeking interim or summary relief to prevent the parallel imports.

Footnotes

1. Less than a year before the formal dissolution of the Soviet Union and two years before Czechoslovakia split into the Czech Republic and Slovakia.
2. Now found in Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU), published in consolidated form at [2010] OJ C53/47, which replaced the Treaty establishing the European Community from 1 December 2009 as a result of the entry into force of the Treaty of Lisbon [2007] OJ C306/1.
3. Articles 11-13 of the Agreement on the European Economic Area [1994] OJ L1/3.
4. Case 187/80 *Merck & Co v Stephar* [1981] ECR 2063; see also Joined Cases C-267/95 and 268/95 *Merck & Co v Primecrown* [1996] ECR I-6285.
5. Case 187/80 *Merck & Co v Stephar* [1981] ECR 2063, para 11.
6. Act of Accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia [2003] OJ L236/1, Art 22 and Annex IV.2; Act of Accession of Bulgaria and Romania [2005] OJ L157/11, Art 21 and Annex V.1. The specific mechanism does not apply to Cyprus or Malta.
7. See Feddersen [2003] EIPR 545; Lemaire [2005] EIPR 43; Regulation 469/2009 [2009] OJ L152/1, Article 20.
8. For instance, patentees in Spain have successfully argued that the TRIPs Agreement means that pharmaceutical product patents filed before they were permitted in Spain (7 October 1992) are now valid: *Ratiopharm España v Warner-Lambert* (26 October 2006, Madrid Court of Appeal); *Eli Lilly v Cinfa et al* (17 January 2008, Barcelona Court of Appeal). See Valls & Zamora, "Recent developments in Spanish Patent Law", in Osterrieth et al, "Patentrecht - Festschrift für Thomas Reimann" (Carl Heymanns Verlag, 2009), 501-510. Parallel importers might try to assert similar arguments in CEE countries.

Authors

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