Is the Specific Mechanism Achieving its Objectives of Preventing “Unfair” Parallel Trade?

Introduction

The Accession of ten “new” Member States¹ (MS) to the European Union (EU) on 1st May 2004 was greeted with acclaim on the streets of Warsaw and Bratislava. The EU pharmaceutical industry however, remained reserved, fearing that enlargement would bring with it an erosion of patent rights in the “old” Member States².

The concerns arise from three main factors:

- the peculiarity of the pharmaceutical sector whereby the price of medicines is mainly fixed by the national authorities;
- the socio-economic disparities between the “new” and the “old” MS resulting in considerable variations in the price of medicines; and
- the differences in the level of patent protection afforded to some medicines in the “new” MS compared to that prevailing in the “old” MS.

The pharmaceutical industry was therefore worried that enlargement would result in a flood of parallel trade of medicines between “new” MS (generally lower priced countries) and “old” MS (generally higher priced countries). In order to remedy this undesirable outcome, the pharmaceutical industry successfully pressed for and obtained the insertion of a specific mechanism in the Accession Treaty³ governing the entry of the “new” MS into the EU.

This article aims to explain how the Specific Mechanism works, highlight the difficulties arising from its implementation and consider whether it is proving effective in practice.

Background

Since 1 May 2004, any commercial activity among economic players in the enlarged EU is governed by EU law. EU law embraces two key concepts: the principle of free movement of goods (expressly provided for in the founding Treaty of Rome) and the principle of exhaustion of IP rights (developed in the jurisprudence of the European Court of Justice (“ECJ”)).

Briefly, the conjunction of these two principles means that a medicine placed in the EU by the patent holder (or with its consent) should be able to circulate freely within the EU. Therefore a medicine placed in the market of a “new” MS should be able to be imported into another MS (as long as the medicine is registered in the importing country). The patent holder will not be able to invoke its patent rights to oppose such imports.

The Specific Mechanism provides under certain circumstances for a derogation from the application of these two key principles, by setting up a mechanism which entitles the patent holder to prevent the importation of patented pharmaceutical products.

The Specific Mechanism

This is not the first time that the EU has attempted to prevent the erosion of patent rights resulting from the enlargement of the EU. A similar provision was inserted in the Accession Treaty of Spain and Portugal⁴. However, that mechanism was heavily criticised by the pharmaceutical industry for

¹ Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia, Slovakia.
² Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, Netherlands, Spain, Portugal Greece, Sweden, Ireland, Italy, United Kingdom.
³ Chapter 2 to Annex IV of the Act of Accession signed on 16 April 2003.
providing insufficient protection, due in particular to its limited temporal application. The “new” Specific Mechanism is unlimited in time\(^5\) and reads as follows:

> With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent of supplementary protection certificate for a pharmaceutical product filed in a Member State at the time when such protection could not be obtained in one of the above mentioned “new” Member States for that product, may rely on the rights granted by the 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.”

The wording of this provision, which at first glance looks clear, raises a number of issues which then give rise to a further number of questions. A number of these key issues will be addressed below.

**The Conditions for the Application of the Specific Mechanism**

This provision provides for a derogation from the principles of free movement of goods and exhaustion of patent rights. The import of a medicine falls within the scope of the mechanism if:

- the import at stake falls within the geographic scope of the provision;
- it was impossible to obtain a patent or supplementary protection certificate (“SPC”) for the pharmaceutical product in the “new” MS at the time when a patent or SPC was filed for the same product in the MS of import; and
- a patent is in place in the MS at the time of importation of the pharmaceutical product from the “new” MS.

The first two points require some further analysis.

**(i) Geographic Scope**

The Specific Mechanism only applies if the medicine originates in one of the “new” MS (except Malta and Cyprus) and is imported into another MS.

One issue which is likely to arise in litigation is what is meant in the provision by the term “Member States”. Does this embrace the 10 “new” MS or does it only relate to the “old” MS?

The Accession Treaty does not define the term “Member States”, so one could argue that this means any of the 25 EU MS.

However, one could also argue that the spirit behind the derogation was to avoid the erosion of patent protection in the “old” MS due to the enlargement by the 10 “new” MS, where the same level of patent protection in these countries was not available at the time the patent holder filed its patent application. This issue may not be relevant for that many products as patent protection in the 8 “new” Central European Member States became available between January 1991 (Slovakia/ Czech Republic) and July 1994 (Hungary). However, it is possible that this issue could arise for example with exports from Hungary into Slovenia or from Poland into the Czech Republic.

Another issue would be whether this provision would apply in the case of parallel imports from these eight “new” MS into an EFTA country party to the EEA Agreement\(^6\)? EFTA countries party to the EEA Agreement are party to the EEA Agreement.

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\(^5\) The Specific Mechanism will last for the life of a patent and/or a supplementary protection certificate, if these fall within the application of the Specific Mechanism.

\(^6\) Iceland, Liechtenstein and Norway are the EFTA contracting parties to the EEA Agreement.
Agreement are clearly not covered by the provision. However, a statutory instrument extends the scope of the Specific Mechanism to the EEA territory.7

Summary of the Geographic Scope – Is the Specific Mechanism Applicable?

Is there a risk that an ingenious parallel importer will try to bypass the Specific Mechanism by trying to transit via a MS outside the scope of the provision (e.g. Cyprus or Malta which are not within the scope of the provision (as explained above) or an “old” MS where no protection is in place)? In such circumstances, the competent authorities are likely to conclude that the parallel importer is simply trying to circumvent the derogation put in place by the Accession Treaty and the rule of origin, meaning, that what is relevant is the country where the product was originally placed in the market and not the latest country from which it is imported (see Figure 2 below).

(ii) What Type of Patent is Covered by the Specific Mechanism?

The Specific Mechanism concerns pharmaceutical products which have been placed on the market of the 8 “new” MS at a time when there was no similar patent or SPC available in those countries (from the wording of the Specific Mechanism “such protection could not be obtained”). In order to assess whether the Specific Mechanism is applicable to a specific case, it will be necessary to determine

whether patent protection was available in those countries\(^8\) and whether the patent protection available was similar.

Once again the Treaty does not define the term "patent". What type of patent is the Specific Mechanism referring to: product patent, formulation patent, process patent?

Patents are national rights which are enforced by national courts. Therefore, this issue would be a matter for national courts which may ultimately refer the interpretation of the Specific Mechanism to the ECJ.

However, the report on the results of the negotiations on the Accession prepared by the European Commission seems to refer to product patents. This means that the Specific Mechanism is likely to apply to formulation patents which are product patents but the question remains as to whether it would also apply to process patents should be considered as similar to patent protection already in place in the importing country.

**What are the Obligations of the Parallel Importer?**

The second paragraph of the provision provides that a parallel importer who intends to import a pharmaceutical product covered by the Specific Mechanism must:

- notify the patent (or SPC) holder or the beneficiary of its intention to import a pharmaceutical product; and
- demonstrate to the competent authority that the patent holder or beneficiary has received "one month's prior notice".

**(i) What would Constitute Proper Notification?**

The notification requirement is crucial for the pharmaceutical industry as the absence of a notification requirement was one of the weaknesses of the mechanism introduced in the Spanish and Portuguese Accession Treaty.

Under the “new” mechanism, patent holders have the option to launch legal proceedings in order to prevent the importation of the medicine. This is clearly a better option, as under the previous mechanism the patent holder was only able to react once it became aware of the illicit importation.

The parallel importer is under an obligation to notify the patent holder or beneficiary and to demonstrate that such notification has taken place one month prior to the import licence application being submitted.

Does this imply that the competent authority has an obligation to assess whether the relevant entity has been notified? In practice, it seems that the competent authority (often a regulatory authority e.g. the MHRA in the UK) will find it difficult to assess whether the relevant entity has been notified as it will not have direct access to the name of the entity holding the patent (patent office) or its beneficiary. Therefore one could assume that a parallel importer could be required to submit with its application for an import licence, a copy of the official registry confirming the identity of the patent holder or beneficiary.

What would then be the consequence of an erroneous notification? One could argue that the import licence, if issued, should be withdrawn by the competent authority. Certainly the period of one month’s prior notification should not start to run until the relevant entity has been properly notified. However, there is no clear guidance on any of these points.

**(ii) What should be the Content of the Notification?**

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8 The product patent protection was introduced in the “new” Member States at the following dates: Czech Republic & Slovakia (January 1991); Slovenia (April 1992); Latvia (March 1993); Poland (April 1993); Lithuania (February 1994); Estonia (May 1994); and Hungary (July 1994) (Malta and Cyprus?)
Although the wording of the provision does not expressly describe the content of such a notification, the well-know principle of "effet utile" (principle of effectiveness) requires that the notification should indicate at least:

- the medicine concerned by the importation;
- the country of origin; and
- the country of import.

If the notification does not contain the above mentioned information, the application for an import licence should be sanctioned in the same way as discussed above.

(iii) Is the Patent Holder (or Beneficiary) Waiving its Patent Rights by not Reacting within the One Month Period?

The use of the word “may” indicates that the patent holder has the option of opposing the importation, but is by no means obliged to do so. Would the patent holder lose the right to enforce its patent rights if it does not start proceedings within the period of one month of prior notification? The answer may well be by analogy of the application of the jurisprudence of the ECJ in trademark cases. Here, the ECJ has ruled that the silence of a proprietor does not constitute a waiver of its IP rights. However, by failing to react within this one month period, the patent holder will make it more difficult for itself to obtain an interim injunction from a national court or could even reduce the amount of damages awarded, as the judge may consider that the patent holder has not used its best endeavours to mitigate its loss.

How can a Patent Holder Enforce its Patent Rights?

The normal route would be for the patent holder to start proceedings against the parallel importer before the national court in the country where it intends to enforce its patent rights. The patent holder (or the beneficiary) would be entitled to rely on the Specific Mechanism, since although it is a provision of the Treaty of Accession of the “new” Member States, the provision is sufficiently clear, precise and unconditional and can therefore be directly invoked and applied by EU national courts.

The patent holder will have to demonstrate that the importation falls within the Specific Mechanism and that it is entitled to prevent the importation of the pharmaceutical product concerned. If the proceedings require the interpretation of EC law, the matter will ultimately be referred to the ECJ in accordance with Article 234 CE.

The patent holder could also try to launch proceedings against the competent authority for an erroneous application of EC law (for example, by not investigating whether proper notification has actually been given to the patentee). However, such proceedings are uncertain since the obligations of the competent authorities are not expressly set out in the Specific Mechanism.

The Commission has another course of action against a MS which does not implement the Specific Mechanism, namely under Article 226 EC. If the MS is condemned by the ECJ for failure to implement the Specific Mechanism, the patent holder will be able to seek damages from the MS in question.

Conclusion

The Specific Mechanism has clearly rendered illegal attempts to import medicines falling within its scope. The very existence of a legal remedy embodied within the Specific Mechanism may, in certain cases, have acted as a disincentive to parallel importers. Therefore in this respect, the Specific Mechanism has achieved its objectives.

In practice, however, parallel importers have been sending speculative letters to pharmaceutical companies informing them of their intent to import and waiting for the companies to write back threatening legal action under the Specific Mechanism.

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The Specific Mechanism is a crucial instrument for the pharmaceutical industry in trying to preserve its patent rights. Considering the lack of clarity of some of the terms of the provision, it would have been expected that the implementation of the Specific Mechanism would generate a lot of litigation in relation to its application. However, this may not happen as pharmaceutical companies do not like to expose valuable patents to litigation in relation to parallel imports and the ECJ may soon confirm the Opinion of Advocate General Jacob in a recent case relating to stock management programmes. It if does, then this is likely to result in economic measures being put in place by pharmaceutical companies limiting the volume of medicines supplied to a specific territory. This will then have the effect of substantially limiting parallel imports.

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10 Case C-53/03, Synetairismos Farmakopoion Aitolias & Akarnanias (Syfai) and Others v. GlaxoSmithKline AEVE, available on http://www.curia.eu.int/