CMDh Questions & Answers on Usage Patents

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‘Usage’ Patents claim novel ‘uses’ (indications, formulations, routes of administration, dosage schedules, patient populations etc.) for known / already patented active substances.

To the extent that the ‘usage’ patent satisfies the requirements for a valid patent, it confers an independent full period of patent protection in relation to the claimed invention.

This can give rise to potential patent infringement in the event that a generic of an innovator product for which the initial patent protection period has expired but which is still protected by a ‘usage’ patent is authorised by a competent authority which would normally require the generic authorisation to
conform to that of the innovator with respect to the summary of product characteristics and package leaflet and labelling as appropriate.

There is a non-harmonised approach across the EU with respect to national patent office approaches to granting ‘usage’ patents resulting in a typical differential ‘usage’ patent status across the EU. This in itself could lead to difficulties in operating the mutual recognition procedure (MRP) and decentralised procedure (DCP) for generic products where such patents are established. In an attempt to address this problem the European Commission introduced changes in the Review of the legislation.

**Directive 2001/83/EC**

**Art. 11:**

The summary of product characteristics shall contain (...) the following information: (...) For authorisations under Article 10, those parts of the summary of product characteristics of the reference member medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

**Question 1**

1. *Can an approval of a medicinal product be granted even if some parts of the summary of product characteristics of the reference product are under patent?*

Yes, there is no change with regard to the previous legislation. However, Article 11 of Directive 2001/83/EC allow marketing authorisation holders to exclude those parts from the product information (summary of product characteristics, package leaflet and labelling) referring to indications or dosage forms still covered by patent law.

**Question 2**

Is it possible not only to delete the patented indication, but also to change/delete further sentences in other sections directly connected to this patented indication, e.g. in posology, contra-indications or warnings?

**Answer:** The Directive states only the exclusion of information referring to indication and dosage forms. Any other deletion connected to the patented indications or dosage forms must be properly justified and discussed with the member state concerned.

**Question 3**
Has the Coordination group for mutual recognition and decentralised procedure (CMDh) agreed any standard statement to explain to patients why therapeutic indication(s) or dosage form(s) may be lacking in the package leaflet?

**Answer:** The CMDh acknowledges that it is a national decision of Member States (MSs) to include a statement to explain why therapeutic indication(s) or dosage form(s) may be lacking in the package leaflet.

However, the CMDh has agreed on the following standard statement to be included in the package leaflet of the MS requesting this information, using the ‘blue box concept’:

‘(Active substance) which is contained in (product) (may also be/is also)* authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.’

* (as appropriate for the national market)

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**Question 4**

2. In MRP or DCP the patent protection situation could be different among MSs. Which summary of product characteristics is the basis for the evaluation and recognition by the concerned member states (CMSs) for an application according to Article 10(1)?

**Answer:** The basis of an application according to article 10(1) is the summary of product characteristics of the reference medicinal product in the reference member state (RMS) (or the summary of product characteristics of a European reference medicinal product in cases where no reference products exists in that MS). The patent situation in the different MSs concerned by the application do not have an impact during the MRP/DCP itself as this is out of the scope for competent authorities when evaluating the documentation. No information due to a ´usage patent´ will be deleted in the final common product information (summary of product characteristics, package leaflet and labelling) in English recognised by all member states concerned at the end of a successfully concluded MRP/DCP.

**Question 5**

3. How should the authorities know which product information to approve nationally if some indications/dosage forms should be deleted in a MS?

**Answer:** The MSs will recognise the final summary of product characteristics, package leaflet and labelling including all indications and dosage forms but it is up to the applicant to inform the authorities of the modifications needed to the final national approval taking into account the patent situation. This must be finalised within 30 days from the end of the MRP or DCP procedure which means it is important for the applicant to inform the national competent authorities as soon as possible, preferably when the national translation is submitted.

**Question 6**
4. Is it possible not only to delete the patented indication, but also to change/delete further sentences in other sections directly connected to this patented indication, e.g. in posology, contra-indications or warnings?

The Directive states only the exclusion of information referring to indication and dosage forms. Information directly related to the patented indication can be deleted from sections 4.1 Therapeutic indication, 4.2 Posology and method of administration and 5.1 Pharmacodynamic properties of the SmPC, unless the information could be considered necessary for the safe use of the medicinal product. An indication may be deleted, but not modified. For public health reasons, safety related information in sections 4.3 to 4.8 of the SmPC should be maintained. Any other deletion connected to the patented indications must be properly justified by the applicant and discussed with the member state concerned preferably already during the assessment phase. A member state who receives such request is advised to discuss any uncertainties in the assessment in CMDh before taking a decision.

5. Which version of the product information will be published?

Answer: The final common product information (summary of product characteristics, package leaflet and labelling) will be published in the MRI Product Index.

It is up to the national competent authorities to publish the national product information according to national practise, but the product information published will be according to the national marketing authorisation.

6. Has the Coordination group for mutual recognition and decentralised procedure (CMDh) agreed any standard statement to explain to patients why therapeutic indication(s) or dosage form(s) may be lacking in the package leaflet?

The CMDh acknowledges that it is a national decision of Member States (MSs) to include a statement to explain why therapeutic indication(s) or dosage form(s) may be lacking in the package leaflet.

However, the CMDh has agreed on the following standard statement to be included in the package leaflet of the MS requesting this information, using the ‘blue box concept’: '(Active substance) which is contained in (product) (may also be/is also)* authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.’

*(as appropriate for the national market)

7. What will happen with the authorisation when the patent expires in a specific MS?

Answer: The marketing authorisation holder must contact the national competent authority and propose revised product information. A national notification/variation procedure has to be used. For the procedure to follow please consult the MS concerned.

Question 7
8. Is it possible to delete one of the indications of a medicinal product already authorised via MRP or DCP due to patent law?

Answer: Yes it is possible. The MAH has to inform the national authority on a pure national level. A national notification/variation procedure due to national legislation has to be used for this issue.

9. How will the marketing authorisation for a patented dosage form be handled?

The marketing authorisation for the dosage form will be issued but at the discretion of the MAH not to place the product on the market until the patent has expired. This is a case where exemptions from the sunset clause are applied.