SPCs - Advanced manufacturing waiver

Dr Gareth Morgan
What is the issue?

- SPC rights within the EU often expire after ex-EU rights

- Places EU generic/biosimilar industry at a disadvantage in the global marketplace

- Ex EU-based generic manufactures have a head-start in ex-EU early entry markets

- Is it a desirable/intended result of the SPC right?

- Main stated aim was to compensate MA holders in the EU marketplace for delays incurred generating data to approve products
What is the suggestion?

- To provide a carve-out from the SPC right to permit EU generic/biosimilar manufacturers to compete on a level playing field with ex-EU manufacturers

- This would necessarily impact the scope and/or acts of infringement attaching to the SPC

- Significant issue as it goes to the heart of the right created

- No longer would the SPC have the same legal scope as the patent
Is this really being considered?

• European Commission is keen on this idea

• Recent staff working document outlines this project as a priority

• Could/likely to form part of the workplan of the next Commission

• Could be implemented through an amending Regulation
What about the Parliament?

• Parliament has approved in committee and full session a report calling for this right to be created

• Since the “Moscar report” was approved MEPs have tabled a series of questions to the Commission

• Maintaining pressure on intent and timelines
Example question

In May 2015, Parliament’s Committee on International Trade expressed to the Commission its position of support in favour of the SPC export exception.

The SPC export exception will allow pharmaceutical compounds and/or generic medicines to be exported during the SPC period to third countries where no patent or extension of the patent is in place. This will help stimulate growth in pharmaceutical production in Europe, creating thousands of jobs and producing more high quality knowhow.

— What is the Commission’s position regarding the SPC export exemption?
— Will the Commission grasp this opportunity to boost the European generic medicine industry and the business of European manufacturers of active pharmaceutical ingredients?

Ramon Tremosa i Balcells (ALDE)
Example answer

The Commission is aware of the interest that the European Parliament Committee on International Trade has expressed in the need of the EU based generic pharmaceutical industry to benefit from a so-called export waiver to supplementary protection certificates (SPC). The current SPC regulatory framework does not allow for this. Any potential Commission initiative to change the current framework will have to be preceded by profound analysis and evaluation of the SPC legislation and subsequent consultations with SPC stakeholders.

Answer given by Ms Bieńkowska on behalf of the Commission
What is the likely timetable

• A consultation phase will likely follow

• EGA is keen on this idea

• Commission sees this as an opportunity for EU manufacturing industry when global markets will likely see a rise in use of generic medicines in the coming years

• The EU legislative process is likely to take a number of years at the fastest – possibility for 2019?
What are the main issues?

• How to distinguish between manufacturing for export and stockpiling – introduces additional evidential and intent issues into infringement analysis

• Will such a waiver make launches at risk easier?

• Does it make SPCs less politically justifiable within the EU?

• What is the impact on EU patentees in their ex-EU markets and is this measure proportionate?
Points to watch in the proposal

• Assuming that a proposal is coming…..

• What will be the justification – evidence currently being collated

• How will the waiver be implemented – assume an amending EU Regulation

• Will it include any formal audit or disclosure provision?

• Will the introduction of the waiver result in increased litigation?
For more information
please contact:

Dr Gareth Morgan
+44 207 067 3267
Gareth.Morgan@olswang.com

Brussels
+32 2 647 4772

London
+44 20 7067 3000

Madrid
+34 91 187 1920

Munich
+49 89 203 031 300

Paris
+33 17 091 8720

Singapore
+65 6720 8278

Thames Valley
+44 20 7067 3000

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