European Federation of Pharmaceutical Industries and Associations

31 January 2015

COMMENTS

CONSULTATION / PATENTS AND STANDARDS, A MODERN FRAMEWORK FOR STANDARDISATION INVOLVING INTELLECTUAL PROPERTY RIGHTS

Respondent Profile

- The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.
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Comments

The European Federation of Pharmaceutical Industries and Associations ('EFPIA') thanks the Commission for the opportunity to comment on the issue of patents and standards and how to provide a modern framework for standardisation involving intellectual property rights. Operating in an industry not depending on standards, EFPIA would only like to flag a limited number of comments to the attention of the Commission.

The 2013 study on "Patents & Standards" ('the 2013 Study') rightly points out to standardisation as an essential driver of innovation, as a means to facilitate market adoption of innovative technologies by establishing the conditions for inter-operability. Efficient licensing of patent-protected technologies included in these standards is an essential pre-condition for the success of standardisation processes. Ensuring an appropriate balance between incentives to invest in developing new technologies and the wide diffusion of knowledge is critical.

To that purpose, while we appreciate the value of thinking out-of-the-box and looking at experiences and lessons from non-standard dependent industries, we would like to urge caution as to drawing analogies between industries that rely on standards and those that don't. Though different industries can be perceived as having similar issues, the variety of situations and objectives should not be overlooked when considering such analogies. Therefore, we believe any conclusion or recommendation from this survey should not be extended to industries not relying on standards. As points of distinction, EFPIA notes that whereas the rationale for integrating patent-protected material in standards is often to bring together, from their many different owners, all the assets relevant to a particular technology, it is normally the case in pharmaceuticals that the final product is covered by a limited number of patents owned by the same entity or entities which have entered into a limited number of bilateral licensing arrangements.

On key issue 1 – Fields of standardisation involving patents

M-health agenda: In the framework of the eHealth Action Plan 2012-2020 and in response to the Public Consultation on the European Commission's Green Paper on mobile health, EFPIA

supported collaboration to increase interoperability of apps and devices, especially in terms of data collection, format and analysis. As this collaboration develops, it may rely on a limited standardisation process involving intellectual property rights. However, EFPIA believes that interoperability should remain a secondary consideration to a given healthcare solution's effectiveness.

On key issue 3 – Patent transparency

The 2013 Study suggests that non-standard dependent industries experience similar IP-related problems as standard-dependent industries, inhibiting efficient licensing opportunities and thereby standardisation processes for the latter and innovation in both. These problems reportedly include 1) a large number of patents, 2) the lack of transparency as to patent information, be it existence, validity or scope and 3) royalty-stacking.

The 2013 Study suggests that patent thickets and as a consequence, royalty stacking exist in the pharmaceutical industry (p. 214), though the particulars of this latter are not discussed at length.

We would like to highlight the fact that patent thickets have different meanings to different companies and industries. However, based on the definition provided in the consultation document, i.e. "a situation where a multitude of patents bear on a specific product and where these patents are held by different entities", we do not believe that patent thickets exist in the pharmaceutical industry. Each medicine is covered by a limited number of patents only, mostly owned by the same entity or entities, which have entered into a limited number of bilateral licensing arrangements. Hence it is relatively straightforward to identify existing patents covering a product, as well as their scope, validity and ownership. As a consequence, we do not agree that patent thickets or royalty stacking are an issue in the pharmaceutical industry.

The situation in our industry is far from being comparable to the situation in e.g. the industry of information and communication technologies. The different structural market features of the pharmaceutical industry are partially acknowledged in the 2013 Study[1] and we would urge the Commission to account for these fundamental differences and not to draw hasty or overbroad conclusions on IP-related problems and especially the lack of patent transparency for non-standard dependent industries that were not the focus of the 2013 Study.

- **Patent landscaping initiatives.**

In our industry, in-house and service providers are used extensively in the pharmaceutical industry and commercial operators do not have significant difficulties in establishing the IP surrounding a product at the point at which it becomes available for generic production.

On key issue 5 – Patent pools

One of the solutions suggested by the 2013 Study to address the challenges of sub-optimal licensing conditions in standard-dependent industries are collaborative licence programs, i.e. patent pools.

The example of the Medicines Patent Pool ('MPP') is developed as far as pharmaceuticals are concerned. As pointed out in the 2013 Study, the MPP aims at accelerating access to a number of treatments in low-income countries by facilitating partnerships and lowering transaction costs. As such, it plays the role of an intermediary agent. Its nature, its role as well as the incentives for and obligations of companies to participate to the MPP are therefore very

[1] The 2013 Study, p. 220, 4th paragraph, points to examples of combination treatments, for which around 20 patents only are to be licensed.

different from the role of pools in standard-setting processes. The MPP is playing a valuable role at the intersection of two market failures (neither of which is related to patents or standards). The first is the lack of effective market demand in the beneficiary countries and the second, associated issue, is the signalling of specific medical needs. Caution should also be employed in describing treatments as "standards" as this understates the extent to which medical use of specific medicines can evolve over time.

Traditional pools in the sense of standard-setting processes would make little sense in the pharmaceutical industry, where the number of patents, of licensors and licensees as well as the level of inter-dependence between the different patents are too low to justify a pool. Hence such an example should be handled with care.

Whereas standardisation – and pools as a facilitating tool thereof – aims at spurring innovation by enabling efficient cross-licensing and thereby ensuring inter-operability, pools are rarely needed in our industry. Because the level of interdependence between technologies is low, companies increasingly focus on early collaboration schemes through research partnerships to speed up innovation while optimising resources, e.g. IMI and IMI2.

On key issue 7 – Patent dispute resolution

Although the experience of the pharmaceutical industry is not directly applicable to the resolution of disputes relating to standards-essential patents, we endorse the need for timely resolution of patent disputes.