Policy Position

EXPORT MANUFACTURING EXEMPTION DURING SPC/PTR EXTENDED PATENT TERM: GLOBAL POSITION

The Issue

Proposals have been made recently[1] to introduce a manufacturing exemption during the term of protection granted by incentive mechanisms, such as the Supplementary Protection Certificate (SPC) and Patent Term Restoration (PTR)[2]. These mechanisms are critically important to preserve incentives to develop new medicines and distribute them to patients by compensating for erosion of the patent term due lengthy testing requirements before an MA can be obtained.

Such proposals would provide an exception to existing norms of intellectual property protection by allowing generic and biosimilar producers to manufacture pharmaceutical products during the SPC/PTR term for export to countries where no patent or other relevant intellectual property rights protecting concerned products are available, or where these rights have expired.

The Industry's Position

IFPMA members view these proposals with significant concern and are therefore opposed to them. For the reasons stated below, we advise against the adoption of these or similar proposals which would weaken the incentive regime.

The research-based pharmaceutical industry needs strong incentives

- Intellectual property rights, especially patents, incentivize and enable research and development that delivers valuable new medicines to patients who need them. Patents help give biopharmaceutical innovators the certainty they need to invest the significant resources it takes over many years to develop new medicines and demonstrate that they are safe and effective. As such, intellectual property rights are the backbone of the research-based pharmaceutical industry**.**

- SPC/PTR mechanisms are designed to compensate for the erosion of the standard patent term due to the lengthy development, testing and regulatory approval timelines in the pharmaceutical sector. To fulfill this purpose, the legal protections afforded during the SPC/PTR term should be the same as those afforded during the regular patent term.

- Undermining the right to exclude others from manufacturing, which a patent confers, weakens patent exclusivity rights – those very rights needed to incentivize knowledge-based investments and affect innovation.

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[1] For instance, see EGA's statement: http://www.egagenerics.com/index.php/press-room/press-releases/2015/487-spc-manufacturing-waiver-urgently-needed-to-stimulate-pharmaceutical-manufacturing-in-europe. Considerations by IP Australia: http://www.pc.gov.au/__data/assets/pdf_file/0006/194469/sub023-intellectual-property.pdf , pp 9-10.

[2] Many countries provide similar mechanisms. For instance, Japan and Australia afford Patent Term Extension (PTE). Although each mechanism is slightly different, they all have the same policy objective: to provide incentives for the research and development of medicines by extending the exclusivity period for innovative companies to partially offset the complex regulatory requirements inherent to obtaining marketing approval of pharmaceutical products.

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Practical challenges

- IFPMA members believe it would be difficult and burdensome, if not impossible, to enforce such a measure to ensure that products manufactured under this exemption are only exported to, and remain in countries without patent protection.

- For example, it would be difficult to distinguish whether manufacturing activities are carried out for export to countries without IP protection, in support of export to countries where there is still IP protection or to impermissibly stockpile products for commercial purposes in the country of manufacture. This alone would render enforcement of IPRs more burdensome and increase litigation costs.

- A further complexity arises with respect to cross-border trade in a regional market, as the absence of internal customs would make it difficult to prevent product diversion, further frustrating the purported purpose of the proposals.

- It also may be difficult and burdensome, if not impossible, to limit the proposals to their intended purpose. Among other potential enforcement issues, there would need to be strict obligations to ensure that products only reached permitted countries, for example by requiring the originator to be notified of quantities produced and the destination of those products, requiring compensation to the innovator, and requiring affirmative steps to prevent diversion. These considerations underscore the complexity of this matter, and it is our view that such proposals should be rejected as causing unintended consequences not narrowly tailored to the asserted objectives of the proposals.

- Furthermore, there are risks of facilitating infringement in importing countries, e.g., where other relevant patents may be unknown to the manufacturer, where IP rights are pending but not yet granted or where appropriate enforcement is not available. If such an exemption were in place, it would be difficult or impossible for the courts in the country of manufacture to assess the existence or validity of patents in the importing countries and act to prevent potential infringements.

Conclusion

The pharmaceutical industry is a strategic, knowledge-based, IP-intensive industry, which delivers new medicines for today and the future. It creates a significant number of jobs and fosters growth worldwide. Such proposals that weaken the current IP framework risk jeopardizing innovation and consequently undermine patients' ability to access new treatments.

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