Industry Blames Weak EU Patent System for Generic Drug Delays

"The introduction of patent linkage presents the single biggest barrier to generic competition," said Greg Perry, director general of the European Generic Medicines Association (EGA), launching a report on patent-related barriers to market entry for generic drugs in the EU on 2 June 2008.

Patent linkage, which is not part of current EU pharmaceutical legislation, is the practice of linking market approval for generic medicines, as well as their pricing and reimbursement status, to the patent status of the original reference product. It prohibits granting market authorisation to generic drugs until all original drug patents have expired and it has been determined that the patents are not being infringed, invalid or unenforceable.

According to the EGA, the national medicines agencies, who decide on the authorisation, are under growing industry pressure to apply this complex practice, but lack clear rules on how to apply it. This obliges them "to make ill-informed judgements on complex patent issues that normally can only be determined in specialised courts". The EGA argues that the patent linkage "is inconsistent with European law" and must not become regular practice to ensure that "no hurdles exist to hinder the access of generic medicines to markets immediately upon patent expiry".

The report lists a number of other ways in which patents are used "to prevent innovation and competition rather than to stimulate the creation of truly innovative products". These include granting patents for "poor quality follow-on patents" created in quantities "in the hope that at least one of them will be granted and survive a litigation challenge". According to the EGA, this is to a large extent due to a lowering of the patentability requirements, in particular regading to their innovativeness.

Furthermore, the association argues that patent holders "abuse" the judicial system as they unduly delay solving patent litigation procedures introduced by generic companies in order to maintain the existing advantageous status quo. Altogether, these hurdles point to the legal and regulatory framework around the European patent system failures to ensure an "appropriate balance between incentives and competition".

Earlier this year, the Commission raided the offices of a number of top pharmaceutical companies to find out whether anti-competitive practices in the sector had hindered innovation and blocked the entry of cheap generics on the European market. The EU executive said the sectoral inquiry was launched as it had indications of commercial practices by pharma suppliers, such as patenting or the exercise of patents, which "may not serve to protect innovation but to block innovative and/or generic competition".

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