EFPIA Proposal for Increased Transparency of Key Medicines Patents to Facilitate Early Resolution of Patent Disputes

Objectives. The core policy objective for the proposal is to increase legal certainty for both innovators and generic manufacturers before generic launch. By enabling commencement of infringement proceedings at an earlier stage than is possible today, it would be hoped that many disputes could be resolved before generic launch, thereby providing certainty to generics as to the legality of their launch plans and preventing any irreparable harm from being caused to the innovators through the premature launch of infringing products.

In addition, it would rectify a current systemic imbalance arising from the facts that:

(i) A generic company can but has no obligation to 'clear the way' at any time to achieve legal certainty (e.g. by seeking to revoke a patent) whereas the patent owner cannot initiate legal proceedings for infringement until commercialization is imminent and that

(ii) Pre-trial interim relief (of the kind needed to prevent an imminent launch) is often practically not available to the innovator even if the generic has made no attempt to clear the path.

Though – rectifying this imbalance – the ERM would primarily be a procedure of benefit to innovators, enhanced legal certainty would definitely benefit both sides of the industry as well as national health systems and all other stakeholders:

(i) **For innovators**, the system would ensure effective protection of intellectual property rights and protection from the irreparable harm caused by generic entry at risk in the many cases when injunctive relief is practically unavailable and where the innovator subsequently wins at trial;

(ii) **For generics**, early resolution removes risk and provides the legal certainty of a secure IP position within which multiple generics can invest to bring a product to market. Any IP challenge will be the subject of a full review of fact and law, rather than the necessarily limited *prima facie* factual and legal review involved in hearings for interim relief;

(iii) **For regulators**, the increasingly scarce administrative resources of authorities would be reserved for applications where the generic company has the opportunity to assure itself of the IP position. Administrative bottlenecks caused by speculative applications for "at risk" products would be reduced or eliminated. Regulators and authorities would not be concerned by patent issues because such issues would be the subject of early resolution by an expert judicial tribunal;

(iv) **For national health systems**, there would be increased certainty as to the availability of generic alternatives to innovative products, the time at which such generic products are likely to become available and that the supply of such medicines would not be interrupted by subsequent IP challenges. This will significantly help with the forward planning of medicines budgets and will allow health system resources to be more efficiently deployed;

(v) **For patients and society,** the uncertainties over sources of supply associated with an unpredictable transition from the exclusivity period to the post-exclusivity period would be reduced.

Finally, such an improved enforcement mechanism would align European pre-launch litigation opportunities and conditions with its trade partners, be it the U.S., Japan or Korea, which all benefit from mechanisms to the same effect. However, in contrast to their linkage system, EFPIA's Proposal does not interfere with regulatory procedures and only involves medicines agencies to a very limited extent. It instead relies on ordinary judicial patent dispute resolution procedures, but changes the timing of dispute resolution to achieve more legal certainty.

Our Proposal is summarised and presented in details below.

The ERM process – Overview

The ERM enables the innovator to initiate patent infringement litigation from the moment a generic company applies for a marketing authorization in cases where this latter would have failed to clear the way and would thus launch at risk.

1. **Transparency of the innovator's IP position.** In order to facilitate assessment by generic companies of their infringement risk at launch, innovative companies would identify certain classes of relevant patents covering the product *before* the data exclusivity period expires.

2. **The trigger.** The availability of the ERM would be triggered by the disclosure by medicines agencies of certain additional information on the marketing authorisation applications relying on third party data, i.e. generic applications. Sufficient information about the planned generic product would have to be disclosed to allow for **legal assessment of patent/SPC infringement by the innovator.**

3. **An actionable mechanism.** The publication of the marketing authorisation application would permit the innovator to initiate ordinary patent/SPC infringement proceedings in a court of law, which should be resolved before the generic applicant is able to launch.

1) Transparency of the Innovator's IP Position

Before the expiration of the data exclusivity period, the innovator would be required to identify certain classes of relevant patents covering the product so as to enable generic companies to assess their infringement risk. These could be for example the same classes of patents that are listed in the US Orange Book. We believe that the details of the relevant classes should be agreed among experts, but the underlying principle is that there should be a balance between the information made available by the generic and the innovator.

The relevant classes of patents could be published by each company on its website at least one year before the expiration of the data exclusivity period, i.e. 7 years after the marketing authorisation, so as to give generic sufficient predictability and certainty.

The generic company would be in a position to make an informed initial assessment of the key IP and expiry dates as a result of the innovator's information and would thereby be able to preliminarily assess the infringement risk.

2) The trigger

The trigger has to be an act, which indicates at least initial preparation for launch of a generic product and has to be early enough to enable the majority of infringement cases to be resolved by the court before grant of the marketing authorisation to a generic product. Disclosure by regulatory agencies of information regarding an application for a marketing authorisation (MAA), which relies either directly or indirectly on the originator's data for an approved medicinal product, appears to be a simple and practical trigger for the early resolution mechanism.
Currently, the EMA lists monthly information on applications for centralised marketing authorisation received for evaluation. For generic and biosimilar medicines, this list includes the INN/common name (active moiety) and the therapeutic area only. Under this mechanism, additional but limited information would have to be disclosed - whether from the EMA or a national agency – and would include a consistent level of information about the product comprising at least the name of the applicant, the API and salt and the indication(s) applied for. Beyond this point, medicines agencies would not be further involved or hampered in their standard procedures.

The parallel disclosure of information about both the innovator's IP position and generic marketing authorisation application would allow the innovator to assess whether the generic product to be launched would infringe key patents in its portfolio. Both the innovator and the generic company would then have the opportunity to achieve a fuller assessment of the infringement risk through confidential exchange of additional product information.

This would substantially contribute to clearing the way without requiring unrealistic and/or unacceptable levels of transparency by either party. The extent and modalities of disclosure required by both parties should be agreed between the different stakeholders.

3) Initiating proceedings

Unlike today, where there are differences in member state practice with regard to the granting of injunctions, the disclosure of selected information concerning the MAA would enable the innovator to bring patent/SPC infringement proceedings immediately before the UPC.

These would be ordinary full patent infringement proceedings 'on the merits', with the filing of the generic MAA being deemed as the 'act of infringement' as being a relatively certain indication of a generic company's intention to launch. As such, it would depart from the current exemption under the EU 'Bolar' provisions. However, where the generic MAA is submitted 8 years after the first innovator's marketing authorisation, this would often allow for the litigation to be resolved before the generic is effectively allowed to launch, i.e. after 10 years from first innovator approval.

If the proceedings were not completed before the generic is allowed to launch (after 10 years) then the Court seized of the case would make a decision on whether a preliminary injunction should be granted within the framework of the already on-going full proceedings. The Court would normally be in a better position to assess the case than under the existing system.

The patent holder would be expected to bring proceedings on each patent that he would reasonably be able to determine infringement for on the basis of the information disclosed by the regulatory agency or provided in pre-litigation correspondence between innovator and generic.

Relevant patents that would not be in classes to be identified (e.g. process patents) and that for which there was no reasonable evidence of infringement based on the information provided by the regulatory agency publication or by the generic company in pre-litigation correspondence could still be asserted in the current way at the point of imminent generic launch. Conversely, a failure to make known patents in the required classes or a failure to invoke relevant patents for which there is reasonable evidence of infringement in the information provided by the regulatory agency publication would prevent them from being asserted through the ERM. An innovator would have to wait until actual launch of the generic to sue on these patents and it would likely be difficult if not impossible to get pre-trial injunctions in such cases where an action could have been brought earlier on the basis of generic MAA disclosure.

Patent infringement proceedings under this mechanism would however not be necessary where an applicant for a generic MA provides an appropriate undertaking that the generic product will not be placed on the market until after expiry of the innovator's relevant patent rights. In addition, this proposal would not prevent multiple generic companies freedom to use the currently available legal means to 'clear the way' if wishing to do so, including by seeking to invalidate the innovator's patents in advance of seeking regulatory approval.

Litigation framework

The ERM would change litigation conditions and must satisfy the key policy rationale of increasing legal/business certainty for both sides, reduce the need for multiple litigations as well as be balanced between innovator and generic. Because of the complexities inherent to the current patent litigation system, and the various options that a generic can use to achieve a MAA in Europe, this cannot realistically be achieved in the current national litigation systems.

A more workable opportunity exists in the new unified patent litigation framework because the new Court's decisions will cover most Member States and ultimately all but national patents. Setting up this system within the framework of the Unified Patent Court (UPC) would also be a significant incentive for companies to use this new Court more rapidly.

Implementation

The system would apply to both European patents (granted by the EPO without unitary effect) that have not been opted out from the UPC system during the transitional period and to upcoming unitary patents granted by the EPO. Post-UPC transitional period, the system would apply to all European patents, with or without unitary effect.

Comparison with US "Orange Book"

Contrary to the US orange book system, the ERM would limit the medicines agencies' involvement to disclosure of relevant information regarding generic MAAs. It would not involve stay of grant of marketing authorisation or constrain the agency's decision process in any way. Further, there would be no requirement for a generic assertion of non-infringement: it would merely simplify communication and timely patent dispute resolution. This system is thus consistent with the current Community Code relating to medicinal products for human use.