

## EFPIA Comments

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### Consultation on the respect of intellectual property in public procurement procedures

The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomes the possibility to provide comments in response to this Consultation and thanks the European Commission for this opportunity. 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 quality of life around the world.

The European Commission recently adopted a Communication<sup>1</sup>, acknowledging intellectual property rights as one of the driving forces of innovation and a key contributor to competitiveness and employment in the EU. The Communication focuses on the enforcement of intellectual property rights (IPRs), which should mostly target commercial-scale IPR infringements. In this framework, the Communication notes the public contracting authorities' responsibility to screen public procurement for IP-infringing products and calls on the Commission to develop, promote and publish a guide on best practices for public authorities. EFPIA strongly supports such an initiative: public authorities should ensure a high standard of protection for IPRs in their operating procedures. It is of the utmost importance that public authorities take a leading role with regard to the respect of IPRs, trade secrets or the confidential aspects of tenders<sup>2</sup>.

The Commission Communication further provides that the Commission will undertake a first sectoral pilot exercise to determine the scale of the problem in the medical sector. EFPIA again supports this initiative, as the pharmaceutical sector is highly specific in many relevant respects.

The pharmaceutical supply chain and national systems for the procurement of medicines are characterised by a wide diversity across the EU, varying from one Member State to another. As a result, public procurement procedures may be a more or less important feature of the medicinal products procurement systems depending upon a number of factors including (i) the level of intervention of the different Member States, (ii) their respective health policies, in particular their reimbursement policies, as well as their administrative structures and (iii) the IP-status of the medicinal products concerned.

The public authorities may buy the products directly or via a public insurance scheme and supply them to the health institutions and pharmacies. This mostly concerns public hospitals, but also serves in many countries to purchase pharmaceuticals for a specific public function (e.g. vaccines). The AOK Rheinland case law<sup>3</sup> clarified the status of some entities by deciding that where a public insurance scheme is in place that finances healthcare entities, whether

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<sup>1</sup> Communication « Towards a renewed consensus on the enforcement of IPRs: an EU Action Plan » (COM(2014)0392)

<sup>2</sup> Please see on Confidentiality Article 21 of [Directive 2014/24/EU](#) of the European Parliament and of the Council of 26 February 2014.

<sup>3</sup> Case C-300/07 *Hans & Christophorys Oymanns GbR, Orthopädie Schultechnik v AOK Rheinland / Hamburg* [2009] ECR I-04779

sickness insurance funds or hospitals, whether directly or indirectly, those entities will have to recourse to public procurement procedures for their supply of medicinal products. Private hospitals or retail pharmacies will generally buy their medicines supplies directly from pharmaceutical companies/wholesalers and only a few Member States apply such procedures for pharmaceuticals in ambulatory care distributed through the retail pharmacies. IP enforcement issues are however analogous in all these cases.

It is therefore difficult to assess whether public procurement procedures are more affected by IPRs infringements than comparable private-to-private procurement processes in response to question C9. As noted in E3, both are however equally vulnerable to two issues, which we see as risks specific to our sector:

First, there can be a marked level of legal uncertainty in our sector as to the transition from on-patent to off-patent product markets. There are substantial first-mover advantages in the generic market which can be an incentive for generic companies to launch products despite the fact that they know there is risk of patent infringement proceedings.

Early, “at risk”, launch of generic products, before the expiry of relevant patents, can cause irreparable harm to innovative companies, especially due to the impact of price and generic substitution regulations. As a result, the pharmaceutical industry is particularly vulnerable to IPR infringements, including within the framework of public procurement procedures. EFPIA has suggested the introduction, in the Unified Patent Court framework, of a mechanism, which would allow resolution of most patent disputes before generics launch “at risk” but which would not delay lawful generic entry<sup>4</sup>. Introduction of this system would promote respect for IP in public procurement processes as it reduces the possibility of public procurement systems procuring patent infringing products.

Pending the introduction of this mechanism, EFPIA therefore calls on the Commission to ensure sufficient awareness of IP issues in public procurement procedures and issue guidance to ensure respect for intellectual property rights.

A second issue concerns the procurement of generic medicines, which can be used for several indications where one of more of those indications is patented and one or more is no longer patented. In this situation there is a real risk that the generic drug will be procured and supplied not only for the unpatented indication(s) but also for the patented indication(s). A number of recent Court cases in the Netherlands, Germany and United Kingdom have highlighted this risk – please see Annex 1 for details.

EFPIA has consistently supported competitive off-patent markets where they deliver savings for healthcare systems whilst respecting intellectual property rights so as to safeguard innovation incentives. It is therefore in the public interest that the generic can also be procured and supplied for the off-patent indications(s) but that the innovator’s patent is respected by ensuring that only its product can be procured or supplied for the patented indication(s).

Such a differentiated approach is essential in order to ensure that research and innovation remain among the main drivers of future growth in Europe. Public authorities should make the best strategic use of public procurement to spur innovation<sup>5</sup>. In order to do so and to limit the risk of public procurement procedures procuring drugs which infringe IPRs, where drugs are on-patent (including drugs with patented indications), the negotiated procedure without

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<sup>4</sup> Please see [EFPIA Proposal](#) for an Early Resolution Mechanism.

<sup>5</sup> Please see Recital 47 of Directive 2014/24/EU.

publication, as provided for in Article 32, paragraph 2(b) of Directive 2014/24/EU, should be used in priority because this is a situation “where the [...] supplies [...] can be supplied only by a particular economic operator for any of the following reasons [including] (iii) the protection of exclusive rights, including IPRs”<sup>6</sup>.

At the very least, for the procurement of pharmaceutical products with several indications, some of which are already off-patent, public tenders should specify the relevant indications.

**In summary, EFPIA would suggest that:**

- A mechanism to allow for resolution of patent disputes, before generic launch, is introduced, as suggested by EFPIA in its Early Resolution Mechanism Proposal.
- Clearer guidance about best procurement practices is issued to the attention of both contracting authorities and tenderers, to ensure full awareness and respect of intellectual property rights, trade secrets and confidential information of tenders within public procurement procedures, thereby safeguarding research and innovation remain among the main drivers of future growth in Europe<sup>7</sup>.
- Tenderers have the obligation to declare that their tender is not infringing any IP right while contracting authorities have the obligation to exclude any IP-infringing tender, including those without declaration.
- For the procurement of pharmaceutical products with several indications, some of which are already off-patent, public tenders should specify the relevant indications.
- For the procurement of on-patent drugs or indications, the negotiated procedure without publication should be used in priority so as to limit the risk for public procurement procedures of infringing IPRs.

EFPIA remains at your disposition for further discussion.

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<sup>6</sup> Please see Article 32(2) of Directive 2014/24/EU.

<sup>7</sup> Please see Recital 47 of Directive 2014/24/EU.

## ANNEX 1

**Novartis AG vs. Sun Pharmaceutical Industries BV, Hague Court of Appeal, 27 January 2015.** In this case, Novartis' product [zoledronic acid] was approved for two indications: the first indication, Paget's disease, represents about 2,7% of the market and is off-patent whereas its second indication, against osteoporosis, was still patented. Sun Pharmaceuticals had obtained a marketing authorisation for a generic version of this product, omitting from its labelling the osteoporosis indication. However, in October 2013 Sun registered for a so-called tender of healthcare insurer VGZ. By means of this tender procedure VGZ selected a number of preferential products, including a zoledronic acid 5mg/100ml product for patients to whom the infusion is administered at home. Sun won the tender. This meant that its generic product was the only zoledronic acid 5mg/100ml product that would be compensated by VGZ. The preferential policy used by VGZ comprised that one single product was designated for any patient insured with VGZ that are treated at home with zoledronic acid in a dosage of 5 mg/100 ml, without distinguishing the indication for which it was prescribed. The Hague Court of Appeal ruled that it was unavoidable that Sun product would be provided for osteoporosis as well as Paget's disease, and therefore found Sun to have indirectly infringed Novartis' patent. This decision was appealed by Sun. A similar case is pending in France.

**Warner-Lambert Company, LLC vs. Aliud Pharma GmbH, Regional Court of Hamburg, 2 April 2015.** Aliud Pharma had entered into a discount agreement with the health insurance provider (AOK) for Warner-Lambert's pregabalin, for which one indication, pain, was still patented. Neither the tender nor the agreement was limited to the non-patented indications of epilepsy and generalised anxiety disorder. Though Aliud Pharma had 'carved out' from its label the patented indication, in the light of its unconditional participation in an unlimited tender of discount contracts combined with the obligation for pharmacies to dispense to insured people the lower-cost drug, the Regional Court of Hamburg concluded the result was the same as if Aliud Pharma had not carved out the protected indications from its label. The Regional Court of Hamburg therefore found that Aliud Pharma's full accession to a discount agreement, not restricted in terms of therapeutic indication, constituted a contributory infringement of Warner-Lambert's patent for use of pregabalin for the treatment of neuropathic pain.

There are a number of parallel cases in Germany with similar first instance decisions. Also, in the context of preliminary injunction proceedings in the UK, a High Court decision dated 2 March 2015 ordered the National Health Service of England to issue central guidance aimed at avoiding the prescribing and dispensing of generic pregabalin for the treatment of pain.