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We do IP.

WHAT THE ENVISAGED MODIFICATION OF THE BOLAR EXEMPTION WITH THE EU-PHARMA PACKAGE COULD MEAN FOR IP RIGHTS HOLDERS?

01 As the discussions on the proposal for a new Directive establishing a European Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC (so-called "EU pharma package") are set to resume soon, this is the opportunity to bring focus on one envisaged amendment of the draft directive concerning the so-called Bolar exemption and draw attention to the practical consequences that the adoption of this amendment could entail for patent and supplementary protection certificate (SPC) proprietors against premature, infringing roll-outs of generics or biosimilars.

The current regime of the Bolar exemption

02 The Bolar exemption was introduced into EU law by Article 10(6) of Directive 2001/83/EC to allow trials for the purposes of obtaining a marketing authorization (MA) especially for a generic or biosimilar product to be conducted in the EU while a patent or SPC is still in force, instead of having to be delocalized outside the EU.

Placed under a chapter entitled "*marketing authorization*", it provides that "*conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4* [related to generic and biological medicinal products] *and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*."

This provision was then implemented into European national laws.

Current application of the Bolar exemption in France

03 The scope of the Bolar exemption is a question of balancing, on the one hand, the interests of generics manufacturers in preparing for the launch of a generic or biosimilar product even before the patent protection expires to enter the market as soon as the invention falls into the public domain and, on the other hand, the legitimate protection of the rights of patent and SPC owners against imminent infringement by the premature roll-out of a generic or biosimilar.

04 In **France** for instance, under Article L. 615-3 of the intellectual property code (IPC), a right holder can request a preliminary injunction in expedited proceedings in case of "*imminent infringement*" of the rights under the patent or SPC. This allows rights holders to act preventively when it appears that a generic or biosimilar is about to be launched before the patent or SPC is expired, which unless prevented would cause them irreparable harm in terms of their position on the market.

The only way to prevent irreparable harm is for them to apply for a preliminary injunction, which however requires that an "*imminent"* act of infringement be proved, which is no piece of cake when the product is not yet on the market.

05 Although a few decisions in the past may have accepted the announcement of an impending launch in a brochure as proof of imminent launch (e.g. Judicial Court of Lyon, 21 July 2009, Mundipharma Laboratories et al. vs Medochemie Ltd. et al.), generics manufacturers have long been careful to inform pharmacists of the forthcoming launch of their generic drug only by word of mouth, making it difficult to prove the imminent launch.

06 The only option left to IP right holders is for them to flag the existence of their industrial property rights to the competent administrative entities and to monitor the progress of the administrative procedures initiated by their generic competitors.

While it is well-established that, as per the current version of the Bolar exemption, requesting and being granted a marketing authorization do not qualify as imminent acts of infringement, French courts consistently consider that requesting a price and reimbursement decision for a generic or biosimilar of a patent-protected drug can. This is because obtaining a price and having a drug registered in the list of refundable medicines are the last administrative steps before a generic or biosimilar can be put on the market.

07 Currently, the framework agreement between the French Economic Committee for Health Products (CEPS) and the pharmaceutical companies (Article 3) provides that the latter who hold IP rights can notify them regularly to the CEPS, who is the body in charge of pricing, and the CEPS makes this list available to all companies.

The same article also provides, as a general principle, that generics or biosimilars cannot be entered in the list of reimbursable medicines more than 6 months before the expiry date of the declared IP rights.

However, this delay does not apply if, upon information by the CEPS of the existing IP rights, a company applying for pricing and reimbursement declares to the Committee that it deems to be in a position to market the product at issue without infringing the said IP rights.

In such a case, CEPS, in turn notifies the manufacturer of the patent-protected product of the upcoming registration of the medicinal product at issue on the list of reimbursable medicines.

French courts consider that such a notification to the patent or SPC holder by the CEPS is enough evidence of imminent infringement within the meaning of the above-mentioned provision: it shows that the generic company is aware of the patentee's rights and is still willing – or at least considering – to market its drug without waiting for the rights to come into the public domain, which is an indicator of imminent market entry (e.g. Judicial court of Paris, 3 June 2022, Biogaran vs Novartis; Judicial court of Paris, 10 August 2012, Sanofi vs Mylan).

08 This possibility of **preventing** impending infringing activities – rather than simply stopping ones that have already started – should be preserved. For it is the ability to prevent the launch of a generic product prior to its lawful commercialization that effectively safeguards the rights and interests of the IP rights owner.

Once a generic or biosimilar has prematurely entered the market, the damage cannot be fully compensated. This triggers a cascade of consequences:

- the price of the reference drug automatically undergoes a massive decrease pursuant to Article 24, a) §1 and 2 of the framework agreement between the CEPS and the pharmaceutical companies (dropping by 20%, while the price of the generic drug is set 60% below the original price of the reference product);
- the loss of market share for the IP rights owner (under the double effect of the arrival of competitors offering copycat products at a much lower price and the substitution rule imposed on pharmacists);
- the recall of the infringing samples from the channels of commerce (including the sending of letters to wholesalers and pharmacists) is usually considered burdensome and as such rarely granted, albeit a necessary corrective remedy, to the prejudice of the IP rights owner.

The possibility of bringing an action for a preliminary injunction to **prevent imminent infringement** makes it possible, if granted, to avoid the consequences that would ensue from an injunction which would only occur after the market entry of the infringing generic drug and which would prove difficult to fix.

Foreseeable consequences of the draft amendment to the Bolar exemption on the legitimate balance of interests

09 But this well-balanced situation may be about to be called into question, to the prejudice of patent or SPC owners, by the contemplated amendment.

10 The Draft directive proposes to significantly extend the scope of the exempted activities: the latest version of Article 85 of the envisaged directive would end up expanding the reach of the Bolar exemption as we know it by including "*necessary studies, trials and other activities*" conducted not only for the purpose of obtaining a MA but also for *"pricing and reimbursement approval*".

11 If the proposal were to be adopted as currently drafted, meaning that the Bolar exemption would cover all "*pricing and reimbursement approval*" activities, it could have far-reaching practical consequences for patentees.

Should it pass into law, generic or biosimilar manufacturers may well use this amendment to object to a preliminary injunction, arguing that it might be interpreted as blocking the possibility which exists today under French law for a patent of SPC holder to take legal action in a useful timeframe, i.e. preventively before the actual infringing launch, based notably on the application for a price and reimbursement decision for a generic or biosimilar.

If these administrative actions were to be exempted from IP rights protection due to the envisaged EU legislative change, the French CEPS notification procedure, meant to allow IP rights holders to take legal action in due course if they consider that their rights are about to be infringed, would lose all purpose and effect. As a result, it might become ever more difficult, if not impossible, to demonstrate imminent infringement within the meaning of provision L. 615-3 IPC.

This legislative modification of the Bolar exemption would then leave IP rights holders with no preventive remedy to effectively assert their rights against the premature, unlawful roll-out of generics or biosimilars.

12 The same issue would certainly arise in other EU countries, such as Germany, Belgium or the Netherlands, where a preliminary injunction may typically be requested against a generic or biosimilar product once a generic company has applied for a listing in the national drug database and/or once a pricing and reimbursement decision has been issued.

Similarly, the Unified Patent Court (UPC), which is required to find an imminent act of infringement for granting a preliminary injunction (UPC Agreement, Article 62(1)), considers that evidence of such imminent infringement would typically be an application for a price or reimbursement decision or the existence of pricing negotiations (UPC, Local Division Düsseldorf, 6 September 2024, Novartis et al. vs Celltrion, CFI_165/2024 and CFI_166/2024)

13 The discussed amendment to the wording of the Bolar exemption at the EU level is therefore likely to make it even harder for IP rights holders to meet the burden of proving imminent infringement for taking emergency actions in the EU, at the risk of depriving them of any effective legitimate remedy against unlawful premature launches.

In practice, the envisaged legislative change under Article 85 of the draft directive could deprive EU judges of the possibility to grant a preliminary injunction, even in the case of otherwise manifest infringement of the patentee's rights.

The legitimate balance of rights is at stake here. The possibility of requesting a preliminary injunction in case of premature launch is the only way to properly safeguard the patentee's rights : it is of the essence of the right that the patentee can have a third party injuncted from using the invention before the protection lapses. Where patentees have to wait for a generic or biosimilar to actually enter the market (on a premature basis), the harm can hardly be compensated, and this undermines the very purpose of the patent system in the first place: encouraging the development of innovative medicines.

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