

- [News and Events »](#)
- [Topical Issues »](#)
- [Synapse Toolkit »](#)
- [Practical Help](#)
- [Contact Us](#)

Share |

Pre-expiry offers to supply after patent term expiry

Austria

Patent infringement by pre-expiry offer to supply a product after the patent has expired is an area of acute difficulty in Austria.

In Austria, two lists are of significant importance for pharmaceutical companies who intend to market a new product: the reimbursement list of the Austrian Association of Social Security Institutions (Hauptverband der Sozialversicherungsträger, HVB) and the product list of the Austrian Pharmacists' Publishing House. The first contains all those products which – upon prescription by a physician – are reimbursed by health funds. The reimbursement list is the key to important sales figures in Austria. One prerequisite for a product to be listed on the reimbursement list is its availability from the moment that the pharmaceutical company applies for the product's listing.

At this stage, the Pharmacists' Publishing House product list comes into play. This list contains all products which are distributed by Austrian pharmacies. The HVB accepts the list as proof of availability and also requires it to be presented when applying for the listing of a product onto the reimbursement list.



One particular problem that generic companies regularly have to face is caused by the fact that the product list is issued once a month, but patents may expire on any day of the month and this is not necessarily the day after the product list's issuance. The question arises whether publication in the product list pre-expiry is to be considered an infringing "offer for sale" in the sense of

section 22 of the Austrian Patent Act, particularly given that the product must be available for delivery.

In two cases concerning Nebivolol, the Austrian Supreme Court has considered the inclusion of an infringing product onto the reimbursement list prior to patent expiry. The Supreme Court held that - provided the product falls within the scope of the patent - an application for inclusion onto the reimbursement list must always be considered a patent infringement, because this means the product is available at the moment of the application. The Supreme Court also expressed a non-binding view that offering to deliver a product at a time after the expiry of a patent must also be considered infringement, because such an offer may prevent people from purchasing the patented products from the patentee – they may foresee that in the near future an alternative (and in most cases, cheaper) product will become available.

Now, in its latest decision, the Supreme Court (referring to the Nebivolol cases) confirmed a decree from the Appeal Court which had considered the question of inclusion onto the reimbursement list, and has extended this ruling to apply to cases concerning the inclusion of a product onto the product list of the Pharmacist's Publishing House: *"The listing in the product list of the Austrian Pharmacists' Publishing House is a use reserved to the patentee like the application for inclusion into the reimbursement list is, because it is linked to the communication of a price and documents availability – might it be for a moment after patent expiry, because it is qualified to influence material planning of customers to the disadvantage of the patentee."*

In other words: even if the product included into the product list was not available prior to patent expiry (but the (early) listing was due to the fact that the product list is issued only once a month and the applicant wanted to be ready to apply for cost reimbursement immediately after patent expiry), the Supreme Court declared the inclusion of a product into the product list to be an infringing offering for sale.

Germany

In Germany, a company that wants to sell pharmaceutical products needs to first list the products in the so called "Lauer Taxe". Listed products are allocated a pharmaceutical reference number which is mandatory for sale in Germany. The Lauer-Taxe contains all products that are sold via the German pharmacies.

The Lauer-Taxe is published every two weeks.

Listing can be made in general up to three weeks in advance of the publication date. This makes it difficult for companies that want to launch products at a specific date, for example the day following the expiry of a patent or supplementary protection certificate. The case law of the German courts is very clear: Any pre-expiry offer is considered as patent infringement.

In the *Simvastatin* case, the Bundesgerichtshof held in 2006 that the publication of generic simvastatin in the Lauer-taxe was an infringement, even in circumstances where it was indicated that supply of the drug would take place post-patent expiry.

This is due to the fact that the German Patent Code considers not only the delivery of the product as patent infringement, but also the "offer" of a product. Hence, the German Federal Supreme



Related pages

[Protecting and enforcing intellectual property](#) ■



Rainer Schultes

Rainer is a partner in the Patents group based in our Vienna office.



Anja Lunze

Anja is a partner in the Patents group based in our Munich office.



Paul England

Paul is a Professional Support Lawyer in the patents group based in our London office.



Court held that the offer is an activity independent from the actual delivery of the product. An offer does not require that the product will be sold or that the offeror is willing to deliver the product. The practical argument of the Federal Supreme Court was that a pre-expiry offer will already affect consumer's choice: If medical doctors, pharmacists or end consumer know which generic product will come onto the market after the expiry of the patent, they might delay orders until the time after expiry. This interferes with the patentee's exclusivity rights until the expiry.

Consequently, any promotional activity, i.e. any advertisement, any pre-expiry offer for post-expiry sale, any pre-expiry information on the post-expiry ability to deliver the relevant products will be considered as infringement of the patent. Even a clear statement of the offeror not to sell the products pre-expiry will not have any legal effect as long as the products are offered in public pre-expiry.

In summary, any public pre-expiry offer for post-expiry sale is considered as patent infringement by German courts.

UK



Offering to supply an infringing product during the term of a patent that covers that product is an infringing act. However, a pre-expiry offer to supply a product after the patent has expired is not in itself considered to be an actionable infringement. In particular, a clear statement by the offeror that the product will not enter the market until after patent expiry should defeat an attempt by a patentee or their exclusive licensee to obtain a preliminary injunction against the offer to supply.

However, there is no principle by which a preliminary injunction cannot be granted on the basis of pre-expiry activity that indicates an infringement might be about to take place. For example, the Patents Court recently ordered a preliminary injunction to prevent the sale of generic efavirenz (an anti-retroviral used in the treatment of HIV/AIDS) *before* it entered the market¹. However, the circumstances were unusual. In particular, the marketing authorisation for generic efavirenz was obtained a full two years before the date of patent expiry. The defendant was also asked by the claimant to disclose its marketing intentions for the drug, but refused to do so. Furthermore, the court noted that the case followed not long after the defendant had marketed another drug, atorvastatin, 'at risk'. This last point in particular, appears to have swayed the court to grant the injunction.

If you have any questions on this article or would like to propose a subject to be addressed by Synapse please [contact us](#).

¹*Merck Sharp Dohme Corp & Anor v Teva Pharma BV & Anor* [2012] EWHC 627 (Pat).