

EIP



Prior use rights and wrongs

One of the aspects arising from the judgment in *Lundbeck v Infosint* [2011] EWHC 907 (Pat) is the potentially narrow scope of prior use rights.

A fundamental test for the patentability of an invention is novelty, i.e. whether information about the invention had been made publicly available before the priority date of the patent application. If so the invention will usually not be considered patentable in the UK (excepting a very strict set of circumstances relating to breaches of confidence or rare types of exhibitions). However, this definition of novelty leaves room for the invention to have been practiced in secret by a third party before the priority date of the application without jeopardising the novelty of the application.

In order to prevent such a third party from being unfairly disadvantaged by the grant of the patent, Section 64 of the UK Patents Act provides the third party the right to continue to do an act that would infringe the patent so long as they had (in good faith) done the act before the priority date of the patent, or made serious and effective preparations to do so. This is commonly known as a prior use right.

This provision was relied upon recently in the case of *Lundbeck v Infosint*. Infosint had a patent related to the production of citalopram by a particular (5-cbx) method. However, Lundbeck had been producing and importing citalopram made via a low-temperature method before the priority date of Infosint's patent. Despite this low temperature method falling within the scope of the claims of Infosint's patent, Lundbeck had established a prior use right and hence its dealings with citalopram produced via this method were not held to infringe. In response to learning of Infosint's patent, and in order to remove the need to rely on Section 64 to avoid accusations of infringement, Lundbeck changed its production process to utilise a "two pot" 5-cbx method which it believed fell outside the scope of Infosint's patent.

However, during prosecution of the case, it was established that this "two pot" method also fell within the scope of Infosint's patent claims. Worse still for Lundbeck, their acts performed before the priority date of Infosint's patent were construed narrowly by the judge to include only the production and importation of citalopram made by the earlier, low temperature process. As a result, this defined the extent of their rights under Section 64 and the importation of citalopram made by the later "two pot" method was deemed to be an infringement. This resulted in the unfortunate state of affairs where Lundbeck's attempts to avoid infringing Infosint's patent had ultimately caused infringement where previously there had been none.

An interesting further question raised by this judgement is that whether by moving entirely to the "two pot" process, Lundbeck has lost the ability to argue that it has "continued" to work the low temperature process, and hence whether or not it could still rely on the safe harbour of Section 64 at all (should it seek to fall back to its old production methods). However, the judge declined to address this issue as he did not believe it was directly raised.

Another interesting insight results from the finding that Lundbeck's prior use right only related to the manufacture of citalopram and that they had no prior use rights in respect to escitalopram, an enantiomer of citalopram. Duly, Lundbeck's importation of escitalopram was found to be an infringement even though its importation had been occurring implicitly as a result of the importation of citalopram (a racemic mixture made up of 50% escitalopram) since before the priority date of Infosint's patent. The judge's decision turned on the different properties of the two materials, and that as a result they were treated in the market as different articles of commerce.

This ruling therefore takes a relatively narrow view of prior use rights, confirming that the right attaches only to what was actually done before the priority date. Deviating from what was previously done can constitute an infringing act if what is being done is not

substantially the same as what was done before.