

## Ukraine: interim injunctions in pharma cases

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The Ukrainian Supreme Court in Merck Sharp & Dohme Corp v Aurobindo Pharma Limited has recently introduce a bold approach to applying interim injunctions in disputes between originators and generics over the registration of patented pharmaceuticals.

MSD learned that Aurobindo had filed an application for registration of an allegedly infringing pharmaceutical with the State Expert Centre of the Ministry of Health of Ukraine (the "Centre"). MSD argued that a compound protected under its patent was used in Aurobindo's pharmaceutical.

MSD filed an application for interim injunctions: (1) prohibiting the Centre from issuance of a report regarding recommendation of the pharmaceutical registration; (2) prohibiting the Centre from making any amendments to registration documents of the pharmaceutical, and (3) prohibiting Aurobindo from placing the pharmaceutical on the market of Ukraine.

The measures (1) and (2) are, in general, likely to be granted by the court, whereas the third one is granted very rarely. The reason for rejecting a request for prohibiting a defendant from placing allegedly infringing products on the market is that this measure is considered to be identical to resolving the dispute on the merits.

The first instance court allowed the MSD's application (ruling of 1 March 2018 <http://reyestr.court.gov.ua/Review/72794640>), while the court of appeals reversed the ruling and dismissed the application (order of 12 June 2018 <http://reyestr.court.gov.ua/Review/74720527>). The court of appeals reasoned that state registration of the pharmaceutical, as well as any preparatory actions without actual placing of the product on the market, are not included into the concept of "use" of a patented invention within the meaning of Article 28(2) of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models".

With its ruling of 14 August 2018 (<http://reyestr.court.gov.ua/Review/75896089>), the Supreme Court dismissed the order of the court of appeals and upheld the ruling of the first instance court.

The cassation court relied on the considerations inspired by the concept of "probable infringement": the court must evaluate evidence suggesting that a certain infringement probably would take place and if there is sufficient risk then apply an interim injunction in order to prevent the potential infringement.

The three main arguments presented by the Supreme Court in favour of the interim injunctions are as follows:

1. The injunctions should be proportionate to the relief sought by the plaintiff. In this case, there is a link between such interim injunctions and the relief sought: since pharmaceuticals may be used in Ukraine after their state registration only, the first instance court has not restricted placing this product on the market and the measures do not prevent the defendant from carrying out its activities, but are rather aimed at abating a probable infringement on the plaintiff's rights.
2. The court of appeal has established an extraordinary and expectedly unsustainable standard of proof for the plaintiff, taking no account of the aim pursued by the person who applies for state registration of a pharmaceutical and the effects of achieving such an aim.
3. In view that, after the pharmaceutical is registered, the defendant will be permitted to use it in Ukraine, including importation, the plaintiff will have to make significant efforts and incur considerable expenses to remove from the market and to destroy the infringing products. Enforcing the judgment would need taking actions against an indefinite number of persons who will be able to claim that they purchased legitimately the product and will have rights to further resale.

Though the Centre disallowed the application for registration of this pharmaceutical upon Aurobindo's request, the Supreme Court noted that anyway this did not prevent the Aurobindo from filing repeatedly such application, so that the ruling granting the interim relief should be upheld.

Any criteria the courts should meet to evaluate whether it is appropriate to grant such injunction as prohibiting from placing the product on the market are extremely hard to find in the Ukrainian case law. So, the legal certainty will increase by having implemented the standard of proof and introduced the notion of probable infringement.