



Making medicines affordable

Scenario for Generic Medicine “A” under the EU Directive on Enforcement of Intellectual Property Rights

Fourtuo Report

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EGA asks to exclude patents from the scope - generic producers are not criminals!!!

Introduction

All major markets should have specialist courts but beware: political or local big employer influence; slow bureaucratic court procedures, a smaller court could be influenced by the IP right holder telling it of interim success in a bigger court. Therefore, concerning a patent dispute, the judge not always has enough expertise to take a neutral and independent decision.

If IP enforcement Directive is approved and implemented (as actually drafted), IPR holder (*from now on "X"*) can take the following actions against Generic Producer (“GP”):

Actions which could be taken against generic producers under IP enforcement Directive:

1. At any time before launch, X on providing “reasonably accessible evidence” to court that GP has information on “infringement “ of X’s patent(s), obtains court order that any of GP’s banking/financial/commercial information should be disclosed to X. GP only discovers this when court bailiff arrives at GP office or CEO’s/Chairman’s home.
2. At the same time, X alleges the need to preserve evidence, so also gets “without notice” order for GP to supply description/chemical formulae or samples of GP’s product. The products themselves as well as the promotional material including technical/delivery vans/even cardboard boxes can be seized. If any of GP’s product is filled/labelled/in any way “produced” within the EU, all equipment and material used can also be seized. Includes anything from a vial to software.
3. To get the court order reviewed, GP must ask for a date. (In UK court will set date itself). If the action takes place shortly before the court summer vacation, in some countries the next available date will be at least 6 weeks later.
4. Only sanction against X if GP fails to start main proceedings within next month is discharge of court order and possible compensation. Same if X continues but no infringement ultimately found 2 or 3 years later. Compensation will be bigger but “infringer” may have suffered structural damage by then.



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5. In addition, X can obtain another “without notice” order against distributors/warehouse; packagers; refrigerated service suppliers; couriers; providers of contract sales forces; wholesalers; sales training providers etc etc. to deliver up any information on GP’s product/distribution network/customer addresses.
6. In addition, X can obtain a “without notice” injunction preventing any “infringing” acts either by GP or any associated third party and the seizure of the goods. This affects all stages in the supply chain. Recurring fine if continues.
7. If “infringement is on a commercial scale” and X alleges recovery of damages will be difficult (because e.g. GP’s holding company is non EU), will get seizure of offices, office equipment, warehouse, vans, laptops, all documents not already taken, and have the bank accounts blocked. Again, this is a “without notice” order.
8. If infringement proven (notwithstanding legal/scientific advice to contrary) X can obtain order that at GP’s expense, all infringing goods with GP and any third party, and any equipment/material within EU used for “production”, be destroyed or given away for charitable purposes e.g. to Third World (all at GP’s expense). GP can ask for damages to be levied instead.
9. In addition, X can obtain order that GP pays double the royalties if IPR had been licensed, or (post-launch) loss of profits, + damage to reputation and anything else court considers fair. This applies even if GP did not know there was an infringement. (So obtaining legal/scientific advice is no defence).
10. In addition, GP can be ordered to place adverts at its own expense in the national, international and trade press to notify the decision.
11. Criminal sanctions are potentially still in the draft: anyone within EU jurisdiction such as CEO/Chairman/management team/ legal, scientific or regulatory staff who knew of/were involved in/attempted to/instigated the infringement would be subject to fines and terms of imprisonment. Any of the measures above relating to seizure of information/documents/equipment can be carried out by bailiffs at employee’s home for example because office building is closed.

In Conclusion:

This case scenario is a useful analogy as to why this Directive does not suit the complex patent world - it will be very easy to delay the launch of a product for a minimum of 1 month; harass suppliers and distributors; get disclosure of commercial secrets; and use the threat of criminal penalties against company executives.

Generic producers need to be protected against these kind of abuses, to continue producing and distributing affordable medicines to the EU citizens.