VIETNAM

Who is responsible when imported drugs infringe patents?

Tilleke & Gibbins
Hanoi

Loc Xuan Le

Are importers and distributors responsible for patent infringement related to the products they import and distribute? This seemingly simple question has still only been partially answered in Vietnam, when the Superior People's Court of Ho Chi Minh City rendered a judgment on July 28 2020 sending a case back to the first-instance court for a retrial.

The plaintiff in the case is a multinational pharmaceutical company, the owner of a valid Vietnamese patent protecting a compound used for the treatment of diabetes. The plaintiff had discovered a medicinal product circulating in the Vietnamese market, under a valid marketing authorisation granted by the Drug Administration of Vietnam, that contained the active ingredient protected under the patent. This product was manufactured in Pakistan and exclusively imported and distributed by a local Vietnamese company.

The plaintiff decided to initiate a patent infringement lawsuit, but chose to sue only the importer/distributor of the infringing product, not the manufacturer. The strategic decision not to sue the manufacturer was based on factors that could lead to a delay in the resolution of the case, including the manufacturer's lack of a strong commercial presence in Vietnam, the manufacturing process being carried out in Pakistan, and the procedural complications associated with filing a lawsuit against a foreign entity.

At the first-instance level, the Vietnamese importer/distributor acknowledged that the medicinal product might be patent-infringing and, as soon as the lawsuit started, ceased its import and distribution activities for the product. However, the defendant also held that it was not responsible for the patent infringement because: (i) there was a provision in the import and distribution contract between the defendant and the manufacturer under which the manufacturer took full responsibility for all IP issues; and (ii) as merely an importer and distributor, the defendant should not be responsible for a product it did not itself manufacture.

These arguments were rejected by the plaintiff because, as a general rule, any act of use of a patented invention without the permission of the patent owner is considered an infringement. Further, "use of a patented invention" is clearly defined under Article 124.1 of Vietnam's IP Law, and includes the acts of import and distribution of patented products. In addition, the manufacturer's contractual commitment to be responsible for IP issues was only binding on the manufacturer and the defendant, and was meaningless and irrelevant to any third party.

However, the first-instance judgment issued by the People's Court of Ho Chi Minh City in July 2019 ruled that the defendant did not commit patent infringement because the plaintiff had not previously sued the manufacturer, and there was no judgment declaring that the drug was manufactured in violation of the invention patent. In other words, the court ruled that it was necessary to determine first that the manufacturer had committed an act of patent infringement before determining whether there was any patent infringement by the distributor/importer. This was a controversial ruling, as it appeared to be a denial of the general principles, understanding, and application of patent law in Vietnam.

The plaintiff immediately appealed to the appellate court, the Superior People's Court of Ho Chi Minh City. At the appellate level, the controversy revolved around the questions of whether an importer/distributor is required to bear responsibility for patent infringement, and whether terms agreed to in a distribution contract are applicable to outside parties. The appellate court, with the desire to clarify the manufacturer's role, invited a representative of the manufacturer to participate in the case as a person with related rights and obligations. The manufacturer's representative insisted that the case was not related to them, and refuted their distributor's arguments.

The appellate court ruled that the case should be sent back to the first-instance court for retrial, pointing out that the court had made serious mistakes in the application of the law. Specifically, the plaintiff has the right to sue whomever it chooses, and the court's right to adjudicate is limited by the scope of the plaintiff's petition—the court cannot tell the plaintiff who it should have sued. Additionally, the defendant, as the importer and distributor of the products, must bear independent responsibility for its own business activities. Finally, the court also ruled that the distribution contract between the two parties affected only the two parties themselves, without being binding on any other third parties.

The case now awaits the retrial of the first-instance court. It will be interesting to see how closely the guidance of the appellate court is followed. In principle, the first-instance court is not constrained in any way in how it handles the retrial. Thus, the judgment of the first-instance court will be a test to see whether the courts are unified in their jurisprudence.