

VIETNAM

The new patent battleground

Tilleke & Gibbins

Hanoi



Loc Xuan Le, Linh Duy Mai
and Hien Thi Thu Vu

Over the past two years, Vietnam has become a battleground over IP rights in the pharmaceutical industry, especially in protecting and enforcing patent rights to prevent the illegal production and marketing of certain generic drugs. While previous decisions by the authorities have left pharmaceutical innovators puzzled and disappointed, a recent case shows that real progress is being made.

Alleged infringement

Near the beginning of 2015, our firm was engaged by a European pharmaceutical giant to handle a patent infringement case. The European company, owner of a patent protecting a compound that lowers blood sugar levels in patients with a type of diabetes, had encountered a locally produced drug circulating in Vietnam that it believed contained the patented compound as an active ingredient.

As a first step in the case, the firm obtained an expert opinion from the Vietnam Intellectual Property Research Institute (VIPRI) with a finding of infringement. The patentee then moved forward with an administrative action by filing the case with the authority in March. The authority then, in cooperation with the federal police, inspected the factory of the putative infringer.

At the inspection, the local producer, which had previously been sanctioned for another patent infringement, tried to dismiss the infringement charge. However, the patentee strongly argued the infringement, citing a clear comparison between the claim set and the product in question. In the end, although the authority did not conclude the infringement at the inspection, they ordered the infringer to cease any infringing produc-

tion pending further resolution.

Facing an uphill battle with the patentee, the infringer then engaged an IP agent that had successfully deflected a patent infringement charge in a similar case the year before. This IP agent employed almost the same approach as in the previous case, attempting to cut down the scope of protection of the patent in question to refute the charge of patent infringement. They argued that their client's product was in the crystalline form, while the scope of protection of the patent in question did not cover specific forms of the compound such as polymorphic, amorphous, crystalline and anhydrous forms. They cited other patent applications claiming such forms to fortify their allegation of the narrow protection of the patent in question.

Claim interpretation as a decisive factor

In response to the counter-arguments of the infringer, the patentee stuck to the claims set out in the patent to protect its position, emphasising that the protection of compounds via essential features such as structural formulas and chemical names of the compounds is a typical form of protection for many new compound entities in the world, not just in Vietnam. Such features protect the compound even in polymorphic, amorphous or crystalline forms. These forms simply relate to different arrangements of the molecules of the compound in space, while the structure of the compound's molecule remains unchanged, and therefore falls within the scope of the patent. In principle, the patent has the broadest scope of protection for the compounds, regardless of the forms of the compounds falling within the formula.

The patentee also pointed out that a compound patent does not preclude the subsequent grant of protection for other forms of the compound. The former and the latter patents are referred to as dominant patents and dependent patents, respectively. Still, as a matter of law, such dependent patents cannot be used without falling within the scope of protection of the dominant patent. In light of the relations between the dominant patent and the dependent patent, the patentee successfully protected the broad scope of

protection of its patent.

In order to fortify its position, the patentee then called on the enforcement authorities to query the National Office of Intellectual Property (NOIP) about the possibility of infringement, so as to obtain a professional opinion on the scope of protection of the patent, as well as to determine whether the product in question was infringing. Upon receiving a favourable opinion from the NOIP, and in light of the successful arguments and the fact-finding, the enforcement authority (the Inspectorate of the Ministry of Science and Technology) rendered the final conclusion of the case in the patentee's favour at the end of July, ordering the infringer to, *inter alia*, cease the infringement, recall the infringing drugs, and withdraw the marketing authorisation of the infringing drugs at the Drug Administration of Vietnam – a resounding victory for the patentee.

The interpretation and application of patent law in practice is never simple, especially in developing countries, even with principles and situations that are widely recognised. However, this case marks a decidedly positive development in Vietnam, considering that in a virtually identical case the previous year, the authorities ruled in favour of the alleged infringer.