Novartis AG Triumphs in the Journey to Protect Vildagliptin Patent in Vietnam

Novartis AG, a leading global pharmaceutical corporation, holds the patent for the active ingredient "Vildagliptin", a crucial component in the treatment of type 2 diabetes. In Vietnam, this groundbreaking invention is protected under Patent No. 5529. Soon after, counterfeit products emerged in the market, significantly cheaper than the genuine product, causing confusion among consumers. Novartis AG did not stand idly by. Extensive investigative efforts revealed the reality: Novartis AG's patented product was being severely infringed upon in Vietnam.

KENFOX IP & Law Office, with 15 years of experience in advising and representing rights holders in complex IP disputes and infringements, provides insights into two "Vildagliptin" patent infringement cases, one handled through administrative measures and the other through civil proceedings. The aim is to help patent holders identify the challenges they face, understand the actions and strategies they need to take to effectively enforce and handle <u>patent infringement</u> in Vietnam.

Bringing the infringer to Justice

Initial evidence revealed that Meyer - BPC Joint Venture Company ("**Meyer BPC Company**") had illegally launched "Meyerviliptin" pharmaceutical products containing the active ingredient Vildagliptin on the market. After extensive market investigations to gather infringement evidence, Novartis AG clearly identified the parties responsible for patent infringement.

To establish a basis for requesting the intervention of the Vietnamese authorities, Novartis AG proactively filed a patent infringement appraisal request with Vietnam Intellectual Property Research Institute ("VIPRI"). Based on the review of the documents provided, VIPRI issued an appraisal conclusion stating that there was sufficient basis to confirm the IPR infringement in Patent No. 5529.

Armed with the gathered evidence and the <u>appraisal conclusion</u> from VIPRI, Novartis AG submitted the case to the Inspectorate of the Ministry of Science and Technology ("**Inspectorate of MOST**") requesting the handling of Meyer BPC's patent infringement.

A raid by Inspectorate of MOST

The Inspectorate of Intellectual Property (IIP) conducted a raid at the headquarters of Meyer - BPC Company and discovered that the company had blatantly infringed on the patent of Novartis AG. Specifically, the company had "manufactured" a pharmaceutical product under the brand name "Meyerviliptin" containing the active ingredient Vildagliptin, infringing on the right to the patent "2-cyanopyrrolidine derivatives substituted at the nitrogen position" under Patent No. 5529 protected in Vietnam for Novartis AG under Article 126 of the IP Law and was administratively sanctioned as per Article 13.5 of Decree No. 99/2013/NĐ-CP.

The number of goods infringing on the patent rights discovered during the inspection is: 324 boxes of Meyerviliptin medicine, with a value of: 324 boxes x 120,000 VND/box = 38,880,000 VND (in words: thirty-eight million eight hundred eighty thousand dong) (of which: 321 boxes recorded according to report No. 237/2019/CV-LD dated October 24, 2019 of Meyer-BPC Joint Venture Company and 03 boxes kept by the Inspection Team; unit price of the product according to the Inspection Record drawn up on September 30, 2019).

8 Years Seeking Justice: Novartis AG Wins Patent Infringement Case

In another case, in October 2023, the High People's Court in Ho Chi Minh City opened an appellate hearing for a patent infringement <u>lawsuit</u> filed by Novartis AG. The case lasted for 8 years through two levels of trial (first instance and appellate) with the ultimate victory for the patent owner. Accordingly, in the appellate ruling, the Court:

(i) Ordered the defendant - Dat Vi Phu Pharmaceutical Joint Stock Company (Dat Vi Phu Company) to:

 Destroy all stockpiles of Vigorito tablets (containing the active ingredient Vildagliptin 50mg) and the raw materials used to manufacture and market the infringing product.

- Withdraw the registration number of Vigorito tablets with the Drug Administration Department of the Ministry of Health.
- Issue an apology and rectification in the Vietnam Journal of Pharmacy and Cosmetics.

(ii) Declared that the defendant Dat Vi Phu Company had infringed on Novartis AG's Patent No. 5529.

(iii) Ordered the defendant Dat Vi Phu Company to:

Publicly apologize and rectify to the plaintiff in the Health and Life Magazine for 3 consecutive issues.

(iv) Ordered the defendant Dat Vi Phu Company to <u>compensate</u> Novartis AG for the following:

- Material damages to Novartis AG in the amount of 500,000,000 VND (five hundred million dong) due to the infringement of Patent No. 5529 during the term of the patent.
- Payment to Novartis AG of 300,000,000 VND (three hundred million dong) for legal fees.

Final thoughts

Millions of USD invested in research, testing, and decades of tireless creativity to create breakthrough products in the medical field to serve the interests of the community. Each medical product is the crystallization of intellect, sweat, and tears. It represents hope, for the lives of millions of patients.

However, the fruits of this intellectual labor are blatantly "**stolen**" by acts of copying and patent infringement. This act is not only blatant theft, but also the ultimate injustice to scientists and researchers who have poured their hearts and souls into their inventions. It can also be seen as an act of "**robbing**" public health. Counterfeit products pose a risk to quality, treatment efficacy, and even serious health risks to users. Furthermore, patent infringement causes significant losses to the patent owner. They suffer financial losses, damage to brand reputation, and consumer confidence.

Therefore, on any scale, whether individual or organizational, patent infringement cannot be tolerated and must be strongly condemned.

Vietnamese intellectual property law is uncompromising with this infringement. Therefore, the enforcement of IPR is established on a "dual" mechanism, <u>combining both administrative</u> and <u>civil</u> <u>mechanisms</u> in IPR protection. Therefore, in addition to requesting the administrative enforcement agency to arrest and punish infringers, the patent owner also has the right to file a lawsuit with the court to demand compensation for the losses they have suffered. This means that Novartis AG can fully sue to demand that Vietnamese courts issue rulings requiring the infringer to compensate for damages.

The costs of investigating, collecting <u>infringement evidence</u>, and initiating legal action are a significant burden, costing time, money, and resources for the patent owner. Therefore, the journey to seek justice in the two cases mentioned above is not only about the legal battle, but also a testament to Novartis AG's determination to protect the rights and legitimate interests of the patent owner and its responsibility to the community.

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