

Foreign Pharma Companies Face Hurdles in Vietnam

Vietnam's pharmaceutical industry has huge potential, but numerous IP challenges exist. **Thomas J Treutler** explains the hurdles foreign pharma companies face in Vietnam.

Vietnam, with a population of nearly 90 million people, is the 12th most populous country in the world, and the country's pharmaceutical industry therefore has huge potential. Most major pharmaceutical companies have had a formal presence (in the form of representative offices) in the country since the mid-1990s, and they generally have well-established distribution networks in Vietnam. However, foreign pharmaceutical companies that market their products in Vietnam face numerous intellectual property challenges in the jurisdiction.

Trademark Infringement and Unfair Competition

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doing business in pharmaceuticals. In this crowded field, there is huge pressure to compete, and many local and foreign companies mimic the trademarks or trade dress of famous foreign pharmaceutical brands in order to ride on the coattails of these reputable brands.

In the past, prior to registering a pharmaceutical product for circulation in Vietnam, a pharmaceutical company had to submit to the drug authorities proof that the name of the product did not infringe upon the names of other products. This proof could be in the form of a trademark registration certificate, a search report, or a letter from the authorities concluding that the name of the product was not an infringement. However, this requirement has been removed from the regulations. This system often caused confusion among enforcement authorities when requested to take action against potentially infringing products. Specifically, the infringer was often able to convince authorities to

not take action against the infringing product because it claimed that it had provided a “search report” to the drug authorities and had complied with all requirements, and the authorities had licensed its product.

Currently, under Circular No. 22/2009/TT-BYT on Drug Registration, which was issued by the Ministry of Health on November 24, 2009, applicants to register a drug do not need to provide such proof, but are encouraged to register their trademark or conduct a search prior to registering a drug in Vietnam. However, Circular 22 underscores that registrants will be responsible for all intellectual property issues related to their drug names. Circular 22 provides a mechanism whereby the Vietnam drug authorities

will refuse to issue a product visa for a product in cases where a conclusion that a product is infringing, issued by a relevant authority, can be provided to the drug authorities during the process of examining the request to register the potentially-infringing drug for circulation. If an infringement has been discovered after a product has been registered for circulation, Circular 22 provides a mechanism to have a product visa withdrawn.

In the past, Vietnam's intellectual property system generally applied a simple blanket rule in conducting a likelihood-of-confusion analysis during examination, and this approach led to many intellectual property problems, especially in

the pharmaceutical sector. Specifically, so long as two or more syllables of trademarks were different, the trademarks were considered to not be confusingly similar. This analysis ignored the overall impression of the trademarks and resulted in the registra-

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tion of many trademarks that were clear attempts to mimic another brand. The “two-syllable rule” became known among, and

was applied by, enforcement authorities and thus led to many cases where authorities refused to take action against seemingly clear infringements.

In recent years, the authorities have moved away from the two-syllable rule, and rightsholders now have a much higher chance of achieving success in oppositions and cancellations, as well as in infringement cases.



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Vietnam is a first-to-file country, and it is therefore important for foreign pharmaceutical companies to use watch services in Vietnam. A trademark can be opposed within nine months after publication in the Official Gazette. Cancellation actions can be very time-consuming (up to two or three years) and costly in Vietnam, so it is best to timely oppose trademark applications.

Enforcement Mechanisms

Pharmaceutical companies whose products are infringed may file administrative and/or civil cases. In regard to administrative cases, Vietnam recently increased its maximum infringement fines up to VND500 million (US\$25,500), and has been imposing significant fines in the range of US\$10,000 to US\$20,000 over the last year. This is a major improvement over the past, when administrative fines in Vietnam were usually in the range of US\$500 to US\$1,000. As such, the administrative enforcement mechanism in Vietnam is starting to have “teeth” and is an effective route for rightsholders to take action.

Pharmaceutical companies may also take civil action against infringers; to date, however, results have been mixed. In particular, Vietnamese courts do not usually give much deference to the rightsholder's evidence of damages (e.g., lost profit estimates). As such, although the rightsholder may win the case, damages tend to be quite low.

It is important to note that trade dress infringements are very common in the Vietnamese pharmaceutical sector. The “look and feel” of famous pharmaceutical packaging, including the colours, lines, etc., is often copied. Although such copying is an act of unfair competition under Vietnamese law, it is still difficult to take action against such cases in Vietnam. Accordingly, many pharmaceutical companies effectively combat trade dress infringements by registering the entire package of a pharmaceutical product as a trademark or an industrial design (if it is novel). The ability to present enforcement authorities with a registration certificate relating to the package design makes enforcement much more

efficient, as compared to having to submit complex legal arguments on trade dress and unfair competition, which is an underdeveloped area of law in Vietnam.

Counterfeits

It is estimated that 5% to 10% of pharmaceuticals in Vietnam may be counterfeit. Vietnam's Criminal Code contains harsh penalties for those who counterfeit products related to human health, such as pharmaceutical products. Although Vietnam has been criticized for failing to impose criminal penalties on counterfeiters or those who pirate copyrighted works, the pharmaceutical sector is one area where Vietnam has several times actually imprisoned those who deal in counterfeits. In 2006, for example, a young man in Hanoi, who had studied pharmacy and formerly worked as a representative for a drug company in Vietnam, decided he wanted to make some quick money and purchased from a Chinese woman tens of thousands of boxes of counterfeit



product of a famous antibiotic to sell. The fake product was sold at many pharmacies in Hanoi, Vinh, and other northern provinces, but when the pharmacies discovered the product was fake, they turned in the young man. In the end, the young man was sentenced by the Hanoi People's Court to three years in prison.

As another example, in 2008, pursuant to a tip from local citizens, the Ho Chi Minh City police conducted an undercover stakeout outside the Ho Chi Minh City train station. Two men made an exchange, and the police swooped in. The police seized the package the men had exchanged and discovered that it held fake blister packets of a famous drug. Under questioning, it turned out that the person handing over the drugs was just a gofer for a seller from China who was residing in the Chinatown (*Cholon*)



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area of the city, and had brought the fake drugs into Vietnam over the Chinese border in the northern region of Vietnam. A short time thereafter, police raided the rented home of the Chinese citizen, who was ultimately sentenced to seven years in jail.

Patent Protection and Enforcement

Many pharmaceutical companies have registered their patents in Vietnam. In the last year, there has been increased action in the enforcement of patents in Vietnam, especially with the advent and increased activity of “intellectual property assessors” in Vietnam. Intellectual property assessors are licensed to issue opinions on intellectual property matters that, while not binding, can

function essentially as expert witness proof. The assessor's opinion can be submitted to enforcement authorities with a request to take action, and will serve as persuasive proof of infringement. The assessors are intellectual property law experts, such as former intellectual property officials in Vietnam, and can provide very detailed and accurate opinions on infringement cases.

Data Protection

Pursuant to its obligations under TRIPs and the US–Vietnam Bilateral Trade Agreement, in 2006, Vietnam adopted its first regulations on data protection in the form of Decision No. 30/2006/QĐ-BYT Promulgating the Regulations on the Protection of Data in Respect of Drug Registration Application Dossiers, which was issued on September 30, 2006. Decision No. 30 provides a procedure whereby drug companies can apply for data protection in Vietnam. However, pharmaceutical companies have pointed out a number of weaknesses in Vietnam's current data protection system. For example, there is still a misconception that data protection only applies to patented subject matter. Additionally, the regulations do not contain a specific provision whereby the marketing approval of a generic product could be delayed if there is a related data protection period in force. New draft protection regulations were circulated for comment last year.

Domain Names

Pharmaceutical companies should register their company and important product names as domain names in Vietnam early, especially in the popular “.vn” and “.com.vn” domains. Early registration is recommended because at present, there is little practical recourse in Vietnam for companies that fall victims to cyber-squatters in Vietnam. Under Circular No. 10/2008/TT-BTTTT Providing Regulations on the Resolution of Disputes Involving



Pharma companies face new challenges.



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National .vn Domain Names, there are only three methods for handling domain name disputes in Vietnam: (1) negotiation; (2) arbitration; and (3) litigation. Negotiation is not a feasible option unless a company is willing to submit to the high demands of cyber-squatters in Vietnam who typically seek sums in the millions of dollars. Arbitration is not a feasible option because both parties must agree to go to arbitration, and cyber-squatters have no incentive to agree to submit to an arbitration process. Thus, the remaining option is litigation. However, Vietnamese courts have little experience with intellectual property matters, let alone domain name cases. Therefore, the results of litigation may be unpredictable, and the costs may be high, given that court cases in Vietnam often extend more than one year.

Accordingly, thus far, most companies that have fallen victim to cyber-squatters in Vietnam have realized that it is often futile under the current legal regime to attempt to wrest a domain name from a cyber-squatter, and instead are resigned to registering “plays” on their domain name in order to market products (e.g., instead of registering “product_name_x.vn”, the company will register “product_name_xonline.vn” or “myproduct_name_x.vn”).

Conclusion

Clearly, there are a plethora of intellectual property issues that can impact the business of pharmaceutical companies in Vietnam. These include trademark infringement and unfair competition, counterfeits, and cyber-squatters. But as new legal measures are introduced – from strengthened enforcement mechanisms to new provisions on data protection – pharmaceutical companies have an increased number of strategies at their disposal to deal with these issues.

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