Tilleke & Gibbins

Vietnam Pharma Update

December 2017

New Decree Affects Pharma Distribution and Medical Representative Employment in Vietnam

Pharmaceutical companies are being forced to reconsider their business models in Vietnam, based on the provisions of Decree No. 54/2017/ND-CP dated May 8, 2017, guiding the implementation of the 2016 Pharmaceutical Law (Decree 54). Having entered into effect on July 1, 2017, Decree 54 resulted in pharma companies reviewing their distribution channels, setting up subsidiary companies to take part in importing and other aspects of business, and considering relocating marketing staff (known in Vietnam as "medical representatives," "med reps," or "MRs").

Distribution

It has been clear that Vietnam does not intend for foreign companies to engage in the distribution sector for pharmaceuticals. Vietnam's WTO Schedule of Commitments on Services has intentionally excluded pharmaceuticals from the sectors for which market access is open to distribution by foreign investors. Moreover, the Pharmaceutical Law is silent on the distribution right of foreign companies.

However, a few foreign-invested pharmaceutical companies that were established prior to Vietnam's WTO commitments participate in some tangential aspects of distribution (storage and transportation) and appeared to be exempt from these prohibitions, or at least appeared to possibly be grandfathered in and could continue to provide services in the storage and transportation of pharmaceutical products. But under one possible interpretation of Article 91.10 of Decree 54, "storage" and "transportation" may be considered aspects of "distribution," casting doubt on whether any foreign-invested companies may be allowed to participate in such activities.

If foreign-invested companies are unable to participate in storage and transportation, this would result in many pharmaceutical companies having to find new partners and retool their supply chains in Vietnam. For the affected foreign-invested companies, it is unclear how Article 91.10 will ultimately be interpreted or enforced. Companies that were licensed prior to Decree 54 may possibly be able to rely on general investment protection theories to be grandfathered in, or they may attempt to argue that the definition of distribution in Decree 54 has been interpreted too broadly.

As a result of the new uncertainty, many foreign companies are reviewing or considering supplementing any distribution contracts to ensure that there are proper exit provisions, in the event their partners' scope of activity in Vietnam is limited by the new regulations.

Tilleke & Gibbins Honored As Top Asia-Pacific Firm

This November, Tilleke & Gibbins was pleased to be the recipient of several high-profile awards. At the Euromoney Asia Women in Business Law Awards, the firm was honored as **Firm of the Year for Vietnam** and **Best National Firm for Talent Management**, a regional award covering all of Asia. Later, at the inaugural Asialaw Asian Legal Practice Awards, Tilleke & Gibbins took home trophies for **Southeast Asian Firm of the Year**, **Asia-Pacific Intellectual Property Firm of the Year**, and **Thailand Firm of the Year**.

Business Model Changes

Historically, most multinational pharmaceutical companies have done business in Vietnam via a model that includes setting up a representative office (RO) in Vietnam. By law, however, ROs are not permitted to engage in sales or direct business activities. These multinational pharmaceutical companies, therefore, typically work with various foreign-invested companies that were already set up as mentioned above, and have been smoothly managing their local Vietnamese distributors to arrange for the importation and then distribution of the multinational companies' drugs into Vietnam. However, due to the uncertainty of the right to continue doing the "storage" and "transportation" services under Decree 54, some multinational pharmaceutical companies have begun or are considering restructuring their current business models to directly work with qualified 100% local distributors in distribution.

Further, over the last two decades, Vietnam has regularly had rumblings of reducing or eliminating ROs in all sectors and shifting toward multinationals in all fields setting up subsidiaries, rather than ROs. In anticipation of this shift, several multinationals have already established subsidiary companies that can engage in importing and promotion of the multinationals' pharmaceutical products (as noted above, due to Vietnam's WTO commitments, they cannot engage in distribution). Multinationals that have set up importing companies hope that if the business lines of the subsidiaries can be expanded when/if the law is relaxed in the future, they will already have their entities set up, and can quickly adapt to take advantage of the new situation.

Relocation of Med Reps

As ROs are not permitted to engage in sales or direct business activities, they are not permitted to directly employ med reps as a matter of law. This is because an RO, under both the old and the new legal regimes in the pharmaceutical sector, does not fall under the definition of a "drug trader" (under the old legal regime) or a "drug business establishment" (under the new legal regime). These definitions cover, for instance, establishments manufacturing drugs, importing or exporting drugs, providing the service of preserving drugs, or wholesaling drugs, which are profit-generating entities—which ROs, obviously, are not.

At present, the issue of whether an RO may employ med reps is still complicated. Under the old legal regime (i.e., before the effectiveness of the 2016 Pharmaceutical Law on January 1, 2017), though ROs of foreign pharmaceutical companies that were registered with the MOH did not appear to qualify as drug traders, as a matter of practice, med rep cards, which play the role of practicing licenses, had been issued to employees of ROs. In the context that Decree 54 is now in effect, and no further guidelines fleshing out the matter have been issued, some foreign pharmaceutical companies are considering conducting the migration of their current med reps under ROs to the locally qualified pharmaceutical distributor(s). However, this should be considered as a backup plan as long as, in practice, med rep cards are still being granted to employees of ROs of foreign pharmaceutical companies in some cities.

Pharma IP Enforcement Roundup

Vietnam's pharmaceutical laws saw a number of changes in 2017. The new legal instruments are expected to provide more effective protection to IPR holders in the industry. However, even with the new regulations, IP infringement in the pharmaceutical sector remains a significant challenge in Vietnam, and IP enforcement activities continue to play an important role.

Challenges in Enforcement

In practice, IP infringement in the pharmaceutical industry often involves patents. Administrative enforcement bodies tend to be reluctant to get entangled with the complexity of patent disputes; as a result, there has been a noticeable movement toward civil action, and a growing number of patent litigation cases are being handled by local courts. At least a half-dozen major pharmaceutical companies from Europe and the United States have filed civil cases against local infringers in Vietnam this year.

Patent litigation cases often encounter prolonged legal proceedings in court due to a number of factors, such as the defendants' filing of invalidation procedures against the registered patents in question, or constant requests from the court for expert opinions on infringement.

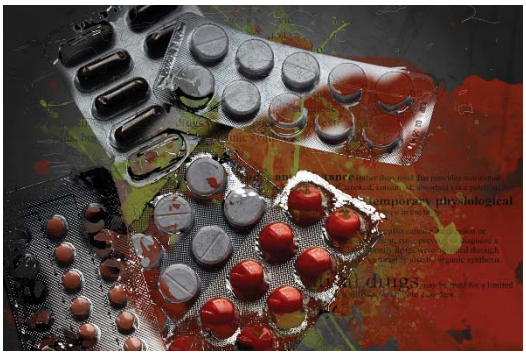
Another challenge facing IPR holders in the pharmaceutical sector recently is that the new Law on Pharmacy (effective January 1, 2017) does not provide legal grounds for the withdrawal of Marketing Authorization (MA) licenses. As a result, the Drug Administration of Vietnam often hesitates to withdraw MAs of infringing generics even after there is confirmation of patent infringement from competent authorities such as the Ministry of Science and Technology (MOST) Inspectorate and/or local courts.

In addition, among the authorities, there appears to be a general tendency to advocate for narrowing the scope of pharmaceutical patent protection in Vietnam rather than expanding it, which could pose challenges for global innovator companies if and when the patent prosecution guidelines are revised.

Notable Cases

Some representative enforcement cases in the life sciences industry from the past year include the following:

- A leading European pharmaceutical company brought an infringement case before Vietnamese authorities in relation to the crystalline form of a patented compound for the very first time. In general, other pharmaceutical patent disputes in Vietnam had concerned the patented compound itself, rather than a crystalline form of it. Assessing the patent infringement in this case required carrying out x-ray diffraction testing. The testing was carried out in Europe as Vietnam is not capable of doing the tests. The unprecedented aspect of this case was the Vietnamese authorities' acceptance of an expert opinion from abroad on a complex technical matter that was unable to be ascertained in Vietnam due to limitations on the technical facilities in Vietnam. This is the first time in Vietnam that pharmaceutical patent infringement has been proven by an x-ray diffraction test.
- A U.S.-headquartered agroscience company won a major victory in applying Vietnam's rarely tested laws on trade secret protection. In this case, the company found that one of its former employees who had moved to a competitor had downloaded massive amounts of sensitive and confidential documents related to formulae, processes, and analytics reports of the company's new products. Such information, if disclosed to the company's competitors, could lead to huge damages and disadvantages for the company in their business. In this circumstance, the U.S. company began its enforcement action with a strongly worded cease-and-desist letter to the former employee. After several meetings and negotiations, the ex-worker finally admitted that he had violated his confidentiality agreement, voluntarily surrendered the stolen confidential information, and signed an undertaking not to use or disclose to any third party any confidential information owned by his former company.
- In what developed into a major criminal case, the Ho Chi Minh City Economic Police raided seven locations in Long An Province and Ho Chi Minh City in August 2016, including separate facilities for packing, printing, and warehousing. During the raids, the police confiscated and seized a large number of counterfeit drugs and materials for manufacturing fake drugs. After the investigation, the police passed the case on to the procuracy for indictment. In September 2017, the court tried the case. In court, the accused admitted to violations of manufacturing and trading counterfeit pharmaceuticals. In the end, the five accused infringers were sentenced to prison for up to 11 years.



- In another criminal case, Nguyen Minh Hung, the director of VN Pharma, was sentenced to 12 years in prison for using his company to smuggle 9,000 boxes of substandard cancer medicine into Vietnam in 2013 and forging related documentation. That first-instance decision, however, was overturned by the High Court in Ho Chi Minh City in October 2017 for transfer to High People's Procuracy of Ho Chi Minh City for further investigation. Still, this case attracted a great deal of publicity due to the findings of significant violations of law, including mistakes made by the competent authorities in granting MAs for VN Pharma.
- In 2017, the competent authorities have been handling Vietnam's very first case relating to the enforcement of medical device patents. In this case, a major European company called on the MOST Inspectorate to investigate and deal with the alleged patent infringement committed by two Vietnamese distributors. One month after the filing, the MOST Inspectorate inspected the two companies and ordered them to temporarily cease any business relating to their alleged infringing products. This action has helped deter further infringement.

Registered Drugs Not Immune From Infringement Charges

Recent patent infringement cases in Vietnam's pharmaceutical sector have revealed the ambiguity of competent authorities' roles in determining whether a patent has been infringed. Such vagueness has caused unexpected delays in legal proceedings.

In a recent suit between a leading international pharmaceutical group and a local generic producer, the court requested the Drug Administration of Vietnam (DAV) to clarify in writing whether the DAV had taken patent issues into account when considering approval of marketing authorization (MA) for the defendant's pharmaceutical products. In response to the court, the DAV issued a letter confirming, for the very first time, that they have no responsibility by law to examine any IP infringement issues during drug registration.

Can Approved Drugs Still Be Infringing?

In the pharmaceutical sector, alleged patent infringers often defend themselves from the accusations by pointing to their MA registrations. They argue that any pharmaceutical products authorized to the market by the DAV must, by nature, be legitimate, and free from IP infringement issues. Therefore, holders of granted MAs should be released from any infringement liability.

Some infringers even contend that IP holders should instead place the blame on the competent authorities, such as the DAV, who approved the suspected infringing pharmaceutical products for circulation and distribution in the market. They presume that the DAV's responsibility to carefully review drug registration dossiers prevents any potential IP infringement prior to the market entry of products. As a result, they argue, the DAV must be liable for any patent-infringing drugs on the market.

An examination of the prevailing laws, however, reveals that such arguments are unjustified. The Law on Intellectual Property explicitly requires every individual and organization to respect the intellectual property rights of IP owners. Meanwhile, the independent and separate laws on drug registration contain no provisions stipulating the DAV's power and role to consider any IP issues with respect to drugs seeking MA registration. Furthermore, under Article 13 of Circular 44/2014/TT-BYT, the law clarifies that drug registrants or registering entities must themselves be responsible for IP-related issues both during the course of registration and after the drug has been granted a MA number.

The DAV Denies Responsibility

Regardless of the clear stipulation by law, the unjustified arguments of putative infringers have raised concerns among the courts in relation to the DAV's role in the management of drug registration, including IP-related issues. The courts seem to be inclined to side with the defendants and thus continue to seek the DAV's opinions on patent infringement.

In its letter to the court, the DAV strongly confirmed its independent position regarding IP-related issues during the process of drug registration, and reiterated the laws confirming that the Ministry of Health grants MA numbers for pharmaceutical products based only on the evaluation of their safety, effectiveness, and quality, with no obligation to review IP-related issues. The drug registrants, instead, are responsible for any matters relating to IP rights when the drugs are in circulation. In other words, the DAV has no responsibility by law to examine any IP infringement issues during drug registration. Therefore, drug registration does not render MA holders immune from IP infringement charges.

The DAV also acknowledges that under the law, when there is a judicial decision or final conclusion of the IP authorities on the infringement of IP rights, the DAV only needs to *consider* whether or not to revoke the MA or suspend the sale of a drug. Previously, such a decision or conclusion was grounds for mandatory revocation, but under the new Law on Pharmacy 2016 and Decree No. 54/2017/ND-CP, the DAV seems to be given more discretion. In a number of cases, the DAV has been reluctant to withdraw an MA even when there has been an infringement conclusion from an authority such as the Inspectorate of the Ministry of Science and Technology. Thus, there is no clear regime for an IP holder to force the DAV to withdraw and/or cancel an MA, regardless of any decisions on IP infringement from competent authorities.

If the drug registry body has no responsibility to consider IP-related issues during the MA procedures, the courts need to play a proactive role in settling patent disputes to effectively and expeditiously protect the legitimate rights of IPR holders. In the absence of coordination between drug registry authorities and IP enforcement authorities, a drug can be authorized for the market by the DAV if it meets requirements for drug registration, without IP-related issues ever being considered. However, if such drug is later found by the court to infringe others' IP, it could be banned from circulation by an authority like the court, the MOST Inspectorate, or customs, regardless of the MA.

The article above first appeared in the End of Year 2017 edition of Managing Intellectual Property.

Improving Pharmaceutical IP Protection

Vietnam's IP enforcement system has seen great improvements over the last several years. In particular, the Inspectorate of the Ministry of Science and Technology (MOST) has handled many complex disputes in the pharmaceutical sector related to patent infringement, unfair competition, and trademark infringement. Rights holders have generally been quite pleased with the decisions reached by MOST, as well as the expert opinions provided in various cases by the National Office of Intellectual Property (NOIP) and the Vietnam Intellectual Property Research Institute (VIPRI), which are often a precursor to a MOST administrative enforcement action. Nevertheless, with a few tweaks when Vietnam amends its Law on Intellectual Property (the amended law is expected to be issued in 2018), the system can be improved even further to help better protect IP in the pharma sector. Below are a few suggestions for improvement.

Patent Linkage: At present, there is no strong or efficient route to have a marketing authorization blocked or withdrawn in the event of patent infringement. Even when the Drug Administration of Vietnam is notified about a drug's potential infringement, an MA for the drug in question may still be approved. An MA may only be ordered withdrawn after a lengthy administrative or civil suit for patent infringement. In this regard, there needs to be stronger coordination among the IP enforcement and health agencies.

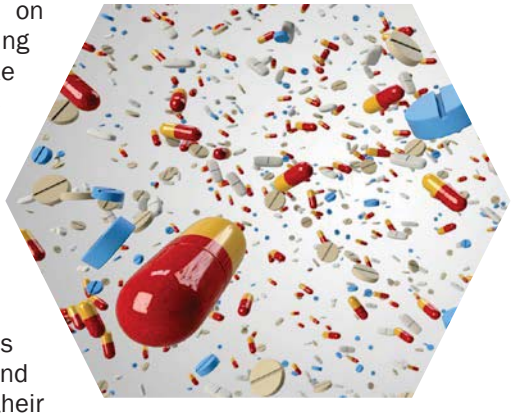
Preliminary Injunctions: So far, preliminary injunctions have not been granted in pharmaceutical patent infringement cases, even in a case where the rights holder submitted to the court three decisions/opinions (from MOST, the NOIP and VIPRI) affirming infringement. The infringer is still being allowed to participate in and win drug tenders at state-owned hospitals, and the rights holder cannot stop the sale despite overwhelming proof that it faces imminent, irreparable damage and will succeed on the merits of the case. Preliminary injunctions should be made available in these situations.

Fast-Tracking of Invalidation Actions: In some cases, such as a case involving agrochemical patents, the court has ruled on patent infringement even though an invalidation action was pending. However, in other cases, the filing of a frivolous invalidation action by the defendant has resulted in a stay being imposed on an administrative or civil action. However, such invalidation actions may take years to resolve, while damages continue to be incurred by the rights holder. Vietnam should adopt systems employed in other countries where invalidation actions heard by the patent office are fast-tracked, and/or a stay is not granted if the invalidation action is not considered to have a high chance of success on its merits.

Damage Calculations: In order to effectively deter patent infringement, Vietnam should adopt a system where patent damages can be trebled in the event that the infringer knowingly infringes a patent (such as by continuing to infringe after receiving a cease-and-desist letter, or after an administrative decision finding patent infringement has been issued). Moreover, the burden of proof of damages in IP cases is higher in Vietnam than in most countries. As mentioned, there are several hurdles in patent litigation in Vietnam, and it is therefore inappropriate that damages should be low if a rights holder can successfully overcome these hurdles and has suffered damages.

Specialized IP Court: Vietnam would be wise to consider adopting a specialized IP Court. When Thailand established its IP Court, a strong message was sent to investors that the country was focusing on improving IP enforcement, and also helped consolidate the best experts in IP jurisprudence under one court for consistent handling of cases.

Compulsory Licensing: Vietnam is considering draft regulations on compulsory licensing. However, the draft regulations are missing several key components, such as allowing the rights holder to take part in the proceedings, and not requiring failed license negotiations as a prerequisite to a compulsory license being granted. Compulsory licensing has not been granted in Thailand since 2007, and has never been granted in Japan; thus, Vietnam should reconsider whether it is truly needed, and in any case needs to ensure that any regulations comply with international commitments.



Parallel Imports: The parallel import of pharmaceuticals has been a nagging problem in Vietnam. Drugs can be imported from countries with different storage conditions (for example, different climates) and other regulatory requirements, or have misleading information on their origin, resulting in drugs being imported into Vietnam that do not meet quality standards. To protect consumers, more stringent regulations are needed. On the bright side, under the recently issued Decree 54, parallel imports in the pharma sector are more strictly controlled.

Special Import Quotas (SIQ): Many IP-infringing pharmaceuticals are imported via fast-tracked special import quotas. There is rarely any public information available on the application or decision to grant the SIQ. As a result, the rights holder cannot take action until the market has already been flooded by the infringing product, thus adding to the damages to the rights holder. Further transparency is needed.

Trademarks Incorporating INNs: Vietnam's trademark registry contains many trademarks that inappropriately incorporate INNs. The registry should adopt a trademark examination system where objections can be raised automatically in certain circumstances involving INNs, and the burden is placed on the applicant to rebut the inference of non-registrability.

The article above first appeared in the February 2017 edition of Managing Intellectual Property.

Life Sciences Services Across ASEAN

Tilleke & Gibbins not only assists top companies in the life sciences industry in Vietnam, but also provides regional representation for life sciences clients in Thailand, Cambodia, Indonesia, Laos, and Myanmar. Our dynamic group is built on decades of practice in the region and is committed to keeping pace with discovery and innovation. Led by experienced attorneys and specialized practitioners in life sciences, the regional services that we offer include:

- **Import Licenses and Product Registration:** Registration of food and beverages; pharmaceutical products; cosmetics; medical devices; hazardous substances; veterinary products; and products including advertising, labeling, and clinical trials.
- **Commercial Agreements:** Partner vetting and due diligence; drafting and reviewing commercial agreements for localization purposes (distributorship, franchising, licensing, etc.); and termination.
- **IP Registration and Enforcement:** Registration of trademarks, patents, design patents, petty patents, copyright, trade secrets, enforcement, litigation, and due diligence.
- **Compliance and Audits:** FCPA, UK Bribery Act, Regulatory, and Product Portfolio Due Diligence and Compliance audits.
- **License-Holding Companies and Local Business Set-up:** Company formation, joint ventures, corporate contracts, corporate secretarial work, licenses and compliance, employment law, visas, and work permits.

To learn more about our regional Regulatory Affairs practice,
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5 Helpful Tips for Food Market Entrants

When preparing for market launch in Vietnam, foreign food manufacturers and distributors would be well advised to note the following regulatory hurdles:

01 The general regulations on the levels, criteria, and requirements for heavy metals, pollutants, microorganisms, etc., related to food safety and hygiene for human health issued by the Ministry of Health have not been updated since 2011 are not in line with corresponding standards in other countries where the products are often produced.

02 Although there is an online submission system for registering food and beverage products in Vietnam, manufacturers are still required to submit original documents such as the CoA, HACCP, and ISO 22000 certificates. This slows down the registration process of the product.

03 Some labeling regulations are not flexible enough to cover exceptions in special cases, such as beverages sold exclusively to bars and food sold exclusively to manufacturers' store systems.

04 Foods circulating in the market are subject to periodic quality testing. However, many labs in Vietnam do not have high-quality operations, which can lead to inaccurate test results, leading to products not being in conformity with the documents registered with government agencies. In this case, the Certificate of Conformity Declaration might be revoked, and a sanction may be imposed against the seller/importer.

05 A common violation of food products is in labeling, when the information on the label is different from the information submitted to the Vietnam Food Administration or when the label changes without notice being sent to the VFA. This can result in a fine being imposed on the seller/importer, and the goods being withdrawn from the market. Manufacturers should closely monitor any changes in their products and labels to ensure compliance.

Our Vietnam Life Sciences Team

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