

## Filing Patent Infringement Lawsuits In Vietnam - What Businesses Stand To Learn?

At first glance, with a series of clear [evidence](#) such as the Assessment Conclusion of Vietnam Intellectual Property Research Institute (**VIPRI**) confirming patent infringement, the Inspection Conclusion of the Inspectorate of the Ministry of Science and Technology (**IMOST**) confirming the act of infringement, the products containing signs of patent infringement were also detained and recorded by IMOST, almost everyone would think that: The picture is clear as daylight, the infringement is obvious, undeniable, the defendant has no grounds to overturn the case. In such sense, it is best to accept defeat and conduct a negotiation with the patent holder to reduce damages. But this case gives us a different, more profound perspective: Winning in administrative procedures does not guarantee overall victory. There is still an opportunity to refute [patent infringement allegations](#) from the patent owner, even when all the evidence seems against them. From the patent owner's perspective, clearly, addressing patent infringement through civil proceedings requires a deep understanding of litigation. Otherwise, a case that appeared nearly won may turn into an irreversible failure.

The patent infringement lawsuit initiated by Merck Sharp & Dohme Company (USA) against Dat Vi Phu Pharmaceutical Joint Stock Company (Vietnam) lasted 4 years, went through two judicial levels, and consumed extensive resources from both the plaintiff and defendant. This lawsuit is not only a legal battle but also a struggle to affirm the value and importance of protecting intellectual property rights.

KENFOX IP & Law Office summarizes the case and highlights the key points, hoping that this arduous yet exemplary journey will help rights holders and related parties better visualize and understand the process. This summary aims to clarify the challenges and valuable lessons that arise from patent infringement lawsuits in Vietnam.

### Background

Merck Sharp & Dohme Company (**MS&D Company**) owns numerous patents in the pharmaceutical field, which are protected in many countries, including Vietnam. In September 2014, MS&D Company identified that Dat Vi Phu Pharmaceutical Joint Stock Company, a Vietnamese company, were granted issued circulation numbers VD-21483-14 and VD-21484-14 for pharmaceutical products named “Zlatko-100” and “Zlatko-50”. Both products contain Sitagliptin phosphate monohydrate, a compound protected under MS&D’s Patent No. 7037.



Photo of the packaging of the drug Zlatko-100

*Cease & Desist Letter:* Accordingly, MS&D Company sent a Cease & Desist Letter to Dat Vi Phu Company, which did not respond.

*VIPRI expert opinion:* To gather more evidence of infringement, MS&D submitted a request to VIPRI for an expert opinion on potential patent infringement. On October 22, 2014, VIPRI issued Assessment Conclusion No. SC008-14YC/KLGD. This document confirmed that the compound Sitagliptin phosphate monohydrate, the active ingredient in Zlatko-100 and Zlatko-50, is indeed covered under MS&D's Patent No. 7037.

*Raid under administrative procedure:* Based on the [expert opinion](#) from VIPRI (in the form of an Assessment Conclusion), MS&D Company submitted a petition to IMOST to address patent infringement actions against Dat Vi Phu Company. On January 14, 2015, IMOST inspected DVP Company. During the inspection, it was noted that *Dat Vi Phu Company had produced 590 boxes of Zlatko-50 on October 23, 2014. Of these, 290 boxes were sold to Gon Sa Joint Stock Company, while the remaining 300 boxes were found at their representative office in Ho Chi Minh City: 290 boxes stored and 10 boxes kept as samples. Unused raw materials included 48.7 kg of Sitagliptin, 36.45 kg of Zlatko-100 aluminum foil, 32.2 kg of Zlatko-50 aluminum foil, 12,300 Zlatko-100 packages, 13,350 Zlatko-50 packages, and 9,800 leaflets.*

*Commitment, but non-compliance:* During the inspection on January 30, 2015, Dat Vi Phu Company admitted to infringing on patent rights and committed to ceasing the production, advertising, and distribution of the infringing medicinal products, Zlatko-100 and Zlatko-50. However, Dat Vi Phu Company did not implement any commitments.

*IMOST Inspection Conclusion:* On March 20, 2015, IMOST issued Inspection Conclusion No. 113/KL-Ttra, stating that Dat Vi Phu Company's production and distribution of Zlatko medicinal products containing Sitagliptin violated Patent No. 7037 (and related inventions), which are protected under Article 126 of the Intellectual Property Law. However, acknowledging Dat Vi Phu Company's cooperative attitude in the case, IMOST temporarily postponed the sanctions. They requested that Dat Vi Phu Company cease production, distribution, and advertising of the products, destroy all existing products and raw materials, and re-export the Sitagliptin within 07 days.

Despite requests from IMOST, Dat Vi Phu Company still did not comply.

*Lawsuit:* On September 7, 2016, MS&D Company filed a patent infringement lawsuit against Dat Vi Phu Company in the People's Court of Binh Duong Province.

*First instance verdict:* More than three years later, on December 4, 2019, the People's Court of Binh Duong Province issued its first instance judgment. The court accepted the plaintiff's entire lawsuit request, notably ordering the defendant to [compensate](#) the plaintiff 800,000,000 VND. Additionally, the defendant must cease patent infringement, recall and destroy the infringing products, and issue a public apology and corrections

*Appeal:* On December 16, 2019, Dat Vi Phu Company appealed to overturn the entire first instance judgment.

*Appeal judgment:* On July 15, 2020, the High People's Court in Ho Chi Minh City issued an appeal judgment. Accordingly, it accepted the appeals from the Procuracies and the defendant, annulled the first instance verdict of the People's Court of Binh Duong Province, and ordered a retrial from the beginning.

## Practical lessons to learn

The High People's Court of Ho Chi Minh City accepted the appeals from the Procuracies and the defendant due to errors in the trial process at the first instance level. However, this case offers valuable lessons from both perspectives—the party accused of patent infringement (defendant) and the patent owner (plaintiff)—that need to be learned.

## [1] Evidence in Petitions to Handle Patent Infringement: What Are the Differences Between Administrative and Civil Procedures?

The most obvious difference in handling evidence when an IP rights holder petitions for an enforcement action under administrative or civil procedures lies in how administrative agencies and courts assess and utilize the evidence. Under **administrative measures**, [agencies](#) can initiate inspection procedures based on preliminary documents and evidence, even if these only suggest a “suspected infringement” (*Article 23, Decree 105/2006/ND-CP*). This approach allows them to determine the existence of an IP infringement without initially confirming the evidence's legitimacy. If a violation is detected during this process, infringing products are immediately detained under administrative procedures, thereby protecting the rights and interests of IPR holders.

However, evidence required under **civil procedures**, especially in IP infringement lawsuits, must adhere to stricter standards than those in administrative procedures. This evidence must meet clear legal conditions outlined in an entire chapter - Chapter VII, Articles 91-110 - of the 2015 Code of Civil Procedure. If any of these conditions are not met, the evidence provided by the plaintiff may be deemed inadmissible and lack probative value, causing all efforts to pursue the lawsuit to evaporate. The annulment of the first instance judgment in the aforementioned case serves as a typical example.

## [2] What Were the Reasons for the Failure of the Above Case?

In the above case, the **First Instance** Court accepted VIPRI's [Assessment Conclusion](#), which affirmed signs of patent infringement, to issue a verdict favoring the plaintiff. This Assessment Conclusion was also accepted by IMOST to initiate enforcement measures, including inspection and temporary seizure of infringing products and materials. Legally, the 2015 Civil Procedure Code recognizes an Assessment Conclusion as one of the ten sources of evidence (Article 94). Additionally, the IP Law of 2022 states in Article 201.5 that an Assessment Conclusion is a valid source of evidence for competent authorities in case resolution.

In civil proceedings, litigants - including plaintiffs, defendants, and persons with relevant interests and duties - have the right to request that the court solicit an Assessment Conclusion or to request one themselves (*Article 102 of the Civil Procedure Code*). Assessment Conclusions are considered valid “**evidence**” of infringement only if “*the appraisal is conducted according to legally prescribed procedures*” (*Article 95 of the Civil Procedure Code*). In the case discussed, the High Court did not accept VIPRI's Assessment Conclusion, even though it had been accepted by IMOST for administrative handling.

So where does the problem lie? In the aforementioned lawsuit, the plaintiff provided documents confirming their status as the intellectual property rights holder (Patent No. 7037 and No. 5684). They believed that the defendant had infringed upon these patent rights, **based on Assessment Conclusion No. SC008-14YC/KLGD** issued by VIPRI on October 22, 2014. However, a crucial detail is that the plaintiff used only the “**Decision No. 437/QĐ-QLĐ dated August 12, 2014, from the Director of the Drug Administration of Vietnam**” for the assessment. This document did not include samples of Zlatko 100 and Zlatko 50 because the defendant had not yet started producing these products at that time.

VIPRI did not examine the “actual samples” of the drugs Zlatko 100 and Zlatko 50. However, the Court of First Instance relied on Assessment Conclusion No. SC008-14YC/KLGD to resolve the case. This reliance is problematic because the conclusion was based solely on documents, not on actual samples of the drugs, which compromises its objectivity. Objectivity is one of the three required attributes for evidence to be considered admissible. Therefore, the evidence provided by the plaintiff, specifically the Assessment Conclusion, violates an important legal principle regarding the admissibility of evidence.

In addition, during the settlement process at the first instance level, the defendant disagreed with the Assessment Conclusion and requested a re-assessment. However, the Court of First Instance did not accept this request and continued to rely on the Assessment Conclusion provided by the plaintiff to resolve the case. This action is in violation of Articles 92.2 and 102 of the Civil Procedure Code.

Speaking more specifically, the defendant exercised their right under civil procedure law to “object to” the expert opinions from the professional agency (VIPRI) provided by the plaintiff. Ideally, if the defendant disagreed with VIPRI's Assessment Conclusion and requested a reassessment, the Court of First Instance should have used the “sample” kept by IMOST for a re-assessment. Had the Court of First Instance directed VIPRI to conduct an assessment based on a “sample” temporarily detained during the inspection at the defendant's headquarters, and if VIPRI's conclusion was based on this

'sample,' the defendant would have no grounds to question the admissibility of the evidence. This would eliminate the basis for annulling the entire first instance judgment and requesting a retrial.

Speaking more specifically, the defendant exercised their right under civil procedure law to 'object to' the expert opinions provided by VIPRI, which the plaintiff had submitted. Ideally, if the defendant disagreed with VIPRI's Assessment Conclusion and requested a [new assessment](#), the Court of First Instance should have used the 'sample' kept by IMOST for a re-assessment. If VIPRI had then conducted an assessment based on a 'sample' (exhibit) temporarily detained during an inspection at the defendant's headquarters, and if their conclusion was based on this sample, the defendant would likely have no grounds to challenge the admissibility of the evidence. This could potentially eliminate the need to annul the entire first instance judgment and request a retrial.

### [3] New Assessment Conclusion Confirms Patent Infringement but Is Rejected: Why?

During the appeal hearing, the plaintiff submitted a new Assessment Conclusion (No. SC036-20YC/KLGD, dated June 12, 2020) from VIPRI, assessing the drug Zlatko-25 to demonstrate that it infringed the plaintiff's patent rights. However, the High Court ruled that the assessment, conducted at the plaintiff's request, did not comply with legal requirements. Additionally, the defendant disagreed with the assessment results, leading the court to declare that Assessment Conclusion No. SC036-20YC/KLGD was not valid evidence for resolving the case.

Why did the Court refuse the Assessment Conclusion when it is considered one of the ten "sources of evidence" as prescribed in Article 94 of the Civil Procedure Code? It is important to remember that Assessment Conclusions are only considered valid legal evidence if "*the assessment was conducted in accordance with the procedures prescribed by law*" (Article 95.6). Article 102.1 of the Civil Procedure Code stipulates that "*a litigant has the right to request that the Court solicit an assessment conclusion or to request the assessment themselves if the Court has previously denied such a request. This right must be exercised **before** the Court decides to proceed to trial under first instance procedures*". Thus, for an Assessment Conclusion provided by a litigant to be accepted as "evidence", two conditions must be met: (i) the litigant requested the Court to solicit an Assessment Conclusion, but the Court rejected this request, and (ii) the request for an Assessment Conclusion was made before the Court decided to bring the case to trial according to first instance procedures.

The High Court may have rejected the Assessment Conclusion supplemented by the plaintiff because it was made contrary to the provisions of Article 102 of the Civil Procedure Code (supplemented during the appeal trial stage). Additionally, the rejection may be due to the High Court applying the Law on Judicial Expertise, which stipulates that "Expertise requesters are those who have the right to request expertise themselves after their requests for procedure-conducting agencies or persons to solicit expertise are rejected" and "*Expertise requesters may only request expertise by themselves before courts issue decisions on first-instance trial of their cases*".

### [4] Assessment Conclusions Should Not Rely Solely on "Paper"

In the case mentioned, the plaintiff did not provide an actual sample product for assessment, but instead provided only the name of the compound in "*Decision No. 437/QD-QLD dated August 12, 2014, by the Director of the Drug Administration of Vietnam, which promulgated the list of 412 domestically produced drugs registered for circulation in Vietnam - phase 146, including the products Zlatko 100 and Zlatko 50 registered by the defendant*" as a basis for assessment. This approach violates Article 48 of Decree No. 105/2006/ND-CP, which requires assessments to be based on specific samples for accurate [evaluation](#). The High Court found that the Court of First Instance failed to collect all necessary evidence and relied on insufficient evidence to make its decision, leading to judgments based on uncertain foundations and compromising the fairness and transparency of the trial process.

### Final thoughts

The lawsuit, which lasted four years and underwent two levels of trial, not only highlighted legal difficulties and challenges but also the considerable consumption of resources and time. While awaiting reforms and a more adaptive judicial approach, it is evident that winning IP infringement cases, particularly in patent disputes, demands that lawyers and IP experts possess a thorough understanding of the complexities of IP law, civil procedure, and relevant regulations. This enables them to shape

appropriate legal strategies to protect clients' IP rights. Preparing sufficient, convincing, and accurate evidence from the outset is essential to increase the likelihood of success and minimize the need for additional evidence later, thus reducing the risk of having evidence rejected.

KENFOX IP & Law Office, with its extensive practical experience and expertise, has successfully supported many IP rights holders in handling and enforcing their IP rights. Please contact us if you need a professional IP representative to effectively handle IP infringements in Vietnam.

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