Patent Litigation 2022

Mexico: Trends & Developments
Elías Ríos, Cesar A. Ramirez, Citlali Carlos and Karen Covarrubias
Vila Attorneys at Law

practiceguides.chambers.com
COVID-19, Oral Drugs and Patents in Mexico

With the exponential growth of the pandemic worldwide, new, safer and rapid treatments are needed to reduce the risk of the progression of the novel coronavirus (COVID-19).

Scientific literature reveals that monoclonal antibodies are currently authorised treatments for at-risk outpatients with COVID-19.

However, said antibodies require administration by means of infusion or injection in a medical setting. Thus, oral agents, such as molnupiravir, may be more practical and patient-friendly for non-hospitalised persons, as they can be administered by the patient at home shortly after diagnosis and their mechanism is independent of mutations in the spike protein of the virus.

In its very first communication of 2022, the Mexican Regulatory Agency (COFEPRIS) announced that the Mexican government had authorised the use of molnupiravir.

Molnupiravir

Molnupiravir is an oral, small-molecule antiviral prodrug (i.e., one that, after administration, is metabolised into a pharmacologically active drug) that is active against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

COFEPRIS recently authorised the oral treatment molnupiravir to be used to treat patients with mild or moderate COVID-19, and those with a high risk of complications.

The approval process began the week of 23 December 2021, when technical information was exchanged with other regulatory agencies; this knowledge transfer process was carried out thanks to regulatory convergence, declared a priority in COFEPRIS in August of last year.

This treatment (on a controlled emergency basis) does not replace the authorised vaccines against COVID-19, and it should not be used without medical indication.

How it works?

Specialised personnel of the Healthcare Authorisation Commission evaluated the submitted evidence presented by manufacturers certifying compliance with the necessary requirements to guarantee quality, safety and efficacy.

Based on the available studies, COFEPRIS determined that this treatment may be authorised for emergency use for the following therapeutic indications:

- treatment of mild to moderate COVID-19 symptoms;
- in adults with a positive SARS-cov-2 diagnostic test;
- where supplemental oxygen is not required;
- for those who have at least one risk factor for developing severe COVID-19, including hospitalisation or death; and
- for whom the authorised, alternative COVID-19 treatment options are not accessible or clinically appropriate.

The drug works by introducing errors into the genetic code of the SARS-CoV-2 virus, preventing it from replicating in the body. It is an
oral medication supplied through capsules for a period of five days.

The role of IP
With a growing range of COVID-19 vaccines and other products coming online, the international community is targeting universal access. This, however, reveals new challenges related to the protection for inventions and inventors.

The Medicines Patent Pool is an initiative that links up interested parties to promote the voluntary licensing practices of pharmaceutical companies, helping the IP-owner enterprises link up with local partners who can widen production and distribution of medical technologies.

Here is where “licensing” comes to the spotlight.

In a licence agreement (a tool for transferring IP) the licensor grants authorisation to a company that has manufacturing capacity and distribution channels to bring the invention to potential users. In other words, the owner of the IP, or the entity that controls the use, allows third parties to develop, manufacture and/or distribute the invention.

The standard licensing model allows a licensor to receive a royalty fee under the agreed financial terms of the agreement.

What about open science?
UNESCO has established that “open science” has the potential to make the scientific process more transparent, inclusive and democratic; and also that it is increasingly recognised as a critical accelerator for the achievement of the United Nations’ Sustainable Development Goals and a true game-changer in filling the science, technology and innovation gaps and fulfilling the human right to science.

Nevertheless, it is necessary to bear in mind that intellectual property is a critical ingredient in solving pressing problems as the bridge allowing diverse parties to work together with clarity, by providing a legal basis for production at large scale and within an efficient timeframe to satisfy demand in a public health emergency.

Common market failures are related to the limited capacity to manufacture the invention in the necessary quantities and the risk of concentrating distribution of the invention only in those places where users can pay a premium.

At its most basic, IP ownership allows technology transfer and derived agreements to offer effective instruments that regulate the collaborative process to reach scientific findings from creators, such as research institutions and universities, or business labs, to public and private users, with the goal of transforming inventions and scientific outcomes into new innovative products that benefit society.

Technology transfer also fosters the multiplication of certain much-needed inventions, such as new pharmaceutical products.

“Emergency”
The official press release launched by COFEPRIS highlights “emergency conditions”.

The Mexican government has issued decrees defining what should be considered a “health emergency” (force majeure, epidemic, etc) and COFEPRIS is entitled to analyse, in accordance with the applicable legal framework, the relevance of reducing the documents required in the equivalence agreements, as well as to granting applicants the registration of health supplies in a shorter period than that mentioned in previous equivalence agreements.
The authorisation for “emergency” use is issued in a controlled manner and requires a medical prescription, considering the details in the authorisation letter to avoid misuse of this drug, self-medication and/or its irregular sale.

“Collateral damage”
COVID has brought the world face-to-face with a scenario where respiratory medications are the tip of the iceberg. As lockdowns and restrictions relax in several locations globally, some people are finding it challenging to get back to “normal” life. Going back out and mingling with other people is a concept that is causing an uptick in fear and anxiety.

Behavioural therapy and medications for treating anxiety, or depression can help those experiencing significant difficulties with this unique and evolving mental health challenge.

Medicines against anxiety and antidepressants are some of the most demanded in the current health crisis and it is necessary to analyse their place as a necessary resource to face this challenge.

**Mexican scenario**
In the past 20 years, the Mexican regulatory framework has radically changed. While in other countries – such as Canada, Australia and Switzerland – it is in the process of being analysed, Mexico is part of a group of countries authorising the drug in record time by arguing that other regulatory agencies have scientific evidence that this oral therapeutic option as safe and effective.

In addition, legal amendments allowing linkage between healthcare registrations and patents of substance or active ingredient, and the signing of the United States–Mexico–Canada Agreement (T-MEC), opening the possibility of patents for second medical use, together with the possibility of granting adjustments to the duration of patents unreasonably delayed, make Mexico an attractive destination to invest in the pharmaceutical industry.

The above is confirmed by an overall scenario of 12 Free Trade Agreements with 46 countries, 32 Agreements for the Reciprocal Protection of Investments with 33 countries and nine agreements within the framework of the Latin American Integration Association, setting the conditions for major transnational companies that have announced multimillion dollar investments in the upcoming years in Mexico to expand their capacity and modernise their plants, in addition to continuing their clinical research and launching new products.

This creates an obligation and an opportunity for the state – and most likely for private advisors too – to set an appropriate health policy and guarantee the population’s access to medicines. This is not only a question of regulation, but of efficiency. Accepted medicines are of little use if they are not accessible to the population.

In closing, Mexico is an attractive destination to invest in the pharmaceutical industry, which coupled with the current COVID-19 pandemic, suggests sustained growth in the coming years for the pharmaceutical industry.
Vila Attorneys at Law specialises in intellectual property. Active across a wide range of sectors and industries – including infringement and prosecution cases involving trade marks – VILA’s patent litigation and enforcement of IP rights practice has grown rapidly. Additionally, the team has been engaged in administrative litigation, enforcing clients’ rights before administrative and judicial courts as well as appearing in legal actions before Mexican customs to prevent counterfeiting products entering Mexican territory. Although there are other law firms that cover these practice areas, there is no one in the west of Mexico that specialises in IP to the extent that VILA does.

AUTHORS

Elías Ríos is a key player in Vila’s IP litigation practice, mainly focusing on patents. He is responsible for assisting universities and pharmaceutical companies, among others with their commercial and litigation strategies. His expertise extends across a spectrum of matters, ranging from freedom-to-operate opinions to full-scale litigation proceedings, as well as the negotiation and drafting of transactional agreements. His experience of IP enforcement for the software industry means that copyrights and franchising issues are also part of his practice. Elías is a regular speaker on IP topics, both in Mexico and internationally.

Cesar A. Ramirez has more than ten years of experience in IP matters. He is heavily involved in Vila’s trade mark prosecution and enforcement efforts and supervises the firm’s litigation team. Criminal actions, border measures and unfair competition remedies are also part of his practice. Cesar maintains a blog on IP matters.
Citlali Carlos renders services to national and international clients, including from practices in Spain and Turkey related to executing business legal agreements. From her position, she supervises all aspects of trade mark practice and is heavily involved in prosecuting international trade mark applications, making her a key asset in the trade mark division structure.

Karen Covarrubias has gained remarkable skills within her professional growth, such as a passion for intellectual property and litigation, mainly focused on patents, as well as case tracking, prospect attraction and business negotiations.

Vila Attorneys at Law
Calle Severo Díaz 38
Arcos Vallarta,
44600 Guadalajara, Jal.
Mexico
Tel: +33 1204 0477
Email: Rios.elias@vila.com.mx
Web: www.vila.com.mx