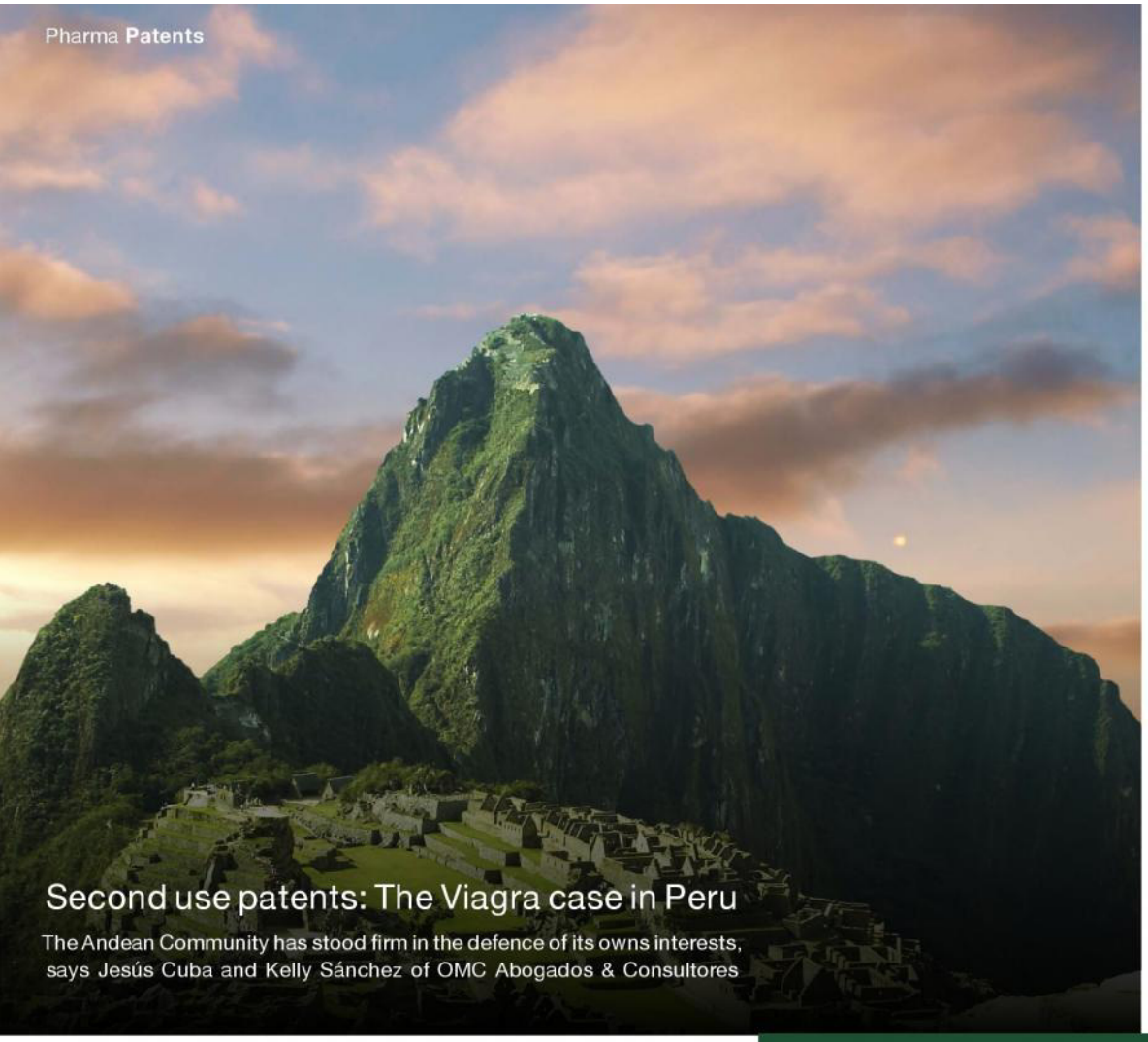

Second use patents: The Viagra case in Peru

The Andean Community has stood firm in the defence of its owns interests, says Jesús Cuba and Kelly Sánchez of OMC Abogados & Consultores

Pharma **Patents**

In May 1994, Pfizer requested, for medical use, a patent covering pyrazolopyrimidine for the treatment of impotence, better known as Viagra, whose chemical compound sildenafil citrate was already used for the treatment of cardiovascular diseases. The application had been rejected on three previous occasions by the Office of Inventions and New Technologies of the National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI) of Peru. It contravened what is stated in Article 16 of Decision 344 and Article 43 of the Legislative Decree No 823, in force at that time, which indicate that the products and processes that are already patented "shall not be the object of a new patent, by the simple fact of a different use from that originally contemplated by the initial patent".

However, in June 1997, Supreme Decree N° 010-97/ITINCI was enacted, in order to clarify and interpret several articles of Decision 344, including Article 16. This Supreme Decree, particularly Article 4, stipulated that "a different use included in the prior state of the art will be subject to a new patent if it meets the requirements laid down in Article 22 of Legislative Decree No.823" (ie, the traditional requirements of novelty, inventiveness and industrial applicability), thus allowing INDECOPI, on 29 January 1999, to grant the patent for Viagra in favour of Pfizer.

Meanwhile, Peruvian laboratories were manufacturing a copy of Viagra, thinking that the patent application of Pfizer would be rejected. Pfizer threatened to sue them on the basis of its newly granted patent. This led to a complaint from the Association of Pharmaceutical Industries of National Origin and Capital (ADIFAN), to the general secretariat of the Andean Community for the violation of Article 16 of Decision 344.

On 12 October 2000, the general secretariat of the Andean Community initiated an action of non-compliance (process 89-AI-2000) in the Court of Justice of the Andean Community against Peru for granting a second use patent covering a pyrazolopyrimidine product for the treatment of impotence, as community law expressly prohibits the patenting of second uses or different uses.

As a result of this action for breach of the treaty, the Peruvian government, through INDECOPI, declared Pfizer's patent to be null and void on 27 August 2002 by not complying with the requirements of Decision 344.

In many jurisdictions, exclusivity can be extended if the patenting of second uses is allowed. For reasons of industrial production, it is practically impossible to separate the production of a drug for a use for which its patent has already expired from the production of the same product for a second indication, for which its patent is still in force. It happens that the exclusivity of the product will be maintained by the person who invented the molecule.

This is a sensitive issue and the debate on the patentability of second uses continues due to the importance of the right to access to health for all people as well as in the treatment of diseases.

In relation to pharmaceutical patents, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) identifies three types of general obligations:

- Patenting: Whether products (a drug, for example) or procedure (for instance, the method of production of chemical compounds for a drug), although the concession remains subject to exceptions.

Pharma **Patents**

> ***While member states are empowered to issue legal tools for proper implementation of Decision 344, such tools cannot introduce changes that affect its structure***

Jesús Cuba, Lawyer, OMC Abogados & Consultores

- Non-discrimination: Commitment imposed on member states to grant patents regardless of the technological field. In other words, if the pharmaceutical inventions satisfy the requirements for patentability (novelty, inventive step and industrial applicability), they will be protected as the rest of patentable inventions that cover other scientific and technical fields. Furthermore, discrimination can not be justified either for the place of origin of the invention or for the fact that the products that composed it are imported or produced in a determinate territory.
- Disclosure: Obligation that addresses the need to ensure that the details of the invention must be contained in the patent application, so they can be disclosed to the public. This duty to disclose the specifications of the product or procedure to patent, can even lead to the disclosure of the steps to reproduce the invention.

We must also indicate that Article 27 of TRIPS does not encourage or forbid second use patents, so member states of the World Trade Organization that accept or reject them, are not acting against TRIPS.

The primacy of community law in Viagra case

The Court of Justice of the Andean Community, through the process 89-AI-2000, annulled the patent that was granted to Pfizer, which was achieved through the application of Article 4 of Supreme Decree No 010-97/ITINC, which textually stated: "To clarify that in accordance with Article 43 of Decree 823, a different use comprised in the prior state of the technique will be the subject of a new patent if it meets the requirements established in Article 22 of Legislative Decree No 823."

While it is true that member states are empowered to issue legal tools for proper implementation of Decision 344, such tools cannot introduce changes that affect its structure.

In the present case, the court found that this article distorted the principles of the Andean Community scheme in contravening the provisions of Article 16 of Decision 344, which expressly forbade second use patents. Furthermore, INDECOPI ignored the commitments made by Peru to the Andean Community by failing to take into account that Decision 344 is just below the Constitution but not under other laws, so no national standard may contradict its provisions.

In conclusion, patents for second uses are prohibited in the Andean Community and in Peru, because they represent a condemnation for technology transfer and access to health. With such patents, the aim is to extend an industrial duty on a product or pharmaceutical procedure that is already part of the state of the art and which is more like a discovery than an invention itself.

Currently in Decision 486, the valid norm at this date, it has conserved the same position about second use patents, as stated in Article 21: "Products or processes already patented, included in the prior art, in accordance with Article 16 of this decision, shall not be the object of a new patent, by the simple fact of a different use from that originally contemplated by the initial patent."

This proves that although the global trend, particularly in developed countries, is to grant second use patents, especially in the pharmaceutical field, the Andean Community has stood firm in the defence of its owns interests, without yielding to the pressure of multinational companies and industrialised countries. **IPPro**

> ***The Andean Community has stood firm in the defence of its owns interests, without yielding to the pressure of multinational companies and industrialised countries***

Kelly Sánchez, Lawyer, OMC Abogados & Consultores