FECC releases study on competition barriers relating to expired patent pharmaceutical products

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AUTHORS

Lucía Ojeda Cárdenas

Felipe García Cuevas

Introduction

Patents are essential for incentivising innovation and the development of new and improved pharmaceutical products. They give innovative laboratories exclusive exploitation rights over their pharmaceutical products for 20 years, after which other laboratories can develop their own generic version to compete with the original product.

On August 9 2017 the Federal Economic Competition Commission (FECC) released a study on the free market and competition in the expired patent drug market. The study analysed the level of competition in various drug markets following the expiry of an original drug's patent.

Study

The FECC used different measures to conduct its analysis, such as:

- the level of competition in each market;
- the speed and intensity at which generic drugs entered the market;
- the capacity of generic markets to reduce prices; and
- the capacity of the innovative laboratory that had developed the original drug to delay competition.

In total, the FECC considered 167 'molecule patent' drugs.(1)

Through this analysis, the FECC concluded that:

- some drugs with expired patents face no competitors; and
- the entry to the market of generic drugs is slow and delayed.

More specifically, the study showed that for four out of 10 drugs analysed, no generic versions existed on the market, even though the original drug's patent was already in the public domain.

This delay in the entry of generic drugs to the market shows that the so-called 'Bolar' clause is not being used. This clause allows laboratories that want to manufacture generic drugs to start experimenting and requesting the paperwork to acquire sanitary registration three years before the original product's patent expires.

According to the FECC, the foregoing is a result of several obstacles to competition relating to industry regulations and the behaviour of the innovative laboratories which develop original drugs and hold the associated patents. These obstacles – which ultimately discourage possible new competitors from developing generic versions of the drugs and entering the market – may be

summarised as follows:

- The existing health legislation restricts the possibility of substituting branded drugs for generic ones when a doctor has not specified a generic name in the prescription.
- There is a lack of transparency in the link between the patent system and the procedures for the sanitary registration of generic drugs.
- There is a lack of public information on the approved sanitary registrations and the deadlines for obtaining one.
- Patent terms can be extended through a secondary patent where:
    - the drug has an additional medical use that may be therapeutically more valuable than the first use; or
    - there have been changes in a prior-approved drug's formulation, dosage or route of administration which will enhance the treatment's efficacy.
- Innovative laboratories can generate a change in demand for the original drug due to a new formulation, which is protected under a newer patent, with the help of doctors and pharmacists.
- The innovative laboratory that develops an original drug and other laboratories which are intending to develop a generic version can enter into a pay-for-delay agreement, whereby the former pays the latter not to enter the market during a given time.
- Trials regarding patents and health registration occur, through which an innovative laboratory may block or delay the entry of generic drugs.

Recommendations

The FECC issued a series of recommendations which aim to increase the number of generic drugs competing in the market and facilitate and accelerate their market entry:

- Transparency of the linkage system between the patent system and the procedures for the sanitary registration of generic versions should be enhanced through the establishment of clear rules. These rules may be important for limiting the possibility of discretional decisions, which would reduce judiciary disputes that aim to delay or hinder the market entry of generic drugs.
- The quality of information should be improved, including with regard to:
    - the specific duration of the process;
    - the existing drugs with valid health registrations and their main characteristics; and
    - the existing patents that protect approved reference drugs.

  Further, the immediate entry of generic drug products to the market should be promoted. In order to incentivise the entry of generic products to the market, the FECC emphasised the importance of the Bolar clause and recommended the establishment of a periodically updated list of drugs whose patents will expire in the next three years.

- Obstacles to the entry of generics to the market caused by regulations should be eliminated by reforming the Regulations on Health Supplies so that:
    - doctors must write a generic name on prescriptions; and
    - pharmacists can disclose an available generic drug where it contains the same active substance, concentration and route of administration and a doctor has not expressly prohibited it in the prescription.
- The demand for generic drug products in the private sector should be promoted to increase public trust in generic drugs. In this regard, the FECC recommended that the Ministry of Health develop communication strategies to increase the trust of doctors and members of the public in the quality of generic drugs.
- Obstacles relating to the purchase of drugs in the public sector should be removed, improving purchase processes and payment times, thus promoting the entry to the market of small and medium-sized competitors that sell generic drugs. This could encourage production levels to rise to those necessary for greater private market entry of generic drugs and enhanced competition.

Comment

The FECC study is an important effort to understand the regulatory obstacles to fair competition in the Mexican expired patent drug markets. However, because the sample used to generate the study was limited, the FECC must perform a deeper analysis of specific cases and continue to study these markets, considering all of the different links in the supply, distribution and marketing chain.

As a result of the study, the FECC may identify evidence of monopolistic practices that are affecting the markets and thus open investigations to unveil such conducts and the parties behind them.

For further information on this topic please contact Lucía Ojeda Cárdenas or Felipe García Cuevas at SAI Consultores SC by telephone (+52 55 59 85 6618) or email (loc@sai.com.mx or fgc@sai.com.mx). The SAI Consultores website can be accessed at www.sai.com.mx.

Endnotes

(1) The FECC has defined a 'molecule patent' drug as a combination of the drug's active ingredient and the patent number that covers it. The criteria used to identify such active ingredients is expired patents.
