European Union

Bugnion SpA

EU offers increasingly interesting market for pharmaceutical trademarks

The European Union offers an increasingly interesting market for pharmaceutical brand owners, thanks to its growing elderly population, above average expenditure on drugs and robust use of branded drugs over generic equivalents

In Italy, any EU-focused and pharma-related IP subject brings to mind the issue of the new post-Brexit headquarters of the European Unified Patent Court. While the Parisian branch of the court will be the main and general office of the three planned venues, the London and Munich offices were meant to specialise in certain areas – London in particular was destined to host the court specialising in pharmaceuticals, chemistry, metallurgy and life sciences.

With the United Kingdom's upcoming exit from the European Union, London is no longer a possible candidate. Italian authorities and stakeholders are therefore preparing an economic-legal dossier that aims to accompany and support Milan's candidacy as a host for the future headquarters of the EU Patent Court from now until 31 October 2019 (when it seems that Brexit may actually take place).

Pharmaceutical companies – manufacturing trends

Despite the decision earlier this year to assign the headquarters of the European Medicines Agency to Amsterdam (and not Milan), it is worth noting that within Europe Italy has the largest number of companies that manufacture for major pharmaceutical brands. These are so-called 'sub-contractors' – an organisational model that allows companies that hold marketing authorisations to outsource production and control pharmaceutical development activities, entrusting them to specialised companies with their own production facilities and laboratories.

The Italian contract development and manufacturing organisation industry is at the top of the podium in Europe with a production value of €1.7 billion and 9,000 employees. Germany is in second place at €1.5 billion, while France takes third place at €1.4 billion. Italy produces 23% of the total EU production of pharmaceuticals and is the largest producer of medicines in the European Union, with:

- the highest growth in exports – an increase of 107% between 2007 and 2017, compared to a 74% increase in the European Union; and
- the highest growth in R&D investment – an increase of 22% since 2012, compared to a 16% increase in the European Union.

Healthcare statistics

In addition to production, the Italian market remains attractive to pharmaceutical companies and offers great value for brand-focused companies.

According to 2018 estimates, life expectancy in Italy is stable for both genders:

- men – 80.8 years; and
- women – 85.2 years.

In the European Union, Italy, Sweden and Malta take first place for male life expectancy. Italy is in fourth place for female life expectancy after Spain, France and Luxembourg (2016 data).

Italy's data fits into the continental context that sees very high average life expectancy in all EU countries. According World Bank Group data, average life expectancy is:

- 81 years in the European Union;
- 79 years in the United States; and
- 71 years worldwide.

In terms of health expenditure per capita – with an average spend of $3,211.40 per capita in 2016 – the European Union spent three times more than the world average (according to data from the Global Health Expenditure database of the World Health Organisation).

Although there are significant variations between countries, the European Union tends to have a population in which:

- the proportion of elderly people is rising;
- expenditure on drugs remains significantly above average; and
- the use of branded drugs over generic equivalent drugs is more robust than in other countries.

According to the Medicines Utilisation Monitoring Centre's 2015 National Report on the Use of Drugs in Italy (published by the Italian Medicines Agency), among drugs with expired patents, the generic equivalents represent only 28% of expenditure and 31% of consumption (ie, 72% of the expenditure and 69% of the consumption of expired-patent drugs is absorbed by branded drugs). Although Italy has one of the highest figures in this respect, the proportion between generic and branded pharmaceuticals in

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most EU countries remains at a ratio of between 1:3 and 1:4. Given these figures, pharmaceutical companies need to pay special attention to their trademarks, in order to take account of the special requirement for pharmaceutical marks.

Comparison of goods

Both the EUIPO and the European Court of Justice have consistently held that the therapeutic indications of a drug alone are not normally sufficient to consider medicines as different; indeed, the use in relation to a particular disease does not outweigh other factors that must be considered when assessing the similarity of products. Although intended for different clinical uses, if two medicines have the same nature, they have substantially equivalent purposes (ie, the treatment of a disease) and share the same commercial channel (Case T-146/06, ATURION; Case T-487/08, KREMEZIN; and CaseT-161/10, E-PLEX).

The possible coincidence of therapeutic indications, however, is relevant in defining the degree of similarity between two pharmaceutical products. From this perspective, the fact that one product is sold on prescription only, while another is an over-the-counter drug is, in essence, irrelevant in determining the similarity of the goods.

Relevant public and degree of attention

The prevailing position on this issue is that in the case of pharmaceutical preparations the degree of attention of the relevant public is relatively high, regardless of whether they are sold on prescription (Case T 131/09, BOTUMAX; and Case T 331/09, TOLPOSAN).

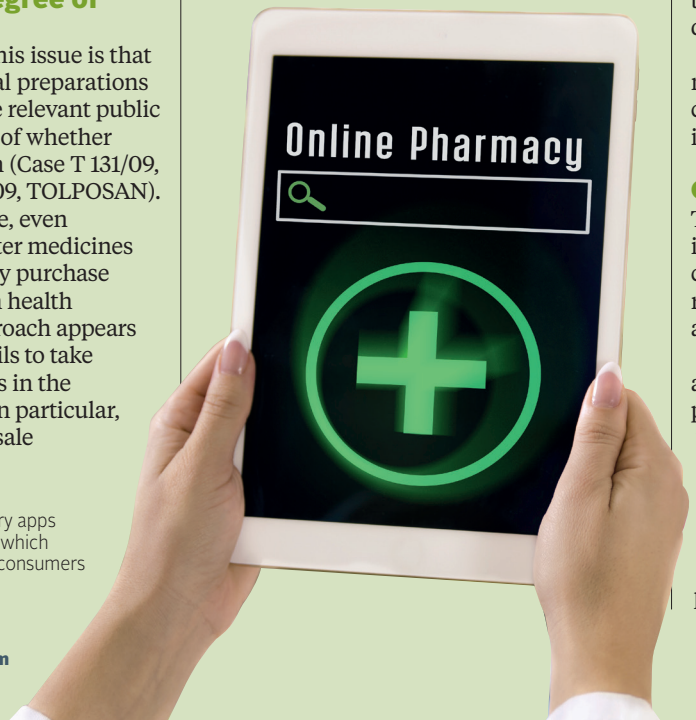
According to this principle, even consumers of over-the-counter medicines are more careful because they purchase products related to their own health concerns. However, this approach appears to be largely outdated and fails to take account of real developments in the pharmaceutical sector and, in particular, of new developments in the sale of medicines.

The allegedly higher level of consumer attention to pharmaceutical products appears to remain reasonably realistic in relation to prescription medicines, as these products are marketed under the close scrutiny of pharmacists. However, it no longer seems reasonable for other medicines, particularly in view of the spread of (legitimate) online pharmacies.

In identifying the relevant consumer and the circumstances in which that consumer makes a purchase, a distribution channel for medicines (including over-the-counter medicines), which is essentially monolithic and based on the monopoly of traditional bricks-and-mortar pharmacies in which even non-prescription medicines were sold by professional personnel, cannot be taken for granted. Today, consumers are buying independently and without supervision medicines that, although once available just on request, previously passed under the watchful eye of a pharmacist. This circumstance, although scarcely considered today, is destined to become one of the determining factors in the global assessment of the risk of confusion.

Other IP rights

The trend to trivialise drugs makes it increasingly necessary to adapt the protection strategy as a result of the changing context. Unlike in the past, pharmaceuticals are no longer merely a means of treating diseases, they have become real products with their own commercial nature.



Online pharmacies and home delivery apps are significantly affecting the way in which pharmaceutical products appear to consumers

PICTURE: PHOENIXNS/SHUTTERSTOCK.COM

Shape, colour, packaging and, in a more radical sense, smell and taste, play an increasingly decisive role both in the identification of products by consumers and in their preference over other products with the same therapeutic indications.

This is even more evident for medicines with expired patents. In this regard, it is more important than ever to consider opportunities to protect not only the name of the medicine, but also the shape of the pills, the design of the packaging and the aesthetic details of the bottle that contains them.

In this regard, the EU provisions on non-traditional marks can prove game changing. Registration as a design is also increasingly important.

Comment

The data demonstrates that the EU market is of increasing interest for pharmaceutical companies and is destined to evolve as a result of the technological innovations that are overturning the whole retail sector.

Online pharmacies, home delivery apps that allow customers to have pharmaceutical purchases delivered to their doorstep, and pharmacies that are increasingly similar to small supermarkets where impulse buying is common, are already having an impact on the way in which products are presented and, in the medium term, are bound to influence the legal approach to this subject. WTR

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