# Pharmaceutics

Closed borders and the lockdown in 2020 made Ukrainian society set its priorities in a different way and review approaches to the implementation of innovations. Naturally, the pharmaceutical industry found itself in the midst of those developments. On the one hand, pharmaceutists should have an incentive to carry out pharmaceutical research and development, which requires huge expenditure; on the other hand, there is the right to the health of a human being, and patients want to have access to modern treatment as soon as possible and at the most affordable price.

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## New Legal Landscape

In response to the long-pending issue of patent reform, the Ukrainian Parliament adopted several key laws in 2020, including Law of Ukraine No.816-IX *On Amendments to Certain Legislative Acts of Ukraine in Relation to Patent Legislation Reform of 21 July 2020*.

The adoption of the law is aimed, first and foremost, at the performance by Ukraine of its obligations under the Association Agreement with the EU signed in 2014. The essence of those obligations is the achievement of an "adequate level of protection and enforcement of intellectual property rights". This is stipulated in Chapter 9 of the Association Agreement.

At the same time, the adoption of new legislation is just one of the stages. An adequate and effective level of protection and enforcement is possible when the entire IP infrastructure operates in a coordinated manner and the state is able to guarantee that, in the event of violation of rights, the right holder may count upon the restoration of justice within a reasonable timeframe and by a competent authority. Ideally, when the legal environment makes it possible to act in a preventive manner, by not letting the violation of such rights occur.

## What can be Protected by a Patent?

First of all, the new legislation is revised to expand the list of objects subject to legal protection.

For instance, a number of initiatives on fighting so-called "evergreen" patents have been implemented, which patents artificially extend the term of patent monopoly for the account of improvements of technology, which are not always substantial.

Firstly, the new law limits the range of technologies that can be patented. Now, only a device or a process (method) may be the object of a utility model, whereas substances (their compositions) may be protected only as inventions for which there exist stricter patentability criteria. It should become a good instrument to fight patent trolling since the qualification examination of utility models is not carried out.

Secondly, surgical or medical treatments, body diagnostic methods are removed from patent protection.

Thirdly, a new patentability standard for inventions is introduced in respect of new forms of medicinal products known from prior art (salts, compositions, etc.), such a new form should substantially differ from the preceding ones in terms of efficacy.

All of the listed novelties will be applicable after the new law comes into effect, whereas the previously issued patents continue to be in force. Therefore, the market will feel the effect resulting from the new rules that will only come in force in a few years.

## Term of the "Patent Monopoly"

The term of intellectual property rights to a utility model is 10 years from the date on which the application is filed, and for an invention, 20 years, though such term may be extended for some inventions.

In accordance with the new law, the right of extension of the term of intellectual property rights to an invention is evidenced by the additional protection certificate.

Due to changes in the rules for additional protection of rights to inventions, the pharmaceutical market will become more predictable for manufacturers of generic drug products. Earlier, the application for extension of the term of a patent can be filed no later than 6 months prior to the expiry of the term of the patent. Manufacturers of generics could not predict when the patent protection would expire: the patent could be extended for a period up to five years at the very last moment.

The new law has changed the rules. A patent holder must now file an application for obtaining the certificate of additional protection within 6 months from the date of publication of information on the state registration of an invention or the date of the first state registration of a medicinal product.

The formula for calculation of the term for which the additional patent protection can be obtained has also changed.

Moreover, to facilitate the fastest market entry of innovative products, the rule has been introduced, according to which one can apply for additional protection if the application for state registration of a medicinal product in Ukraine is filed within one year from the date of such application submission anywhere in the world.

## New Instruments for Pharmaceutical Industry Players

The new law has introduced pre-grant and post-grant oppositions.

Pre-grant oppositions are available in respect of filed applications for inventions. Within this procedure any person can file a grounded opposition against an application for invention 6 months following publication of information about such application.

When a patent for invention or utility model has been already granted, it can be cancelled within the administrative procedure of post-grant opposition.

The time constraints for filing a post-grant opposition are different for inventions and utility models:

(1) for an invention, any person can file a post-grant opposition to the Board of Appeals of the Patent Office within 9 months of the date of publication of information on the state registration of an invention;

(2) for a utility model, a post-grant opposition may be filed during the whole period when the intellectual property rights to the utility model are effective and after the expiry thereof.

The advantages of these new instruments include the following.

Firstly, by contrast with a lawsuit, pre-grant or post-grant opposition may be filed by any person and does not require proof of an infringed right and/or interest. Secondly, post-grant opposition is considered by the UAPTO Board of Appeals for 4 months only (with a possibility of extension that is clearly regulated, subject to certain conditions), which fact, in comparison with statistically average time periods (of approximately two years) required for consideration of similar issues under a litigation procedure, may influence the overall litigation strategy of intellectual property rights protection by pharmaceutical companies in favor of using the administrative procedure. In any case, it remains to be seen how effective this instrument will prove to be.

Patent oppositions are widely used in foreign jurisdictions — this requires much less resources than for challenging a patent in court. To use this instrument effectively comprehensive efforts need to be made to identify new patent applications and address them in a timely manner.

## Market Entry Strategy within the Framework of the Bolar Provision

The Ukrainian patent reform of 2020 also introduced the so-called Bolar provision. Traditionally, the "Bolar provision" provides for a possibility of a generic product's entry to the market immediately after the expiry of the patent for a branded medicine. However, in the laws, as adopted in summer 2020, some understatement regarding this issue still remains.

# AEQUO

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The new rules extend to the period of the additional protection certificate: the manufacture of medicinal products for export during that period is allowed and, 6 months prior to the expiry of the term of additional patent protection, one may, without infringing patent rights, accumulate supplies of generic medicinal products for the purpose of launching them onto the Ukrainian market immediately after the expiry of such protection.

The import of pharmaceutical preparations for research purposes or use of an invention in research for the purposes of preparation for registration of a medicinal product will not be deemed to be an infringement of patent rights. Earlier, when the import of any substances was required to develop medicinal products, companies had to make reference to use "for scientific purpose or by way of experiment". The complexity of proving scientific purpose resulted in one of the most interesting patent disputes in recent times regarding the import of a pharmaceutical preparation.

For a number of pharmaceutical companies, including domestic ones, this is a serious reason for them to revise their strategies and use new opportunities to launch new products on the market.

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## Ukrainian-style Patent Wars: What Next?

Almost half of all patent disputes in Ukraine are related to pharmaceuticals. A Ukrainian-style patent war means three to five expert opinions and a year and a half (or longer) in courts.

Ukrainian courts consider patent disputes between Ukrainian manufacturers and foreign companies, including those involving technologies, disputes about which are going on concurrently in a dozen jurisdictions.

Moreover, patent disputes arose recently, that are new for the Ukrainian market, under actions brought by patient organizations wishing to obtain lower prices for medicinal products.

It is this area where demand for establishment of a specialized intellectual property court is the most acute. As is known, that court was established within the framework of the judicial reform of 2014-2019 so as to increase the quality of justice in that category of cases. Similar courts exist in more than 80 jurisdictions and are a success story almost everywhere. Indeed, the possibility to have an infringed right protected by a competent court and within a reasonable time when a fair court decision is obtained is one of the most important aspects of a country's investment potential and the ability to conduct business in a civilized way. However, the competitive selection procedures for vacancies in that court, the procedures for which began in 2017, were actually blocked at the end of 2019 and so far there is, by all appearances, no political will to bring such a good initiative to its logical solution.

As regards new administrative procedures, the adoption of subordinate legislation is expected (the Rules of the Board of Appeals of the UA Patent Office and others) in order for them to go live.

Furthermore, we expect a new category of disputes to appear: appeals against the decisions of the UA PTO Board of Appeals following on from the results of consideration of patent oppositions (based on the results of pre-grant opposition) and decisions of the UA PTO Board of Appeals following on from the results of consideration of applications for invalidation of patents (based on the results of post-grant opposition). However, several years have to pass until new instruments gain the confidence of market players.

Hence, in the days ahead, as before, patent cancellation court actions (this is currently the most popular category of patent cases) and for termination of patent infringement will be the most typical.