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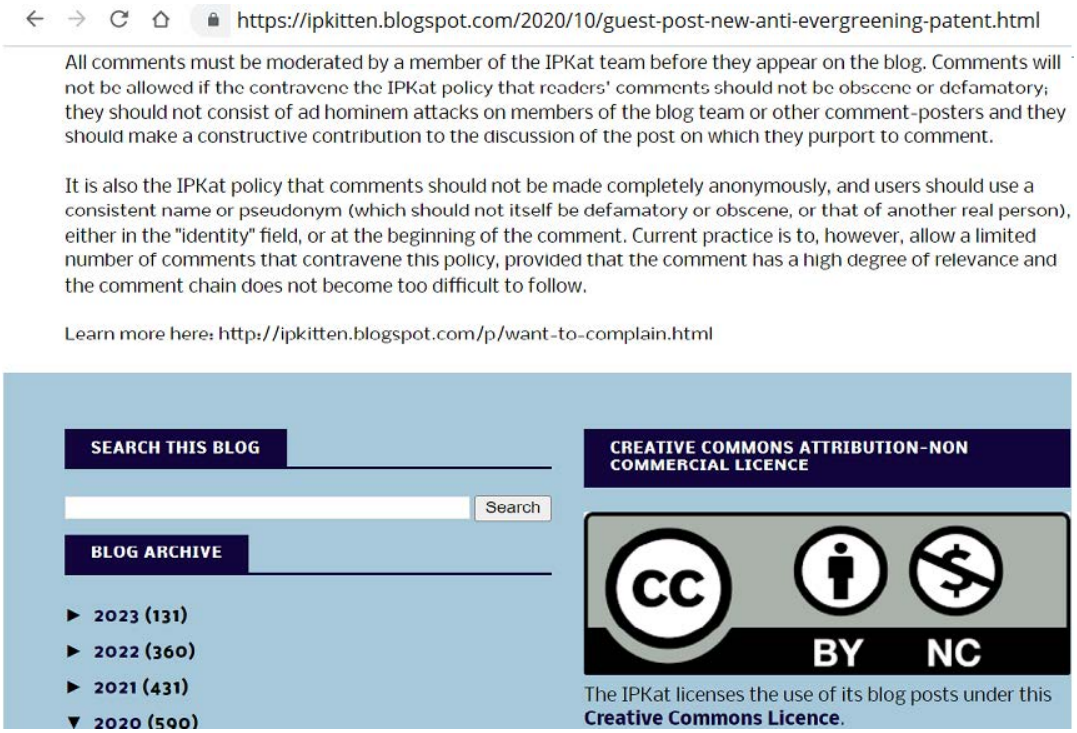

Guest Post: New anti-evergreening patent law in Ukraine

Hayleigh Bosher Thursday, October 08, 2020 - Access to medicines, anti-evergreening, Hayleigh Bosher, patent, Ukraine

In this guest post, patent expert **Dr Olga Gurgula** reports on updates from Ukraine as well as highlighting important next steps for the Ukrainian Patent Office. Olga is a Lecturer in Intellectual Property Law at Brunel Law School, Brunel University London and Visiting Fellow at the Oxford Martin Programme on Affordable Medicines, University of Oxford. Here's what she says:

The topic of patent evergreening has been in the news for quite some time. For Ukraine, it has been an especially painful issue, where the majority of people suffering from illness pay for medicines prescribed by their doctors from their own pockets, and the prescriptions are typically for patent-protected brand-name drugs. Not surprisingly, therefore, that the statistics are far from positive - the majority of the Ukrainian population is not able to buy expensive medicines, including those required for life-threatening diseases like HIV, hepatitis C and cancer. The **WHO, in its 2019 report**, noted that *'spending on medicines was reported as being the main driver of financial hardship for Ukrainian households'*. Therefore, the need for more affordable medicines to be made available for the Ukrainian population has been one of the key issues in recent years. To achieve this, a number of reforms have been put in place, including amendments to the Patent Act 1994.

Prior to these amendments, patent law in Ukraine was patentee friendly, providing broad opportunities for patenting a medicine by covering its active ingredient, process of manufacture and other various aspects, such as salts, polymorphs, formulations, dosages, etc. As a result, pharmaceutical companies in Ukraine were applying for patents on numerous modifications to their existing products, many of these did not bring any benefits to the patient. This, in turn, allowed the companies to strengthen the patent protection of their products, thus maintaining market exclusivity and keeping prices high.

Syoma pondering his goal to improve access to affordable medicines
Image: Olga Gurgula

Such practices have raised fierce opposition from Ukrainian activists and patient groups who have been eagerly advocating for changes to the patentability standards. For more than a decade now, they have been fighting against the evergreening of patent protection on medicines and urging the Ukrainian government to take measures which would restrict such practices and enable faster generic competition to provide access to more affordable medicines. Several draft laws were put forward in the Ukrainian parliament; however, they have not received much support. That is until recently. These drafts were met by significant resistance and pressure from various pharmaceutical lobby groups, as well as the EU and US. One of the approaches suggested in these draft laws was to follow the example of Section 3d of the Indian Patent Act 1970. The latter provides that a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not considered to be an invention. Such an approach, however, was rejected and a compromise was reached somewhere in the middle.

The amendments to the Ukrainian Patent Act 1993 came into force on 21 July 2020 and are considered to be a significant victory that will directly benefit Ukrainian patients. Out of a number of changes that have been implemented in this Act, the anti-evergreening provision deserves specific attention. While, as was noted, the draft law contained a provision inspired by Section 3d of the Indian Patent Act, the amended Patent Act shifted the decision on the patentability of such inventions to the stage of the inventive step analysis. Specifically, in addition to the standard provision in Section 7(7), that the invention will be considered to have an inventive step if it is not obvious to the person skilled in the art, this Section was supplemented with the clarification that:

> *new forms of a known medicine, including salts, esters, ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure form, particle size, isomers, can be considered as matters that obviously follow from the state of the art if they do not differ significantly with regard to efficacy*

While these changes to the patent law have the potential of improving access to medicines in Ukraine, it is now the task of the Ukrainian Patent Office to apply this provision. Therefore, it is important that the Patent Office bears in mind the aim of this provision when interpreting and applying it to specific cases. In particular, the addition of this provision to the Patent Act was a strategic policy decision of Ukraine. Its goal is to improve access to affordable medicines by preventing the patenting of trivial modifications of existing medicines that enable pharmaceutical companies to maintain their market monopoly while bringing little or no benefits to the patient. To help the Patent Office in establishing a uniform and predictable practice, it may be useful to develop specific guidance on how such pharmaceutical inventions should be assessed.

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