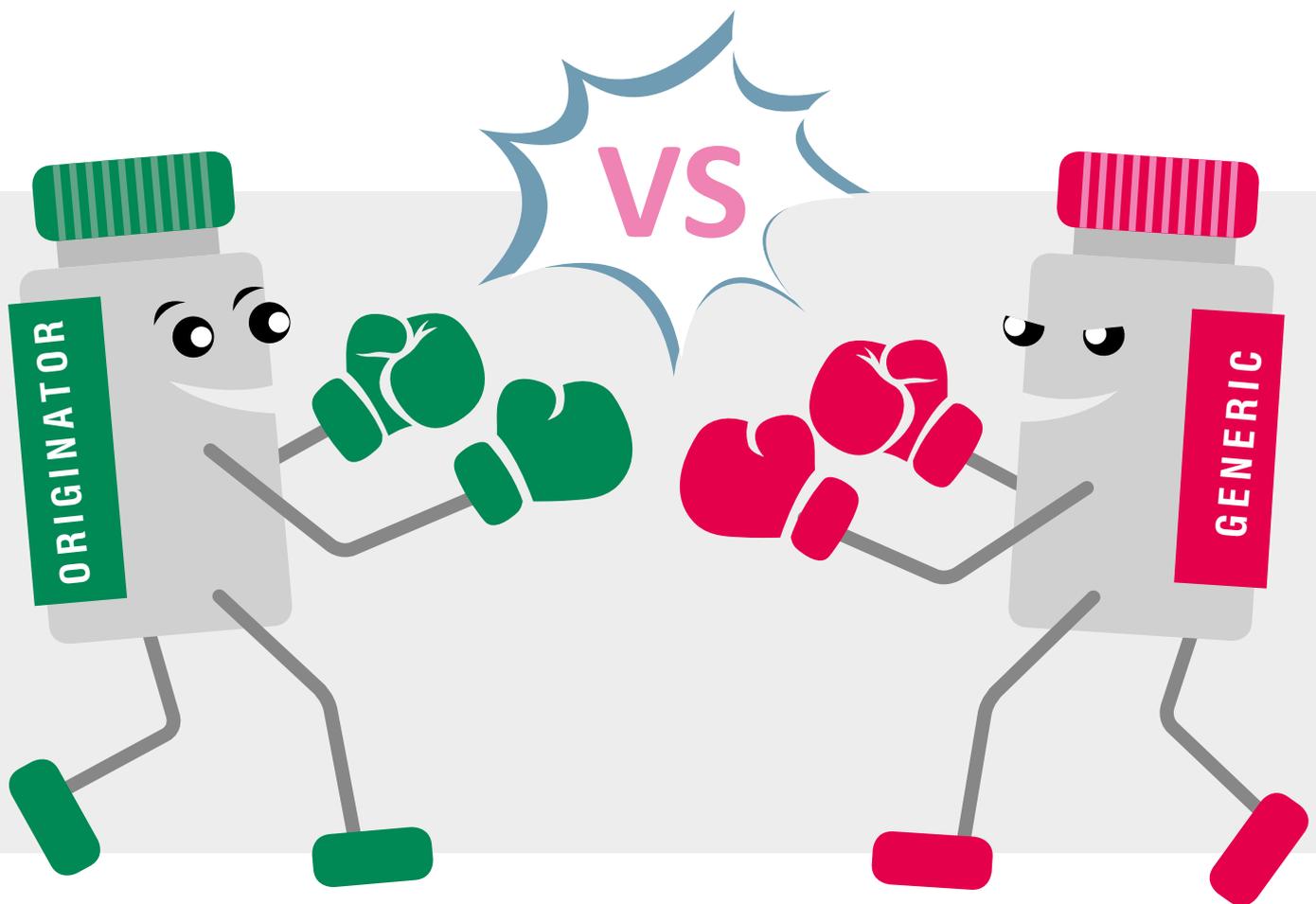


PATENT DISPUTES IN LIFE SCIENCES



SEPTEMBER 2020

EAEU, CIS AND EASTERN EUROPE



ARMENIA



AZERBAIJAN



BELARUS



GEORGIA



KAZAKHSTAN



KYRGYZSTAN



MOLDOVA



RUSSIA



TAJIKISTAN



TURKMENISTAN



UKRAINE



UZBEKISTAN

COURT PRACTICE

INVENTION PATENTABILITY

A method of human genome editing is not patentable



Russia

A patent for a method of editing human genome for creating embryos with advanced HIV resistance is not patentable as it is contrary to public interests.



DNA-Technology v. Rospatent
Case No. SIP-960/2019

PATENT EXTENSION

Partial annulment of a patent does not preclude its extension



Russia

If an extended patent has been partially annulled and a new patent with an updated formula has been issued, the extension does not lapse: the new patent will remain effective until the same extension date.



Rowtech v. Rospatent
Case No. SIP-905/2019
Tarceva (Erlotinib)

The patent holder bears the risk of refusal of being granted SPC if it fails to implement Rospatent's commentaries



Russia

If a patent holder does not implement Rospatent's commentaries to a part of SPC patent formula, it bears the risk of its application for SPC being dismissed in full.



Genentech v. Rospatent
Case No. SIP-417/2019
Ocrevus (Ocrelizumab)

SCIENTIFIC PURPOSE DEFENSE

The clause on the patent's use "for scientific purposes" for a generic must be proven



Ukraine

If a generic importer asserts that the drug's import does not infringe the patent because it will be used for scientific research, such a "scientific purpose" must be supported by documents. In particular, the importer must submit evidence of scientific qualifications of its employees.



Bayer v. Farmak
Case No. 911/165/18
Xarelto (Rivaroxaban)

PRELIMINARY INJUNCTION

No preliminary injunction is granted in disputes on data exclusivity



Georgia

In disputes on the infringement of data exclusivity, courts may not grant the originators' pleas for an injunction on the circulation of the generic as interim relief. Such interim relief is, however, available in patent disputes.



MSD v. Ministry of Health
Case No. N3/2712-20
Januvia (Sitagliptin)
MSD v. GlobalPharm
Case No. 2/27902-18
Januvia (Sitagliptin)

LEGISLATION

An export clause on the use of an invention without contract



The draft law will allow the Government, in the instances and on the terms envisaged in a treaty, to decide to use an invention for the production of generics in Russia for exporting them without the patent holder's consent, but subject to notification and proportionate compensation.

Changes in the procedure for processing patent applications



Accredited scientific and educational organisations, rather than solely Rospatent, will be allowed to conduct the information search and preliminary assessment of patentability, allowing to cut the time required to process an application, and enhance the quality of expert examination of patents.

The Bolar provision is now stipulated in the laws; data exclusivity has been limited



Import of a drug for its registration or research does not infringe the relevant patent. Reliance on the registration dossier of the original product in registering a generic does not amount to disclosure or unfair commercial use of confidential information.

A draft law on mandatory licencing of drugs for treating COVID-19 is in the works



Holders of such patents may claim compensation from the Ukrainian manufacturer, calculated as per the method developed by the Government. Mandatory licencing is proposed for 3 months.

P.S. The Russian COVID-19 vaccine is protected by patent

Rospatent has registered patent for an invention RU 2720614 for the drug Gam-COVID-Vac (Sputnik V) for preventing and treating COVID-19. According to Rossiyskaya Gazeta, the drug will be released into circulation in Russia as early as January 2021.

ABOUT LIDINGS

Lidings is a leading independent national law firm advising Russian and international companies on all legislative aspects of doing business in Russia and CIS

Firm's experts focus on a number of issues particularly important to the global pharmaceuticals and healthcare companies

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