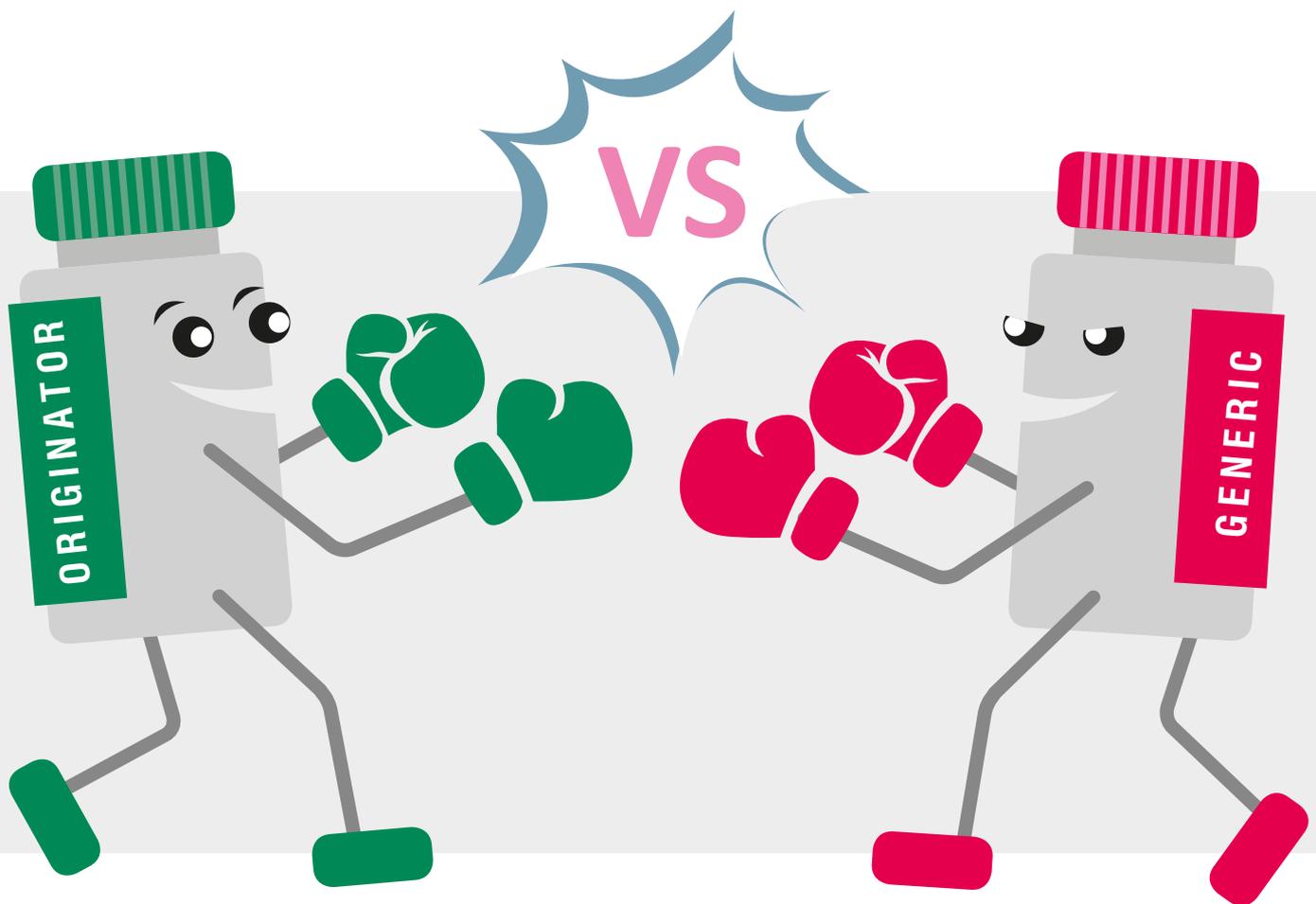


# PATENT DISPUTES IN LIFE SCIENCES



JANUARY 2020

## EAEU, CIS AND EASTERN EUROPE



ARMENIA



AZERBAIJAN



BELARUS



GEORGIA



KAZAKHSTAN



KYRGYZSTAN



MOLDOVA



RUSSIA



TAJIKISTAN



TURKMENISTAN



UKRAINE



UZBEKISTAN

# COURT PRACTICE

## COMPULSORY LICENSE

**Russian courts grant compulsory licenses for dependent patents of generics**

 Russia

The Intellectual Property Court has recognised the possibility of granting a compulsory license to the originator's patent where: (1) the generic has registered a dependent patent that (2) constitutes an important technical achievement, and (3) has material economic advantages. Royalties will be calculated based on the registered reimbursement price.

 **Sugen v. Nativa**  
Case No. A40-166505/2017  
Sutent (Sunitinib)

## CONCEPT OF THREAT OF INFRINGEMENT

**The originator may demand cessation of the threat of patent infringement by the generic's distributor**

 Russia

The Supreme Court has confirmed that the development, bioequivalence studies, and registration of a generic and the reimbursement price create a threat of patent infringement, if carried out within 3 or more years before the patent expires. A claim to cease the threat of infringement may be filed against the distributor of the generic, rather than only against the holder of marketing authorisation of the generic.

 **Bristol-Myers v. Mamont Pharm**  
Case No. A40-246557/2017  
Sprycel (Dasatinib)

## PATENT INFRINGEMENT

**To recover damages for a patent infringement, the originator will have to bear a heavy burden of proof**

 Russia

To recover damages from generics producers under a lost state procurement tender, the originator will have to disclose a lot of evidence (the legal link with its local distributor, the amount of lost profit), and each piece may be critically reviewed by the court.

 **R-Pharm v. Nativa**  
Cases No. A40-273217/2018  
No. A40-273203/2018  
No. A40-273197/2018  
Sprycel (Dasatinib)

## PATENT EXTENSION

**When challenging the SPC, the marketing authorisations held by third parties have to be taken into consideration**

 Russia

The Intellectual Property Court ruled that the SPC can be challenged based on the marketing authorisations for drugs with a similar active ingredient held by any parties, rather than just the patent holder. Minor procedural violations will not affect the validity of the SPC.

 **Novartis v. Izvarino Pharma**  
Case No. SIP-744/2018  
Myfortic (Mycophenolic acid)

**The SPC is subject to any of the alternative elements of a formula claim**

 Russia

The Intellectual Property Court held that the SPC can be granted for a specific stereoisomer, even if the formula claim's wording uses alternative terms and protects several (multiple) alternative stereoisomers.

 **Gilead v. Rospatent**  
Case No. SIP-740/2018  
Sovaldi (Sofosbuvir)

# LEGISLATION

## Combatting evergreening



Ukraine

A new dosage or any new property or use of a drug will not be covered by legal protection. Parallel import of drugs is permitted.

## SPC abolished



Kyrgyzstan

It is no longer possible to extend pharmaceutical patents, either domestic or Eurasian. Maximum protection will not exceed 20 years.

## SPC available



Tajikistan

Pharmaceutical patents can be extended, but for no longer than 5 years.

## An analogue of the Orange Book and a register of active substances will now be used in the practice of drug registration



Russia

The new rules provide for the introduction of an analogue of the Orange Book: a marketing authorisation to a generic will be suspended until the patent expires. Rospatent will keep a public Unified Register of Pharmacologically Active Substances.

## Draft law on a new compulsory licensing model



Russia

The Russian Government may, based on a tender, decide to use an invention without the patent holder's consent, but subject to payment of royalties, if necessary for national defence and security, including protection of life and health (the clause is designed specifically against the originators).

## Interaction of applicants and patent agencies of 11 states simplified



EAEU

Russia and EAEU member states, as well as Azerbaijan, Georgia, Moldavia, Tajikistan, Uzbekistan, and Ukraine agreed that applicants from these countries may directly interact and litigate disputes with patent agencies abroad.

## A unified patent register will be created



EAEU

The EAEU has planned to create a Unified Register of Rights to Intellectual Property that will reflect information on patents to active ingredients and registered drugs.

## 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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