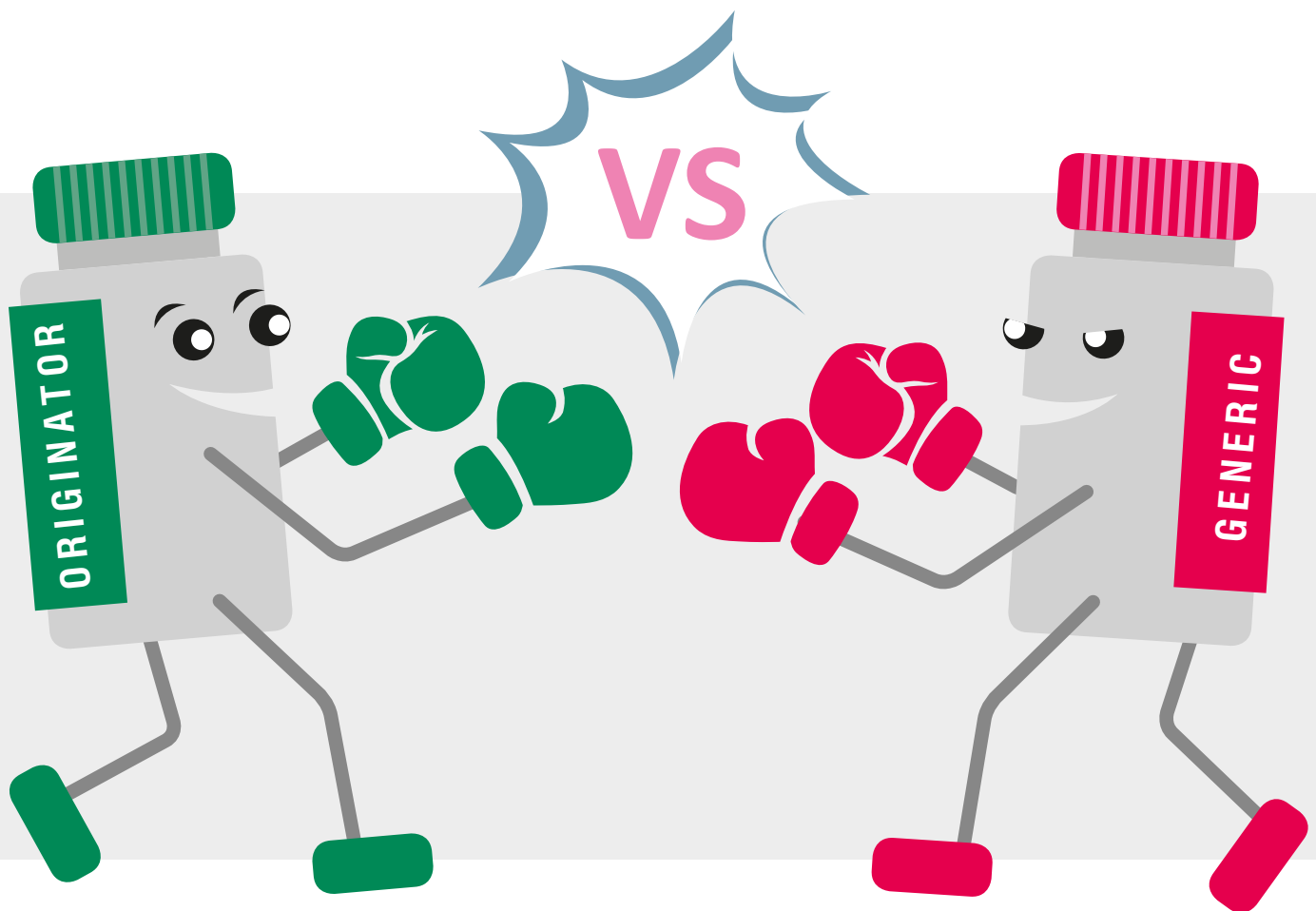


PATENT DISPUTES IN LIFE SCIENCES



AUGUST 2019

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

In a number of cases, courts granted compulsory licenses to a generic where the following circumstances were met: (1) the generic registered a dependent patent which (2) constituted a significant technical achievement and (3) had substantial economic advantages. Lower courts often misinterpret the circumstances, resulting in not a single compulsory license having successfully passed the Intellectual Property Court yet.



Celgene v. Nativa
Case No. A40-71471/2017
Revlimid (Lenalidomide)



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

CONCEPT OF THREAT OF INFRINGEMENT

Even if the patent is not infringed, the originator may seek injunction against the threat of its infringement



Russia

The Intellectual Property Court accepted the application of the Bolar exemption (according to which registration-related action does not constitute an infringement). However, if the patent in question is valid for over 3 years, measures such as the development, bioequivalence studies, and registration of a generic and its maximum selling price constitute a threat of patent infringement. In that case, a court would prohibit patent use in advance.



Novartis v. Nativa
Case No. A41-85807/2016
Tasigna (Nilotinib)



AstraZeneca v. Jodas Expoin
Case No. A40-106405/2018
Iressa (Gefitinib)

INJUNCTION

Georgian and Ukrainian courts grant injunction to originators against generics



Georgia

The court granted injunction to the claimant and prohibited the generic to use the patent until its expiry. The court also ordered destruction of all products discovered at the warehouse of the generic distributor.



MSD v. Globalpharm
Case No. 2/27902-18
Januvia (Sitagliptin)



Ukraine

The Supreme Court prohibited the generic not only to use the patent until its expiry, but also to register its drug. The court also prohibited the MoH from amending the registration dossier.



MSD v. Aurobindo Pharma
Case No. 910/1915/18
Invanz (Ertapenem)

DATA EXCLUSIVITY

Generic's marketing authorization is annulled if it violates the regime of data exclusivity



Kazakhstan

The Supreme Court has for the first time applied the data exclusivity regime. It annulled registration of a generic after data on pre-clinical and clinical trial were identified in the generic's registration dossier.



Celgene v. Dr. Reddy's
Case No. 7527-17-00-2/10588
Vidaza (Azacitidine)

LEGISLATION

Information on applications for state registration of drugs has become publicly accessible from April 2019



Russia

The MoH has for the first time opened access to information on generics pending registration.

In addition to the established concept of a threat of infringement, this information will allow patent holders to track potential threats and promptly block release of generics to the market.

Introduction of a counterpart of the Orange Book in drug registration practice



Russia

New draft laws provide that (1) originators must disclose information on drug-related patents and trademarks, (2) generics must show that these patents and trademarks are not infringed or are invalid.

Introduction of a unified procedure for registering drugs



EAEU

Despite the introduction of a new procedure and a transition period (until 2021), the data exclusivity and patent protection regimes have not been brought in accordance.

It is necessary to revise the strategy of protection for cases of bad faith registration of generics in view of the national and regional rules in the EAEU states.

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

KEY CONTACTS



Andrey Zelenin
Managing Partner

- Corporate and M&A
- Dispute Resolution
- Intellectual Property

T: +7 (495) 989 44 10

E: azelenin@lidings.com



Boris Malakhov
Partner

- Dispute Resolution
- Intellectual Property

T: +7 (495) 989 44 10

E: bmalakhov@lidings.com



DO YOU WANT TO RECEIVE LEGAL DIGEST REGULARLY?

Just let us know by emailing at subscribe_pharma@lidings.com

[Unsubscribe](#)



www.lidings.com