CORONAVIRUS
OVERCOMING THE DIFFICULTIES

SPECIAL RULES IN CONNECTION WITH COVID-19 IN PATENT EXAMINATION PROCEDURES, CLINICAL TRIALS AND MARKETING AUTHORIZATIONS IN RUSSIA

DE BERTI JACCHIA FRANCHINI FORLANI
STUDIO LEGALE

1. With the occurrence of the COVID-19 emergency in 2020, Russia introduced a number of urgent measures aimed at encouraging research and patenting and reducing regulatory accomplishments and timelines, with the objective of accelerating the scientific and industry response in devising and producing new drugs, diagnostic means, devices and agents to strengthen the country's ability to cope with the pandemic challenge.
2. In April 2020 the Rospatent (Russian Patent and Trademark Office) introduced a new procedure for the examination of patent applications on antivirus treatment, prevention and control medicines. The new procedures also extend to the examination of associated and coexisting diseases, like pneumonic fever, and apply to the following items:

   - Antivirus medicinal products;
   - Diagnosis of virus diseases (e.g. diagnosis test systems);
   - Medical devices (e.g. lung ventilation apparatuses, inhalers);
   - Protection means (e.g. medical masks, protective clothing);
   - Sterilizing agents and sanitizers.

   The applicants do not need to file any request for the express (fast track) examination procedure, which will automatically apply without any additional cost or fee.

   In accordance with the express procedure the first document of substantive examination shall be issued and sent to the applicant within 2 months from the date of completion of the formal examination.

   The formal examination of the application is performed by the Rospatent right after registration and includes verification of payment of the official fees and the sufficiency of the documents and materials of the application. Once the formal examination is successfully completed, the substantive examination of the application starts.

The Rospatent also created a special section in its website at https://www1.fips.ru/doc-virus/ with links to patent information on different inventions classified as antivirus medicinal products (e.g. vaccines, antivirus medicals); diagnosis of virus diseases (e.g. diagnosis test systems); medical devices (e.g. lung ventilation apparatuses, inhalers); means of protection (e.g. medical masks, protective clothing); sterilizing agents and sanitizers (skin sanitizers; air disinfectants; sterilizing agents for laboratory equipment and materials) granted in Russia since 2000 to Russian and foreign applicants.

Recently, the Rospatent issued 3 patents to Scientific center of biomedical technologies FMBA of Russia for its new COVID-19 medicines, i.e., patent no. 2728939 for *Leytragin* for use in the treatment of COVID-19, patent no.2728938 for use of *Leytragin* as preventive medication of lung fever and complications from COVID-19, and patent no. 2728821 for use of *Leytragin* in association with other pharmaceutical preparations. The Rospatent advised that these patents concern a new use of a known chemical substance that in other countries was authorized only as pain relief agent.

3. Starting from 06 April 2020 and till 01 January 2021, a special procedure of registration applies to the releasing of lots of medicinal products for use in military activities, emergency, prevention and treatment of diseases dangerous to the public and diseases caused by health hazards. Resolution no. 430 of the Russian Government dated 03 April 2020 provides that ordinary technical tests, toxicological tests and clinical trials for medicinal products are not mandatory in cases of emergency or threat thereof. The certificate of registration of lots released on the basis of this Resolution will be valid till 01 January 2021.

4. On 03 April 2020 the Russian Government issued Special rules (Resolution of the Russian Government no.441) for medicines used in cases of emergency, for treatment of diseases dangerous to the public and the effects of hazardous agents. These Special rules provide for lower requirements for obtaining marketing authorizations for pharmaceuticals intended for such uses, by

   a. Reducing the criteria to assess the risk/effect balance, when the manufacturing or packaging site of a registered medicine is changed;

   b. Replacing the ordinary laboratory experiments with the laboratory tests envisaged by Article 52.1. of Federal Law no. 61-FZ dated 21.04.2010 “On trade of pharmaceutical products” before the placing the medicine on the market;

   c. Providing the documentation required in accordance with the Law “On trade of pharmaceutical products” during the emergency period in electronic form only.

   These simplified rules relate to the second stage of the procedure for obtaining the marketing authorization, which follows the passing of Good Manufacturing Practice (GMP) inspections and clinical trials.

October 7th, 2020

Alisa Pestryakova

ASSOCIATE

a.pestryakova@dejalex.com

+7 495 792 54 92

Ulitsa Bolshaya Ordynka 37/4
119017 - Moscow