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Is this really the end of Brazil's patent backlog?

Joaquim Eugenio Goulart and Bernardo Marinho Fontes Alexandre of Danneman Siemsen discuss the country's recent efforts

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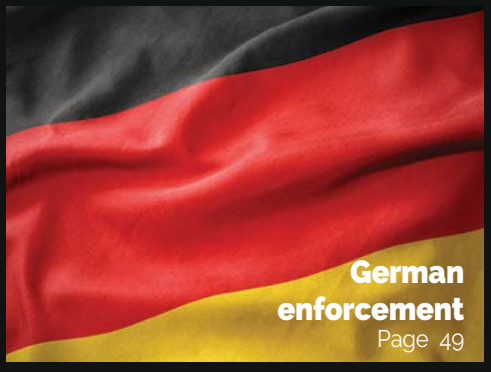

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> **Many people were (and indeed are) still unconvinced.**

Despite the Government's best efforts, many people were (and indeed are) still unconvinced that the security measures were sufficient to ensure watertight protection of people's data.

As in any situation such as this which has inevitably become highly-politicized, public opinion remains polarized. There were numerous commentators concerned that the NHS's proposed centralized approach is fundamentally at odds with data protection and human rights laws, and equal numbers of commentators with exactly the opposite view.

The final nail in the coffin for the Government's app came from reports that it simply did not work well enough, with officials admitting that the app recognized only 4% of Apple devices, and 75% of Android devices during the trial period performed on the Isle of Wight.

How is Apple and Google's solution any different?

Firstly, it should be noted that Apple and Google have not developed an "app". Rather, they have developed an application programming interface (API) which may be incorporated into apps developed by e.g. the NHS. An API is effectively an interface into which users can submit data, and which conveys that data to behind-the-scenes systems and databases, where that data is processed. The API then returns the results of the processing back to the app on the user's device.

The key difference between Apple and Google's system and Government's previous system is that it operates based on a decentralized model. This means that, when a user reports either symptoms or a positive COVID-19 diagnosis, the only information which is submitted to the central database is the (anonymized) identity of that user. The system then periodically transmits the anonymized identities of all of the reporting users to all of the user devices. Then, a determination is made at each user's device whether the user of that device has come into contact with any of the reporting users and provides appropriate guidance. This is referred to as "decentralized" since the details of a given user's interactions and contacts are only ever stored on the user's device, and are never transmitted to a central authority; the risk determination is performed only at the level of the user device based on interaction data stored on that user's phone, and the list of reporting users that is periodically sent to each phone.

From a privacy and data security standpoint, this model is much preferred. One of the main reasons for this is that there is no central repository of all users' interaction data, which may be at risk from attack by nefarious actors.

Apple and Google's proposed system also addresses another serious problem which somewhat thwarted the NHS's previous proposal. In order for the app to work effectively, it is necessary for Bluetooth to be running constantly, but Apple's iOS and the Android operating system are constructed to ensure that Bluetooth is switched off e.g. when a user's phone is "asleep". This means that the contact tracing app would only be effective as long as it is running in the foreground of a user's device – with negative consequences for battery life. However, the system developed by Apple and Google is able to run smoothly in the background, a perk of being designed by the companies who developed the operating systems in the first place.

Of course, Apple and Google's system is by no means perfect. It is still hindered somewhat by the difficulty of measuring distance using Bluetooth. Distance estimates based on the strength of a signal are affected by intervening obstacles, which may be problematic if a phone is in a handbag or a pocket – but it seems that there is no straightforward fix for this problem, short of constantly tracking a user's location, seen by many as too much of an invasion of privacy.

What's next?

Due to the Government's U-turn, nationwide rollout of any fully developed contact tracing app seems unlikely to happen any time soon. And even when the app is available, it will only be useful if a significant enough proportion of the population downloads and uses it. It therefore remains to be seen whether this will be an effective venture.

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Current trends in the patent protection of pharmaceuticals in Russia

Alexey Zalesov, Ph.D. (Law), Russian patent attorney & advocate and Irina Ozolina, Russian patent attorney & advocate, of A.Zalesov & Partners Patent & Law Firm, give a timely update on this topical issue.

Russia is undergoing a dynamic change in patent legislation in pharmaceuticals at the level of by-laws of the Rospatent - the Russian Patent and Trademark Office. Recently, amendments have been introduced into the Examination rules to regulate the assessment of the novelty and inventive step of a pharmaceutical composition. The amendments make it more complicated to obtain patent protection for secondary pharmaceutical patents when the active ingredient and its activity are part of the prior art.

In parallel we see that substantial amendments are being made to the federal law "On Circulation of Medicines" related to the process of receiving marketing authorization for a drug, in which information on patents for pharmaceutically active substances in force in the Russian Federation should be entered, which will be taken into account when deciding on the registration of a medicinal product.

The situation with court enforcement practice regarding compulsory licensing of patents in the pharmaceutical field is also changing dynamically (decisions on these disputes are still awaiting the Supreme Court's assessment, after which the practice will be quite certain).

Let us consider briefly these topics.

In 2018 we saw the first court decision in Russia's history which granted a compulsory license for a patent for an invention. It is no coincidence that this happened in the field of pharmaceuticals and in relation to the vitally important medicine "Lenalidomide".

Earlier this year, the Intellectual Property Court upheld the decisions of the courts of first instance and appeal, which satisfied the counterclaim of the same Russian company Nativa LLC to Sugen about the compulsory licensing of the basic Eurasian patent EA 5996 for the active substance Sunitib. Specialists suggest waiting for the position of the Supreme Court to understand whether reality has changed, but it is already clear that it has changed.

It is noteworthy that in the Lenalidomide case the plaintiff referred to the existence of a dependent secondary pharmaceutical patent belonging to an individual; that is, this is not a

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Résumés

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Irina Ozolina is a senior partner with the Moscow based IP firm A.Zalesov & Partners Patent & Law Firm. She's been practicing IP law with focus on IP litigation since 2003. Mrs. Ozolina is an attorney-at-law and registered Russian and Eurasian patent attorney. She serves as the Executive Secretary to the Russian National Group of AIPPI since 2014.

classic case of issuing a compulsory license due to the insufficient use of the invention by the patent holder in the market. Moreover, claims for the issuance of a compulsory license for pharmaceuticals have been filed in Russia before (for example, in the form of a counterclaim in a patent infringement dispute), but the parties to the dispute settled their mutual claims outside the court procedure, as indicated by the court's ruling on the mutual rejection of claims. The obvious intensification of the process of compulsory licensing in Russia has its political and economic reasons.

A serious part of this compulsory license story belongs to Nativa LLC, a Russian pharmaceutical company whose business model is based on obtaining secondary patents, for example, on new polymorphic forms of well-known pharmaceutical active substances (which always exist in the presence of polymorphism properties). Such secondary patents were obtained for crystalline salts of a number of substances, such as lenalidomide (originator - Selgen), gefitinib (AstraZeneca), dasatinib (Bristol Myers Squibb), sunitinib, nilotinib (Novartis), etc.

It is noteworthy that such dependent secondary patents are issued in a very short time, apparently without causing questions and doubts of the Rospatent's examiner during the prosecution.

Subsequently, Nativa LLC filed to the Moscow courts a lawsuit to obtain a compulsory license (in accordance with clause 2, Article 1362 of the Russian Civil Code), since the originator's patent does not allow the Company to use the dependent patent for the invention, allegedly representing "an important technical achievement and has significant economic advantages over the invention ... holder of the first patent". A number of disputes ended with settlement agreements, a number was resolved by the courts, but is awaiting an assessment by the Supreme Court.

We consider it extremely doubtful that the secondary patents of Nativa have an inventive step, since the new crystalline form in these cases does not give any substantial improvement in biological activity compared to the known original substance, and a different technical result (such as increased solubility, stability, bioavailability, etc.) is essentially trivial and, often, doubtfully confirmed.

Moreover, the patent holder - Nativa LLC, in a patent dispute regarding a new crystalline form of Dasatinib, claims in its suit to the Intellectual Property Court that its invention was aimed only at expanding the arsenal of drugs available - that is, at creating just another crystalline form of Dasatinib, the biological activity which completely coincides with the activity of the known crystalline form, produced by the originator - the company Bristol Myers Squibb.

> **"Russia is undergoing a dynamic change in patent legislation."**

As it is known, an invention in Russia can be protected by Russian or Eurasian patent. So, it is worthwhile to look on the practice of both patent offices to see the full picture.

Currently, experts from the Eurasian Patent Office are developing a critical approach to the examination of applications for such secondary patents in the pharmaceutical field, requiring confirmation of the emergence of a new and unexpected technical result for new crystalline and preparative forms of known pharmaceutically active substances - by analogy with the current rules regarding the examination of selective inventions.

The experts of Rospatent at the International Conference on 16-17 October 2019 also declared support for this approach, but when a more critical approach to the examination of new forms of known substances will prevail in examination and judicial practice, it is not yet possible to say.

Thus, the intervention of the competent state authorities is obviously required in order to develop a balanced approach.

In the framework of this report, we will also try to understand why the regulation of patent activity in the pharmaceutical field is taking place, and Russia is by no means an exception.

It is known that the patenting of medicines as such has been banned for a long time in the legal systems of developing countries as actually violating moral requirements about the inadmissibility of restricting access to technologies for the production of vital medicines and methods of treatment (that is, contrary to the interests of public health). The TRIPS agreement of the WTO introduced a principle of obligatory patent protection of pharmaceuticals for the member states.

Joining the WTO was an important foreign policy task for Russia. In this regard, the question "to patent medicines or not to patent" did not raise doubts among decision-makers. And one can completely agree in principle with this approach, because between the two poles (completely allow or completely prohibit) there is a significant range for fine-tuning the system, which provides a fair balance of interests of pharmaceutical manufacturers and patients who use drugs.

In the modern patent law of the Russian Federation, there are no restrictions on obtaining a patent in the field of pharmaceuticals and methods of treatment. Till very recently Rospatent and Eurasian Patent Office practiced also quite liberal approaches to granting them patent protection are in force.

In particular, the applicable provisions of Articles 1349 and 1350 of the Civil Code of the Russian Federation make it possible to obtain a patent for any object related to pharmaceuticals (product: substance, composition, preparation, microorganism strain, cell culture, method for producing a substance, composition or preparation, as well as the use of the above products for a specific purpose). The only explicitly indicated restrictions relating to patenting in the pharmaceutical field are indicated in Part 4 of Article 1349 of the Civil Code and relate to the prohibition of the grant of a patent for:

(1) Methods for cloning a human.
(2) Methods for modifying genetically human cells.
(3) The use of human embryos for industrial and commercial purposes.

Also, this norm says that the results of intellectual activity cannot be objects of patent rights if they contradict the public interest, the principles of humanity and morality, which in certain cases may relate to individual pharmaceutical products.

The existence in the patent law requirement to disclose the invention in full, and to support it with examples proving the possibility to achieve claimed intended use and technical result, did not prevent the receiving of a pharmaceutical patent with maximum scope of protection. So it was standard practice to file first substance patent with independent claim characterized by the Markush formula (that is, covering hundreds and thousands of new substances with a common structure and, presumably, common properties), indicating that the purpose of this substance is to treat tens and hundreds of diseases (that is, in fact, "a cure for all diseases").

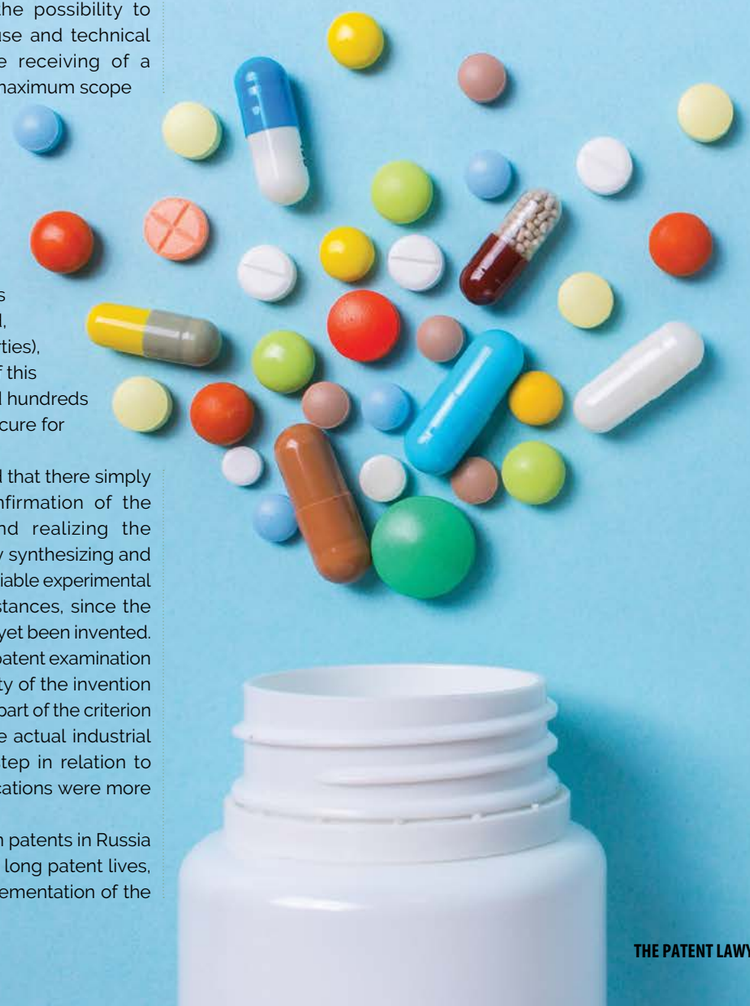
> **"An invention in Russia can be protected by Russian or Eurasian patent."**

It can be confidently stated that there simply could not be any real confirmation of the possibility of obtaining and realizing the appointment (for example, by synthesizing and confirming activity on some reliable experimental model) for the claimed substances, since the "cure for all diseases" has not yet been invented.

In other words, the level of patent examination requirements for the feasibility of the invention (previously this condition was part of the criterion of industrial applicability), the actual industrial applicability and inventive step in relation to pharmaceutical patent applications were more than moderate.

These maximum protection patents in Russia were granted, and lived their long patent lives, ensuring the successful implementation of the business model of innovative companies and the inability to enter the market of relevant domestic developments. A patent with a wide scope of protection in the pharmaceutical field in Russia over the past twenty years has been easy to obtain. Periodically, the requirements of the examination for the presentation of examples confirming the implementation of the declared purpose were somewhat "tightened", which meant sending relevant requests to the applicant. Moreover, any examples presented by the applicant, without any verification of reliability, were accepted by the expert for sufficient confirmation of the implementation. Understanding that the expert has limited opportunities to verify the accuracy and completeness of the information submitted by the applicant.

Regarding the verification of the requirements of the inventive step in relation to the claimed new substance, I cannot but repeat what I heard more than fifteen years ago from really respected chair of pharmaceutical examination department of Rospatent during the hearings in the Chamber for Patent Disputes, a wonderful statement:



"Any new pharmaceutically active substance has an inventive level". We just had to add that, why then is the requirement of an inventive step specified in the law as a condition of patentability if it is satisfied a priori for all new substances? Let us right the law and indicate that the novelty for the patentability of a new substance (due to the complexity of this object) is enough.

The breadth of legal protection provided by truly new pharmaceutically active substances (Markush formula, including with radicals having different properties, an indication of the possibility of using the proposed new molecule for the treatment of all diseases on the list, etc.) is due precisely to the absence of a strict requirement for detailed disclosure and confirmation of implementation destination. Such patents in the pharmaceutical field are also called "primary" patents since they relate to inventions for the first time a synthesized molecule with (presumably or previously established) pharmaceutical activity. So the "ease" of obtaining protection in relation to primary patents is always in practice due to the fact that the very properties of this new molecule, and the method of its synthesis, are sufficient to describe schematically in order to obtain a patent. Presentation of reliable examples of the actual receipt of new compounds declared for protection to convince the experts of the possibility of practical implementation is not required.

A separate discussion deserves the problem of obtaining secondary patents for pharmaceutical preparations, which in fact extend the term of a patent monopoly on a specific drug for several years. Secondary patents are patents whose formulas indicate the following properties of the drug as distinctive features of the independent claims: dosages of the active substance, preferred pharmaceutical forms, composition of excipients, purity properties of the substance, etc. in relation to already known drugs. These "new" features were clearly absent in published primary patents (although often these properties were inherent in actually produced or researched during clinical trials of "patented" drugs). The main "filter" in patent law designed to limit the unreasonable grant of such patents is the requirement of an inventive step, since the novelty of claimed inventions is usually present (taking into account the fact that the initial disclosure is not absolutely complete in a previously obtained basic patent).

Recently such trends came under fire from the law makers of State Duma (Lower House of the Russian Parliament). Now the common place for discussions is that reasonable balance between the interest of originator companies and Russia society is to be found.

We may suggest that recent development in compulsory license practice and restrictions in the examination over the secondary patents (yet related to compositions only) reflect the change in the policy of the Russian State.

> **Let us right the law.**

Moreover, the Federal Antimonopoly Service of Russia last year tried several times to include in a governmental proposal for amendments to the Civil Code with a direct prohibition of secondary patents in the pharmaceutical field. The Russian patent practitioners called such moves deeply erroneous in nature. It is necessary not to prohibit, but to improve and then ensure strict compliance with the requirements of patent law in relation to the requirements of patentability, especially inventive step, industrial applicability, and sufficiency of disclosure.

The proposed changes to substantive and procedural law (along with the possible establishment of a reasonable practice for issuing compulsory licenses), as well as improving by-laws governing the procedure of state patent examinations, are aimed at improving the patent system based on a balance of public and private interests. Compliance with the basic principles of the patent system is much more in the interests of dynamic economic development and sustainable national health than radical calls to ban patenting in the pharmaceutical field. It is hoped that the improvement of patent protection standards will occur due to the improvement of examination approaches aimed at counteracting "evergreen" patent schemes, as well as dubious (in terms of technical result) innovations in the form of new preparative and crystalline forms. At the same time, such a "tightening" must be combined with an effective mechanism for the protection of truly valuable pharmaceutical inventions, including through the improvement of legislation on the circulation of medicines. We should also support the initiative of Rospatent to create an appropriate specialized registry of active compounds protected by a patent.

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The Brazilian trap regarding second medical use claims

Dr. Carlota Vergas, European Patent Attorney at Balder IP, unpicks this complicated area of Brazilian patent law.

One of the most important, if not *the* most important, milestones in the prosecution of patent applications in Brazil is the request for examination.

According to Brazilian practice, the claimed subject matter at the time of requesting the examination of an application sets out the framework for the subject matter that the applicant will be allowed to prosecute; not only in said application, but also in any subsequently filed divisional application. In other words, subject-matter that is not present in the set of claims, for which examination has been requested will no longer be available for prosecution in said application nor in any divisional application thereof.

The legal basis for this practice can be found in Article 32 of the Brazilian Patent Law (BPL), which establishes that *"In order to better clarify or define a patent application, the applicant may make changes until the time of the request for examination, provided* ***these are limited to the subject matter initially disclosed in the application".***

In principle, in view of the wording of the provision, one could understand the reason for this disposition, and the idea behind it, which could be seen to be in line with similar existing provisions in other common patent jurisdictions: to provide applicants with an opportunity to voluntarily amend the application, whilst avoiding that applicants may improve their positions by adding subject-matter not disclosed in the application as originally filed.

The problem, however, is the strict interpretation given to Article 32 by the **Normative Resolution # 093/2013**, hereinafter referred to as "the Resolution", which explicitly states in item **2.2 Changes not allowed in the set of claims** the following:

(i) After request of examination amendments that result in an **extension of the claimed matter will not be accepted** and

(ii) Changes in the claim set, voluntary or resulting from technical examinations (orders 6.1 or 7.1) that will **extend the claimed subject matter**, will violate the provisions of article 32 of the IPL and, therefore, will not be accepted.

Dr. Carlota Vergas

This narrow interpretation of the requirements of Article 32, in not allowing the extension of the **claimed** matter after examination, may have consequences beyond the subject matter available for filing divisional applications discussed above.

In particular, on inventions related to the provision of a compound X for use in the manufacturing of a medicament for treating disease Y, wherein Y is a new disease not disclosed to be treated with compound X in the state of the art, also known as second medical use inventions, the following situation may arise.

As the reader is no doubt aware, an accepted claim format in Europe for claiming these inventions had been the Swiss-type claim format for many years before Decision G2/08. With this decision, Swiss-type claims may not be used anymore in European patent applications filed on, or claiming priority date of, 29 January 2011 or later, making the purpose-limited format

Résumé

Dr. Carlota Vergas
Carlota is a European Patent Attorney with 20 years of experience, specializing in drafting and prosecuting patent applications in Latin America and before the EPO, as well as in the elaboration of FtO reports in the chemistry-pharma field. A Spanish native, she is also fluent in German and English.

Russia