Analysis of megascience facilities legal regulation

A Andreasyan¹ and A Balyakin²

¹Open Law Ltd., Moscow, 119049, Russian Federation
²National Research Center Kurchatov Institute, Moscow, 123182, Russian Federation

anastasia.andreasyan@opravo.ru, balyakin_AA@nrcki.ru

Abstract. Many countries have now understood the importance of high technology for the society development and are now regulating them in a legal area. In the Russian Federation, the creation of megascience facilities is included in the state programme for scientific and technological development. Megascience projects for basic research in various fields are actively developed as an enterprise based on international cooperation. The specifics of work in such projects and the availability of international cooperation require special attention in terms of legal regulation. In addition, it should be noted that in the field of scientific research, a particular approach to regulating issues in the distribution of risks, financing, responsibility etc. is being developed. This paper discusses a number of issues related to the work setup on megascience facilities. Examples of soft law and hoflaw implementations in the field of legal regulation of scientific activity are given.

1. Concept of “megascience”

Scientific projects carried out on unique scientific facilities (also known as megascience facilities) are aimed at conducting fundamental research contributing to obtaining advanced technologies and development. The term “megascience” is often used as an indication of unique large research facilities (complexes) demonstrating the level of global scientific and technological development. Characteristics of such facilities are: novelty (equipment should be modern, otherwise it cannot get world-class results), complementarity (devices that make up an infrastructure object should complement each other), versatility (equipment should provide researchability throughout the cycle, from fundamental to applied research and development).

At the same time, this term (“megascience”) does not currently exist in the Russian legislation, but the Strategy of Scientific and Technological Development of the Russian Federation for 2017-2025 approved by Decree of the President of the Russian Federation No. 642 dated 01/12/2016¹, contains reference to scientific megascience facilities without its clear definition.

As a result of analysis of the best practices of the megascience projects development, the Ministry of Education and Science of the Russian Federation has submitted to the Government of the Russian Federation a list of criteria for classifying Russian research facilities as international scientific megaprojects that was approved by the Russian Government Commission on High Technologies and Innovations on July 5, 2011².

¹ CL RF 2016. № 49. Art. 6887
² The text of the Address was not published officially. Website of the Ministry of economic development of the Russian Federation
These projects include Russian research facilities meeting the following criteria:

- A research facility allows solving large-scale scientific problems; expected scientific results obtained only with its use open up new possibilities in the development of world science and creation of unique breakthrough technologies.
- The facility far outperforms its closest analogue in parameters, and the period of its expected uniqueness is at least 10 years.
- Intention to participate in the creation (and/or maintenance) of the facility was expressed by foreign states.
- Creation and operation of the facility are carried out under an international contract.
- Availability of positive findings of international expert assessment of the project.
- Availability of technical, economic and financial justification for the project.
- Availability of world-class scientific schools in the Russian Federation.
- Estimated cost of participation of the Russian Federation in creation and/or maintenance of the facility within 5 years exceeds 1.5 billion rubles; the financial interest of the Russian Federation corresponds to the world practice for such facilities.

It is apparent that one of the most important criteria is the “uniqueness” of a scientific facility; a corresponding definition is provided in Art. 2, Federal Law No. 127-FZ “On Science and State Scientific and Technical Policy” dated 23/08/19963 [3]. Thus, according to Art. 2 of the Law mentioned above, a unique scientific facility is a complex of scientific equipment operating as a unit:

- designed by an institution conducting scientific or scientific and technological activities;
- focused on obtaining scientific results that can’t be achieved using other equipment;
- unparalleled in the Russian Federation, and, therefore, in demand by other institutions implementing scientific or scientific and technological activities.

Having considered the approach of legislators and having studied performance of megascience facilities, the following definition can be proposed. A megascience facility is a project consisting of unique system integrated scientific equipment that is designed, manufactured and operated with the involvement of resources from various countries through international co-operation to obtain scientific results important for the world community and containing fundamental knowledge that cannot be obtained in any other scientific facilities [1].

As it has been determined that megascience scientific facilities necessarily imply international co-operation, the issue of legal regulation of both the functioning of such installations and distribution of the rights and responsibilities for the result of its activities seems to be important.

This article is focused on the first issue and deals with the regulation of relationships between the operators of megascience facilities using as an example a number of unique scientific facilities operated with the involvement of the Russian Federation.

Regarding the second issue - regulation of the research findings (including in the socio-economic context), two approaches currently exist. Under the first approach (for example, at CERN), an open data policy is implemented, when the research findings obtained by the collaboration are published and are in open access. Open access to raw (unprocessed) data is not intended. The data itself (in the processed form) are stored for a long time and are available for re-analysis by any interested parties. From the business perspective, support for the concept of open data (“no one's data” in business analysts’ terms) [2] is due to impossibility of definite identification of ownership (owner) of the data, and, accordingly, the desire to avoid any ambiguous solutions implying responsibility for unlawful use of information.

---

3 CL RF 1996. №35. Art. 4137
The second approach, implemented, for example, in the European XFEL, is an extract from the European XFEL open scientific data policy for private research. Namely, all raw data and their associated metadata, as well as the results of raw data analysis obtained from private research, are owned exclusively by the client who has acquired the access thereto and are exempt from the European XFEL Scientific Data Policy. With regard to purely scientific experiments, it is assumed that their results will be available after an embargo period (3 years; see the description of the experiment conducted by the CMS CERN collaboration in 2010) [3]. Processed data, intermediate analysis results and associated metadata are not considered by EuXFEL for long-term storage (5 years or more).

2. Regulation of relations between operators of megascience facilities

2.1. European Council for Nuclear Research

Let us consider the experience of the Conseil Européen pour la Recherche Nucléaire (European Council for Nuclear Research) (hereinafter - CERN) in regulating operations of megascience facilities. Administrative bodies of CERN, acting within their organizational and management powers, issue binding instruments determining general rules for formation and operation of international scientific associations/groups [4]. Such instruments can deal with the following issues: ownership regime, risk insurance, rules regarding distribution of intellectual property, procedure for delivery, transportation, installation and dismantling of equipment, mutual responsibility of project members.

For the purposes of this analysis, an interesting example is provided by the Large Hadron Collider (hereinafter referred to as the LHC), as an organization operating at CERN. Research teams dealing with the LHC establish scientific collaborations. The term “collaboration” also exists in the founding documents of CERN and means an organization that ensures collaboration between European states in relation to nuclear research of a purely scientific and fundamental nature, as well as in relation to other studies that are material to “nuclear research” [4]. The LHC collaborations have their own constituent documents collectively known as ‘memorandum of understanding’ [5]. CERN members include 21 states, and the Russian Federation has an observer status.

A memorandum is an agreement between all members of a research team that may govern the issues of ownership of the equipment and the deliverables, risk insurance, distribution of intellectual property, procedure for delivery, transportation, installation and dismantling of equipment, mutual responsibility of the research team members, etc. [5].

A memorandum of understanding is a soft law mechanism allowing collaborators to formalize their agreements.

2.2. Joint Institute for Nuclear Research

In Russia, the Joint Institute for Nuclear Research (hereinafter - JINR) founded in 1956 has been used as the basis for the megascience project Nuclotron-based Ion Collider fAcility (NICA, Dubna, Russian Federation) [6]. Participants in this megascience project are 18 countries. According to p. 4, Art. 7 of the JINR Statute, the member states of the Institute take part in financing the activities of the Institute and have equal rights in the Institute management. It should be noted that the JINR documents provide for an approach similar to that of the CERN and capture the concept of scientific collaborations and a memorandum. For example, the Regulation on organization of experiments conducted by international collaborations using the capabilities of the JINR basic facilities (hereinafter - the Regulation) contains the term “Memorandum of Understanding”, which means a document prepared by an international collaboration upon approval of the experiment project in accordance with the rules adopted in JINR, formalizing an agreement between the research participants and signed by the JINR as the host party with each collaborating member organization participating in the experiment [7]. In fact, this tool for regulating the relations between participants in scientific collaboration is similar to that used when dealing with the LHC.

Section 5 of the Regulation specifies that a Memorandum of Understanding must contain the following information:
• list of collaboration members;
• general provisions;
• financial rules and arrangements, liabilities;
• work schedule;
• conditions for engagement of researchers and specialists for the positions allocated by the collaboration;
• responsibility of the parties for supply, manufacture, installation, maintenance, service and operation of the equipment and software required for the experiment;
• obligations and responsibility of the collaboration member on observance of the rules and norms of labor protection, radiation and nuclear safety rules, sanitary and hygienic requirements, and fire safety requirements at the JINR;
• provisions on the ownership of intellectual property rights, rights and obligations of the collaboration members on the legal protection and use of intellectual property created during the experiment;
• period for which the collaboration is created.

Thus, having considered the JINR regulatory documents, it can be argued that an approach similar to that of the CERN and the LHC is being used, aimed at maximizing the use of soft law and providing an opportunity for the parties involved in the project to agree on all key issues.

2.3. International Thermonuclear Experimental Reactor
A somewhat formally different approach has been chosen for the ITER (International Thermonuclear Experimental Reactor) [8] (hereinafter - ITER). The basic documents establishing the legal status of the ITER megascience project are the Agreement on the Establishment of the ITER International Fusion Energy Organization for the Joint Implementation of the ITER Project (hereinafter - the Agreement) and the Agreement on the Privileges and Immunities of the ITER International Fusion Energy Organization for the Joint Implementation of the ITER Project (hereinafter - the Agreement on Privileges), signed on November 21, 2006 in Paris.

According to Art. 2 of the Agreement, the main task of the ITER is achieving sustained fusion power generation and demonstrating the scientific and technological possibility of using this energy for peaceful purposes. This Agreement defines the key conditions for creation and functioning of the project.

Article 8 of the Agreement defines the basic principles of financing the ITER mega-science project and allocating costs between the project partners. It was also stipulated that contributions can be made by partners in cash or in kind [9].

The share of the European Union in the project costs is 45% (5/11), and that of Japan is 2/11. The rest of the parties participate in the project implementation costs by 1/11 (9.1%). Partners receive equal access to information and data and acquire equal rights to inventions, know-how and technologies obtained during implementation of the ITER megascience project. Commercial income received from the use of the ITER facility and the resulting technologies are distributed among partners in proportion to their contributions [10].

It should be noted that the ITER also uses the Memorandum of Understanding mechanism. Thus, on April 17, 2018, a Memorandum of Understanding was signed between the ITER and the Canadian Department of International Trade to identify specific areas of technical cooperation for Canadian institutions and corporations in the nuclear sector, with a focus on opening business opportunities for Canadian exporters so that they can share their experience and technologies with the ITER project [11].
In fact, it can be argued that the ITER, as well as the CERN and the JINR, use the Memorandum of Understanding mechanism as a way to regulate relations between the Parties, minimize disputes and optimize the cooperation process.

3. Conclusion
Thus, activities of research teams or collaborations are sufficiently regulated by internal acts and do not require any additional intervention of state bodies or development of special legislation. For the lack of standard construction projects and due to particular functional features of each megascience facility, the development of unified rigid legislation in this area appears highly unlikely. A number of researchers note that scientific teams comfortably work and cooperate with no rigid legal regulation and make breakthroughs in science.

At the same time, it cannot be argued that the field of scientific research is absolutely free from litigation and conflicts. Thus, in 2015, a dispute was initiated in the United States over the rights to invention of the CRISPR/Cas9 genome editing system. The technology was described in an academic paper by E. Shernpetier and J. Dudnaya. Earlier in 2012, and later, a research team led by F. Zhang from the Broad Institute announced the discovery of a method for using CRISPR/Cas9 [12]. Research teams from the University of California, Berkeley, and the Broad Institute filed for patent registration six months apart, but the Broad Institute’s application was filed with payment for accelerated procession, and subsequently the Broad Institute received the patent first. In April 2015, the University of California filed an application for commencement of patent claims collision proceedings. In 2017, the United States Patent and Trademark Office recognized the patent right of the Broad Institute [13]. This decision was successfully appealed by the US Court of Appeals in the federal district and, in 2019, the University of California, Berkeley, obtained a patent [14]. An important aspect of this dispute is its commercial component; the research teams, when filing their patent applications, raised investments for implementation and presentation of rights for using their technology under a license agreement. Such legal proceedings unconditionally hinder the development of science and its practical application.

Another important factor is disinterest of the parties in breaching their obligations, since this may hinder achieving the result for which the collaboration was created. We should also note that disinterest in breaching the obligations does not completely exclude a possible dispute. Currently, there is already practice of satisfying the claim of violation of moral obligation of a party. [15], which gives reason to assert in this case that the soft law becomes binding and turns into the so-called - hardlaw (hard+soft law).

Thus, in the scientific field, using the soft law mechanisms, it is possible to settle most of the legal issues that are significant for megascience projects. It is also important to take into account that implementation of megascience projects affects various areas, and the prospects of such projects can have a wide scope. In light of this, regulating the implementation of such projects by law of obligation seems unlikely to succeed. We can agree with the authors who point out that the use of soft law and hardlaw, whose main strength lies in the high degree of credibility and effectiveness of inherent scientific logic objectivity [16], seems more relevant, since international cooperation, joint financing, and the need to distribute risks and rights to the work results make it is much easier for participants to agree on the conditions of participation and work at the beginning of the project implementation.

It appears that megascience facilities have played a significant role in obtaining intellectual results/scientific and technical breakthroughs that affect the entire socio-technological paradigm, and have logically led the legal community to the idea of establishing the foundations of a new branch of law - research law.

Acknowledgments
The paper has been financially support by the federal state-supported institution Russian Foundation for Basic Research (RFBR), and is a part of scientific project No. 18-29-16130 MK.

The authors are grateful to Nurbina M. V. and Taranenko S. B. for useful discussions.
References

[1] Moshkova D M, Lozovskiy D L 2019 Legal aspects of mega science projects implementation. Courier of the university named after O. E. Kutafin (MSAL). No. 7. 7.

[2] McKinsey & Company. Big data: The next frontier for innovation, competition, and productivity. Available online: https://www.mckinsey.com/business-functions/mckinsey-digital/our-insights/big-data-the-next-frontier-for-innovation (accessed 09.04.2020).

[3] CMS releases open data for Machine Learning. Available online: https://home.cern/news/news/knowledge-sharing/cms-releases-open-data-machine-learning (accessed 30.04.2020).

[4] Convention for the establishment of a European organization for nuclear research, Paris, 1st July, 1953 Available online: http://cds.cern.ch/record/330625/files/Convention.pdf?subformat=pdfa&version=1 (accessed 27.04.2020).

[5] Chetverikov A O 2019. Large Hadron Collider as a legal phenomenon. Lex russica. No. 4. 18

[6] Mega science project in the Russian Federation. Available online: http://nica.jinr.ru/ru/megaproject.php (accessed 16.04.2020).

[7] Regulations on the organization of experiments conducted by international collaborations using the capabilities of JINR base facilities. Available online: http://www.jinr.ru/docs/ (accessed 17.04.2020).

[8] THE ITER ORGANIZATION, Available online: https://www.iter.org/org (accessed 17.04.2020).

[9] The agreement establishing the international organization ITER on thermonuclear energy for joint realization of ITER project. Available online: http://docs.cntd.ru/document/902090032 (accessed 16.04.2020).

[10] Gorlova E N, Tkachenko R V 2019. The concept of projects of the "megascience" class on the example of ITER and fire installations. Current problems of Russian law. No. 5

[11] Minister Champagne signs memorandum of understanding with International Thermonuclear Experimental Reactor while in France. Available online: https://www.canada.ca/en/global-affairs/news/2018/04/minister-champagne-signs-memorandum-of-understanding-with-international-thermonuclear-experimental-reactor-while-in-france.html (accessed 17.04.2020).

[12] Battle for rights to crispr/Cas9 genome editing technology, Available online: https://www.wipo.int/wipo_magazine/ru/2017/02/article_0005.html (accessed 21.04.2020).

[13] DECISION ON MOTIONS 37 C.F.R. § 41.125(a), Available online: https://www.washingtonpost.com/news/speaking-of-science/wp-content/uploads/sites/36/2017/02/DecisionsOnMotions.pdf (accessed 27.04.2020).

[14] Berkeley News. Twelfth CRISPR patent awarded to UC team. Available online: https://news.berkeley.edu/2019/09/03/twelfth-crispr-patent-awarded-to-uc-team/ (accessed 27.04.2020).

[15] Chetverikov A O 2018. Organizational and legal forms of big science (megascience) in the context of international integration: a comparative study part I. Magazins as a scientific and legal phenomenon. Legal aspects of megascience functioning in the form of international intergovernmental organizations and national legal entities. Legal science. No. 1

[16] Kashkin S Y 2018. Formation of law science as a new complex branch of law. Courier of the university named after O. E. Kutafin (MSAL). No. 5. 11.