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European Union: Intellectual Property Rights of SMEs Under the Innovative Medicines Initiative

Theresa Papademetriou
Senior Foreign Law Specialist

SUMMARY In the European Union (EU), the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking is designed to develop next generation vaccines and medicines, such as new antibiotics. The IMI2 Joint Undertaking broadens the definition of micro, small and medium-sized enterprises (SMEs) to allow more companies with an annual turnover of €500 million or less to be eligible for funding and participate in IMI2 projects.

Prior to beginning a project funded by the IMI2 Joint Undertaking, participants sign an agreement based on the Model Grant Agreement, which contains the terms and conditions of cooperation and intellectual property issues on exploitation and dissemination of results. A consortium agreement may also be signed. The basic principle that applies to all participants is that results are owned by the participant who generated them. While SMEs that have developed new medications are entitled to certain incentives when submitting applications for marketing, they are not granted greater revenue from intellectual property than other types of participants.

I. Introduction

The Innovative Medicines Initiative (IMI) was established in 2007 as a public-private partnership initiative between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).[1] Such partnerships are based on article 187 of the Treaty on the Functioning of the EU, which provides the legal basis for the EU to establish joint undertakings or any other structure necessary "for the efficient execution of Union research, technological development and demonstration programs."[2] The IMI's long-term objective was to ensure that the pharmaceutical sector produces safer and more effective medicines, and delivers those medicines to patients faster.[3]

[1] Council Regulation (EC) No. 73/2008 of 20 December 2007 Setting Up the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines, 2008 O.J. (L 30) 38, https://ec.europa.eu/research/jti/pdf/councilreg_imi.pdf, *archived at* https://perma.cc/M4NB-8TVD.

[2] Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) art. 187, 2012 O.J. (C 326) 47, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN, *archived at* https://perma.cc/26LL-MN7K.

[3] Commission Delegated Regulation (EU) No. 622/2014 of 14 February 2014 Establishing a Derogation from Regulation (EU) No. 1290/2013 of the European Parliament and of the Council Laying Down the Rules for Participation and Dissemination in 'Horizon 2020 — the Framework Program for Research and Innovation (2014–2020)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking, pmbl. para. 3, 2014 O.J. (L 174) 7, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN, *archived at* https://perma.cc/LMJ6-C6RR; *see also Innovative Medicines Initiative 2: Europe's Fast Track to Better Medicines*, EUROPEAN COMMISSION, http://ec.europa.eu/research/press/jti/factsheet_imi2-web.pdf (last visited June 1, 2016), *archived* at https://perma.cc/K9FK-KKV3.

In 2014, the IMI was succeeded by the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking established under Council Regulation (EU) No. 557/2014 for a period extending to December 31, 2024.[4] One objective of the IMI2 Joint Undertaking is to assist and promote smaller participants, including universities and micro, small, and medium-sized enterprises (SMEs). At the EU level, SMEs, as defined by the Commission, are those companies that employ fewer than 250 persons and have an annual turnover not exceeding €50 million (about US$57 million), and/or an annual balance sheet total not exceeding €43 million (about US$49 million),[5] but as discussed below, the IMI2 Joint Undertaking has a broader definition of SMEs that encompasses larger businesses. To qualify for such a status companies must file a Declaration on the Qualification of an Enterprise as a Micro, Small or Medium-sized Enterprise in order to receive certain benefits under the European Medicines Agency.[6]

The EU encourages and supports the participation of SMEs not only in the IMI2 Joint Undertaking but also in the Horizon 2020 Framework Program for Research and Innovation for the period of 2014–2020.[7] Horizon 2020 is the biggest EU Research and Innovation program ever with nearly €80 billion (about US$91 billion) of funding for the period of 2014–2020.[8] One of its objectives is to ensure the adequate participation of, and research and innovation impact on SMEs throughout its implementation.[9] Those SMEs that wish to participate in "indirect actions," meaning research and innovation activities for which the EU provides financial support or funding under the Horizon 2020 program, must meet the above criteria for SME status established by the Commission.[10] Regulation 1290/2013 also contains rules concerning

[4] Council Regulation (EU) No. 557/2014 of 6 May 2014 Establishing the Innovative Medicines Initiative 2 Joint Undertaking, 2014 O.J. (L 169) 54, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0557&from=PL, *archived at* https://perma.cc/C63E-QQQG.

[5] Commission Recommendation 2003/361/EC of 6 May 2003 Concerning the Definition of Micro, Small and Medium-sized Enterprises, 2003 O.J. (L 124) 36, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF, *archived at* https://perma.cc/3DGD-8PA4.

[6] European Medicines Agency, Science Medicine and Health, Declaration on the Qualification of an Enterprise as a Micro, Small or Medium-sized Enterprise (SME), version 1.2 (Nov. 2015), http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2012/12/WC500135919.pdf, *archived at* https://perma.cc/K2XM-Q5JF.

[7] *See* Regulation (EU) No. 1291/2013 of the European Parliament and of the Council of 11 December 2013 Establishing Horizon 2020 – the Framework Program for Research and Innovation (2014–2020) and Repealing Decision No. 1982/2006/EC, 2013 (L 347) 104, pmbl. para. 22, 34, 35, 37 & art. 22, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0104:0173:EN:PDF, *archived at* https://perma.cc/EHL6-QTHH.

[8] *What is Horizon 2020?*, EUROPEAN COMMISSION, HORIZON 2020, https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 (last visited June 1, 2016), *archived at* https://perma.cc/5H7B-7MML.

[9] Regulation No. 1291/2013, *supra* note 7, art. 22.

[10] Regulation (EU) No. 1290/2013 of the European Parliament and of the Council of 11 December 2013 Laying Down the Rules for Participation and Dissemination in "Horizon 2020 – the Framework Program for Research and Innovation (2014–2020)" and Repealing Regulation (EC) No. 1906/2006, 2013 O.J. (L 347) 81, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0081:0103:EN:PDF, *archived at* https://perma.cc/4DAB-XQMP.

intellectual property rights (patents, copyright, or trade names)[11] that apply to SMEs and other participants in the Horizon 2020 program.[12]

On the other hand, SMEs that participate in the IMI2 Joint Undertaking are subject to distinct eligibility rules for funding and distinct intellectual property rules.

II. IMI2 Joint Undertaking

The IMI2 Joint Undertaking program is a legal entity located in Brussels and has two main objectives: (a) to support the activities of the Horizon 2020 Framework Program for Research and Innovation Activities that are of strategic importance to the EU's competitiveness; and (b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines such as developing next generation vaccines and therapies and improving the drug development process.[13] It began in 2014 and will continue for ten years.[14] The EU will contribute up to €1.638 billion (about US$1.865 billion) from the EU Horizon 2020 program to cover administrative and operating costs, and EFPIA constituent or affiliated entities will commit €1.425 billion (about US$1.623 billion), including in-kind contributions.[15]

The Members of the IMI2 Joint Undertaking include (1) the EU, represented by the Commission; (2) EFPIA; and (3) any legal entity that directly or indirectly supports research and innovation in a Member State or in a country associated with Horizon 2020 that becomes a Member of the IMI2 Joint Undertaking.[16] Such entities are subject to two requirements: acceptance of the Statutes of the IMI2, and contributions to IMI2 funding.[17]

In general, Regulation No. 1290/2013 applies to actions funded by the IMI2 Joint Undertaking,[18] but IMI2 has its own rules on eligibility of funding and intellectual property rules that derogate from the general rules of funding and intellectual property rules provided for in Regulation 1290/2013.

[11] *What is Intellectual Property?*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, http://www.wipo.int/about-ip/en/ (last visited June 1, 2016), *archived at* https://perma.cc/L3EX-TK97.

[12] Regulation No. 1290/2013, *supra* note 10, arts. 41–49.

[13] Council Regulation No. 557/2014, *supra* note 4, art. 2.

[14] *Id*.

[15] *Id*. arts. 3 & 4.

[16] *Id*. art. 2.

[17] *Id*. art. 17.

[18] *Id*. pmbl. para. 17.

A. Eligibility for Funding

The IMI2 limits eligibility for funding to the following groups of participants:[19]

> (a) legal entities established in a Member State or an associated country, or created under Union law; and
>
> (b) which fall within one of the following categories:
>
> (i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply *mutatis mutandis*;
>
> (ii) secondary and higher education establishments;
>
> (iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.
>
> (c) the Joint Research Centre;
>
> (d) international European interest organisations.[20]

While the Horizon 2020 framework program defines SMEs to include companies with an annual turnover of €50 million or less to participate,[21] IMI2 Joint Undertaking's definition of SMEs includes companies with an annual turnover of €500 million or less.

B. Terminology

In the context of the IMI2 Joint Undertaking and the Horizon 2020 Framework Program, the following terminology is used:

Background means:

> any data, know-how or information whatever its form or nature, tangible or intangible, including any rights such as intellectual property rights, which is: (i) held by participants prior to their accession to the action; (ii) needed for carrying out the action or for

[19] The rules on funding derogate from article 10(1) of Regulation No. 1290/2013, *supra* note 10, which extends eligibility for funding to any legal entity established in a Member State or a legal entity established in a third country identified in the work program and any international European interest organizations. SMEs that participate must meet the requirements of Commission Recommendation 2003—that is, have less than 250 employees and have an annual turnover not exceeding €50 million.

[20] Commission Delegated Regulation No. 622/2014, *supra* note 3, art. 1. "International European interest organization" means an international organization, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe. Regulation No. 1290/2013, *supra* note 10, art. 2, para. 12.

[21] Regulation 1290/2013, *supra* note 10, art. 2, para. 13.

> exploiting the results of the action; and (iii) identified by the participants in accordance with Article 45.[22]

Results means:

> any tangible or intangible output of the action, such as data, knowledge or information, that is generated in the action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.[23]

Access rights means:

> rights to use results or background under the terms and conditions laid down in accordance with [Regulation 1290/2013].[24]

Sideground means:

> tangible or intangible output generated by a beneficiary under the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, but which are outside of the action objectives as defined in the grant agreement and which therefore are not needed for implementing the action or for research use of results.[25]

Exploitation means:

> the use of results in further research activities other than those covered by the action concerned, or in developing, creating and marketing a product or process, or in creating and providing a service, or in standardization activities.[26]

Dissemination means:

> the public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium.[27]

C. Intellectual Property Rules Applicable to IMI2 Participants

All participants under IMI2 are subject to the general intellectual property rules contained in articles 41–49 of Regulation 1290/2013 on Horizon 2020. In addition, special intellectual property rules apply to all participants in IMI2 projects "in order to achieve an open innovation model," "to maximize exploitation of project results," and to ensure faster delivery of medicines

[22] *Id*. art. 2, para. 1(4).

[23] *Id*. art. 2, para. 1(19).

[24] *Id*. art. 2, para. 1(1).

[25] Delegated Regulation No. 622/2014, *supra* note 3, art. 2(a).

[26] Regulation No. 1290/2013, *supra* note 10, art. 2, para. 1(9).

[27] *Id*. art. 2, para. 1(8).

to patients.[28] These special rules applicable to IMI2 joint undertakings deviate from the general rules of Regulation 1290/2013 and are contained in articles 2 through 7 of Commission Delegated Regulation No. 622/2014 of February 14, 2014.[29]

Moreover, articles 23–31 of the Model Grant Agreement,[30] which was drawn by the Commission jointly with the Member States and governs the relationship between the Commission or the relevant funding body and the participants, contain intellectual property rules.[31] Intellectual property rules may also be included in the internal agreement concluded by members of a consortium, which may participate in an action. Under a consortium agreement, parties may establish their rights and obligations with respect to the implementation of the action in compliance with the grant agreement, rules on dissemination, and use and access rights, additional to those provided in Regulation 1290/2013 and the provisions in the grant agreement.[32] The Guidance Note of 2010 provides clarification as to the rules applicable to intellectual property matters.[33]

1. Ownership of Results

The general rule is that results are owned by the participants who generated them.[34] However, under the IMI2 results do not include any sideground, such as data, knowledge, and information, irrespective of whether such sideground can be protected or not.[35]

2. Sideground

Each participant must remain the exclusive owner of its sideground; however, a different allocation of ownership could be agreed upon by participants. In addition, participants are not obliged to grant access rights to sideground.[36]

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[28] Delegated Regulation No. 622/2014, *supra* note 3, pmbl. (4).

[29] *Id*.

[30] IMI, Multi-beneficiary Model Grant Agreement for Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU), Version 2.0 (Feb. 3, 2015), http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/jtis/h2020-mga-imi_en.pdf, *archived* at https://perma.cc/9ZZV-NZ37.

[31] Regulation No. 1290/2013, *supra* note 10, art. 18.

[32] *Id*. art. 24, para. 2(c).

[33] Innovative Medicines Initiative (IMI) Intellectual Property (IP) Policy, Guidance Note for IMI Applicants and Participants (Nov. 2010), http://www.imi.europa.eu/sites/default/files/uploads/documents/Intellectual%20Property/GuidanceNote_Draft3-1_10Nov2010.pdf, *archived at* https://perma.cc/SP73-G9PS.

[34] Regulation No. 1290/2013, *supra* note 10, art. 41, para. 1.

[35] Delegated Regulation (EU) No. 622/2014, *supra* note 3, art. 2(a).

[36] *Id*. art. 2(b) & (c).

3. Transfer –Licensing of Results and Background

A participant has the right, without the consent of other participants and as long as such participants are informed and the transferee agrees to be bound by the grant and the consortium agreements, to transfer its results to

- any affiliated entity,[37]
- any purchaser of all or a substantial amount of its assets, or
- any successor entity that results from a merger or a consolidation with such a participant.[38]

These rules deviate from article 44 of Regulation 1290/2013.[39]

A participant is free to license, transfer, or otherwise dispose of its ownership rights in background, subject to any rights and obligations contained in the grant and consortium agreements.

4. Exploitation of Results for Research Use

With regard to access rights for exploitation, the intellectual property rules deviate from article 48 of Regulation No. 1290/2013 and apply the following terms:

Research Use means:

> the use of results or background needed to use results, for all purposes other than for completing the action or for direct exploitation and which includes but is not limited to the application of results as a tool for research, including clinical research and trials and which directly or indirectly contributes to the objectives set out in the Societal Challenge health, demographic change and well-being referred to in Regulation (EU) No. 1291/2013.[40]

Direct exploitation means:

> developing results for commercialization, including through clinical trials, or commercializing results themselves.[41]

[37] "Affiliated entity" means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control of a participant, or that is directly or indirectly controlling a participant. Regulation 1291/2013, *supra* note 7, art. 1(2).

[38] Delegated Regulation (EU) No. 622/2014, *supra* note 3, art. 3.

[39] Regulation No. 1290/2013, *supra* note 10, art. 44, para. 1(4).

[40] Delegated Regulation (EU) No. 622/2014, *supra* note 3, art. 7(a)(1).

[41] *Id*. art. 7(a)(ii).

III. Protection of Intellectual Property

As stated above, the general rule is that results and sideground derived from IMI2 Joint Undertaking projects are owned by the participant who generated them. The choice of the most suitable form of IP protection depends on the type of results, such as an invention, software, or a database, but also on the business plans for their exploitation and the legitimate interests of consortium partners.[42] For example, open access is mandatory for scientific articles and the authors of such articles hold the copyright. Copyright issues have, to a large extent, been harmonized in the Member States based on EU rules.[43] If the product is a website it could be granted protection as an industrial design, copyright, or trademark.[44]

If the outcome of a project is a new medication, it must comply with the rules on centralized authorization by the European Medicines Agency (EMA). In the Commission's view, SMEs that are involved in the pharmaceutical sector are usually innovative companies, and should benefit from a number of incentives by the EMA when submitting applications for marketing authorization.[45] Thus, Regulation (EC) No. 2049/2005 provides for a number of incentives such reduced fees, deference of payment of fees, and provision of administrative assistance.[46] Moreover, the scientific evaluation of a marketing authorization application tends to be reviewed more favorably if the SME has received scientific advice for marketing medicinal products.[47]

If the results involve technical inventions, they can receive protection either by applying to the competent national patent authorities for a national patent or by applying centrally to the European Patent Office. The lack of a centralized system for patent applications entails large administrative fees and is time-consuming for patent applicants, since a patent obtained in one Member State needs to be validated in other Member States as well. According to a study cited by the European Commission, in 2009 it cost at least fifteen times as much to patent an invention in the EU as in the United States.[48]

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[42] European IPR HelpDesk, Fact Sheet, How to Manage IP in Horizon 2020: Project Implementation (July 2015), https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/Fact-Sheet-IP-Management-H2020-Project-Implementation-and-Conclusion.pdf, *archived at* https://perma.cc/64XG-8STG.

[43] *The EU Copyright Legislation*, EUROPEAN COMMISSION, DIGITAL SINGLE MARKET, https://ec.europa.eu/digital-single-market/en/eu-copyright-legislation (last updated Aug. 28, 2015), *archived at* https://perma.cc/P3A3-MJZR

[44] IPR HelpDesk Fact Sheet, *supra* note 42.

[45] Commission Regulation (EC) No. 2049/2005 of 15 December 2005 Laying Down, Pursuant to Regulation (EC) No. 726/2004 of the European Parliament and of the Council, Rules Regarding the Payment of Fees to, and the Receipt of Administrative Assistance from, the European Medicines Agency by Micro, Small and Medium-sized Enterprises, 2005 O.J. (L 329) 4, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:329:0004:0007:EN:PDF, *archived at* https://perma.cc/HA9K-E6RG.

[46] *Id*., pmbl. (3)–(7).

[47] *Id*.

[48] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Europe 2020 Flagship Initiative, Innovation Union*, at 15, COM (2010) 546 final (Oct. 6, 2010), https://ec.europa.eu/research/innovation-union/pdf/innovation-union-communication_en.pdf, *archived at* https://perma.cc/QDD6-4GPE.

As far as biotechnological inventions, the rules in the twenty-eight Member States of the EU have been harmonized, in compliance with the Directive on the Legal Protection of Biotechnological Inventions.[49]

A European patent with unitary and equal effect in the twenty-six participating Member States (except Spain and Croatia) is currently pending. Once the unitary patent enters into force, it will provide uniform protection in the participating Member States on a one-stop-shop basis, and will reduce the fees involved and limit the administrative hurdles.[50] Moreover, a Unified Patent Court for the settlement of any disputes involving patents will offer a single, specialized patent jurisdiction.[51] The unitary patent will come into effect when thirteen countries have ratified the Unified Patent Court agreement.

In June 2015 the Select Committee on the Unitary Patent, a committee established under the European Patent Treaty consisting of all EU member states, explicitly requested the Commission to assist it in the effort to reduce the cost of patent protections, specifically for SMEs. The Commission's Single Market Strategy also identifies the need to support SMEs when filing, using, and enforcing intellectual property (IP) rights, especially patents.[52]

IV. Conclusion

As noted on the IMI's website, the overall concept of the IMI has proven attractive to SMEs. Such companies benefit from funding and from networking with leading experts in their field and accessing new customers and markets. SMEs' participation in the IMI was increased from 13% in 2011 to 16% in 2014, and SMEs' percentage of the IMI budget grew from 13% in 2011 to 15.8% in 2014.[53]

The IMI2 focuses more on mid-sized companies by broadening the definition of SMEs to include companies with an annual turnover of €500 million in comparison to the previous €50 million. As far as intellectual property rights, SMEs are subject to the same general rules regarding results being owned by the participants who generate them.

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[49] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX: 31998L0044:EN:HTML, *archived* at https://perma.cc/8KN9-2GYJ.

[50] Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, 2012 O.J. (L 361) 1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:en:PDF, *archived at* https://perma.cc/X8VX-HCA3.

[51] Council Agreement on a Unified Patent Court, 2013 O.J. (C 175) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:EN:PDF, *archived at* https://perma.cc/W7B5-CXDX.

[52] *Unitary Patents*, EUROPEAN COMMISSION, GROWTH – INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES, http://ec.europa.eu/growth/industry/intellectual-property/patents/unitary-patent/index_en.htm (last updated June 7, 2016), *archived at* https://perma.cc/6GQB-GENV.

[53] IMI, KEY FACTS & FIGURES 5 (Sept. 2015), http://www.imi.europa.eu/sites/default/files/uploads/documents/Publications/FactsAndFigures_Sept2015.pdf, *archived at* https://perma.cc/4WY6-UAVP.

SMEs should be better served when the unitary patent takes effect in the EU in terms of reduced costs, fewer administrative hurdles, and less time involved in obtaining a patent.