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*INTERNATIONAL PROPERTY RIGHTS INDEX 2023*

# THE IMPORTANCE OF IP PROTECTION FOR EUROPEAN BIOTECH COMPANY ARGENX

CASE STUDY BY: **BRUSSELSREPORT.EU<sup>1</sup>**

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## INTRODUCTION

Argenx SE is the leading clinical-stage biotechnology company in Europe.<sup>2</sup> Argenx SE serves<sup>3</sup> as the Dutch parent company of Belgian company Argenx BV as well as other subsidiaries in the Netherlands, Japan, Switzerland, Germany, France, Canada and the United States. The company's statutory seat is in Rotterdam, the Netherlands, and it is publicly listed on stock exchanges in Belgium and the United States.<sup>4</sup>

Belgian bioengineer Tim Van Hauwermeiren co-founded<sup>5</sup> the company in 2008, together with Hans de Haard and Torsten Dreier, and has served as its Chief Executive Officer since July 2008. He holds a B. Sc. and M. Sc. in bioengineering from Ghent University, which is intimately linked to the growth of Argenx.

The company is specialized in developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer. It is thereby focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need.<sup>6</sup>

CIDP, a chronic inflammatory demyelinating polyneuropathy, is an autoimmune disease whereby a patient's nerves are attacked by his or her own immune system. In July 2023, Argenx was able to present<sup>7</sup> material progress with regards to its medicine, Vyvgart, to treat CIDP, enabling it to raise more than 1 billion USD with

<sup>1</sup>CV of the author: <https://www.linkedin.com/in/pietercleppe/>.

<sup>2</sup>"Argenx announces results of Annual General Meeting of Shareholders", May 3, 2023 <https://www.argenx.com/news/argenx-announces-results-annual-general-meeting-shareholders-may-2023> Belgisch megafonds voor biotech in de steigers, De Tijd, 18 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/belgisch-megafonds-voor-biotech-in-de-steigers/10481185.html>.

<sup>3</sup>"Argenx - The European Life-sciences portal" <https://www.life-sciences-europe.com/organisation/argen-bvba-argenx-group-2009-zwijnaarde-flanders-flemish-2001-28409.html>.

<sup>4</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf) ArgenX komt in Bel20, De Standaard, 5 June 2018 [https://www.standaard.be/cnt/dmf20180605\\_03546328](https://www.standaard.be/cnt/dmf20180605_03546328).

<sup>5</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>6</sup>"Argenx - The European Life-sciences portal" <https://www.life-sciences-europe.com/organisation/argen-bvba-argenx-group-2009-zwijnaarde-flanders-flemish-2001-28409.html>.

<sup>7</sup>"Argenx Reports Positive Topline Data from ADHERE Study of VYVGART Hytrulo in Patients with Chronic Inflammatory Demyelinating Polyneuropathy", 17 July 2023 <https://www.argenx.com/news/argenx-reports-positive-topline-data-adhere-study-vyvgart-hytrulo-patients-chronic>.





investors.<sup>8</sup> This also caused its stock price to increase 30 percent in a few days. This medicine is sometimes called<sup>9</sup> a Swiss army knife in the treatment of autoimmune diseases. It is meant to serve to cure not less than fifteen areas<sup>10</sup> of diseases<sup>11</sup>, including CIDP.

Argenx only has a turnover of 360 million euro but is now valued 24 billion euro<sup>12</sup>. The recent success has triggered speculation about a takeover by major pharma corporations.<sup>13</sup>

Throughout its history, the company has been strongly reliant Intellectual Property (IP) Rights. The biotech success story has been stressing how “the company’s main assets are intellectual property rights concerning technologies

that have not led to the commercialization of any product.”<sup>14</sup>

Hereunder, an overview will be provided of the success of Argenx (Chapter I), how IP was key to this (Chapter II), and finally also how despite this success story, intellectual property protection in Europe is threatening to become less solid (Chapter III).

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<sup>8</sup>“De boude plannen van 1 miljard van Argenx”, De Tijd, 19 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/de-boude-plannen-van-1-miljard-van-argenx/10481539.html>.

<sup>9</sup>“Heeft Argenx heilige graal voor auto-immuunziektes gevonden?”, De Tijd, 18 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/heeft-argenx-heilige-graal-voor-auto-immuunziektes-gevonden/10481364.html>.

<sup>10</sup>Argenx Deep Antibody Pipeline of Differentiated Candidates 2023 [https://www.argenx.com/sites/default/files/media-documents/argenx\\_Pipeline\\_PDF\\_20230206.pdf](https://www.argenx.com/sites/default/files/media-documents/argenx_Pipeline_PDF_20230206.pdf).

<sup>11</sup>“Argenx telt af naar dé afspraak van 2023”, De Tijd, 13 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-telt-af-naar-de-afpraak-van-2023/10480459.html>.

<sup>12</sup>“Heeft Argenx heilige graal voor auto-immuunziektes gevonden?”, De Tijd, 18 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/heeft-argenx-heilige-graal-voor-auto-immuunziektes-gevonden/10481364.html>.

<sup>13</sup>“Argenx spurt fors hoger na sterke onderzoeksdata”, 17 July 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-spurt-fors-hoger-na-sterke-onderzoeksdata/10480983.html>.

<sup>14</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

## THE SUCCESS OF ARGENX

### VYVGART

The success of Argenx stands in sharp contrast with some of its competitors. While 80 percent of fellow Belgian biotech firms witnessed their share price tanking more than 90 percent over the last five years<sup>15</sup>, the company's stock almost quadrupled since the beginning of 2020.

There is the success of its medicine Vyvgart, which may deliver one billion USD turnover and ultimately up to 10 billion dollars. According to analysts, this may make it one of the top-selling drugs in the world.<sup>16</sup> Part of the innovative approach of Argenx was to find a way to administer this medicine to patients by injection, so they would no longer need to make it to hospitals but can simply go to a general practitioner or even self-administer at home. Another advantage is that Vyvgart can be administered to less serious cases as well and in an earlier stage of the disease.

Recently, the U.S. pharmaceutical watchdog

Food and Drug Administration (FDA) approved the new technology to enable this treatment by injection – dubbed “Vyvgart Hytrolu”. Argenx already started with this in 2019, and has cooperated since then with Californian company Halozyme, which had the technological know-how, to realise this.<sup>17</sup>

At the moment, treating myasthenia gravis with Vyvgart is the main driver of sales for Argenx. Analysts estimate potential sale opportunities here at 3 billion euro. If it would ultimately be able to use Vyvgart to treat CIDP, that would add a second big sales driver for the company, with sales opportunities of up to 1.5 billion euro. The company hopes to be profitable from 2025.<sup>18</sup>

An industry expert quoted by Belgian finance daily De Tijd explains that “While it proved difficult for other Belgian biotech companies, Argenx succeeded in the translation from development to commercialisation”, adding ‘it also fully controlled the the sale of Vyvgart because it did not partner with a pharma company. And

<sup>15</sup>Argenx is het voorbeeld van perfecte voorbereiding en perfecte uitvoering’, De Tijd, 21 June 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-is-het-voorbeeld-van-perfekte-voorbereiding-en-perfekte-uitvoering/10475962.html#:~:text=%20'CEO%20Tim%20Van%20Hauwermeiren%20laat,'>

<sup>16</sup>Argenx is het voorbeeld van perfecte voorbereiding en perfecte uitvoering’, De Tijd, 21 June 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-is-het-voorbeeld-van-perfekte-voorbereiding-en-perfekte-uitvoering/10475962.html#:~:text=%20'CEO%20Tim%20Van%20Hauwermeiren%20laat,'>

<sup>17</sup>Argenx is het voorbeeld van perfecte voorbereiding en perfecte uitvoering’, De Tijd, 21 June 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-is-het-voorbeeld-van-perfekte-voorbereiding-en-perfekte-uitvoering/10475962.html#:~:text=%20'CEO%20Tim%20Van%20Hauwermeiren%20laat,'>

<sup>18</sup>Argenx-CEO Tim Van Hauwermeiren: ‘We hebben het ondenkbare gedaan’, De Tijd, 31 December 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-ceo-tim-van-hauwermeiren-we-hebben-het-ondenkbare-gedaan/10437858.html>

<sup>19</sup>Argenx is het voorbeeld van perfecte voorbereiding en perfecte uitvoering’, De Tijd, 21 June 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-is-het-voorbeeld-van-perfekte-voorbereiding-en-perfekte-uitvoering/10475962.html#:~:text=%20'CEO%20Tim%20Van%20Hauwermeiren%20laat,'>



it ensured that it always had sufficient access to capital, which is often a problem for many biotech companies.<sup>19</sup>

## LIFE SCIENCES: A CHALLENGING SECTOR FOR INVESTORS

Throughout the search for financial resources, Argenx was up against the challenge that it takes about 15 years to see return-on-investment in the life sciences industry, while eight out of 10 drugs fail after being launched.<sup>20,21</sup>

At the end of 2022, CEO Tim Van Hauwermeiren recalls in an interview the journey of the company: "When we started, there were plenty of crises. Worse than now. To then launch a biotech company was crazy. Then, we were crazy to finance all the studies ourselves and crazy to sell the drug all over the world ourselves, without a partner."

He adds: "I went into the field. Doctors have often never seen a CEO up close. That sends a powerful message and makes an impression. Did I make a difference there? I hope so. (...) I learned by all means that myasthenia gravis is a much worse disease than we thought. Talking to doctors and patients yields powerful stories. You understand better what terms like muscle weakness mean. We encountered people who couldn't swallow or could barely breathe. There was a woman who with Vyvgart was able to use her laughing muscles again for the first time in years. Her grandchildren were scared of her because she was the grandmother who always looked angry. A German patient was still

brought in by ambulance for his first treatment. The second time, he came by bicycle. If you can feed that back to people in the lab, it comes full circle. That motivates everyone. (...) We already have 2,000 patients in treatment now, but there are 17,000 in the U.S., 6,000 in Japan and a proportionate number in Europe. We are going to Canada, South Korea, Australia."<sup>22</sup>

Furthermore, he describes how tricky it is to launch a pharmaceutical product: "We have studied many product launches. There is something peculiar about it. The slope of the curve of the first four quarters determines the rest of the life of your drug. You can't reverse that. We got off to a good start, which sets the tone. We are going fast. There is no pharmaceutical company that has launched a product both in the U.S. and in Japan and in Europe in one calendar year."

CEO Tim Van Hauwermeiren has also made clear how important licensing is for pharma companies like his, saying: "We have bought a voucher to be at the top of the pile at the FDA for new approval files. We simply don't have the time to wait a year for approval every time. That voucher cost us 100 million euros, but you easily recover that over the life cycle of a drug."

When it comes to the debate about the price of medicines for rare diseases, he pleads for a more nuanced debate:

"The price is often shocking unless you understand the context. If you look at the whole life cycle of patients, you come out better and cheaper. We know that in the U.S., 51 percent of

<sup>20</sup>Argenx-CEO Tim Van Hauwermeiren: 'We hebben het ondenkbare gedaan', De Tijd, 31 December 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-ceo-tim-van-hauwermeiren-we-hebben-het-ondenkbare-gedaan/10437858.html>

<sup>21</sup>Tim Van Hauwermeiren, een 'Lucky Luke' van 14 miljard, De Tijd, 6 February 2023 <https://www.tijd.be/ondernemen/farma-biotech/tim-van-hauwermeiren-een-lucky-luke-van-14-miljard/10282506.html>

<sup>22</sup>Argenx-CEO Tim Van Hauwermeiren: 'We hebben het ondenkbare gedaan', De Tijd, 31 December 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-ceo-tim-van-hauwermeiren-we-hebben-het-ondenkbare-gedaan/10437858.html>



our patients are unemployed. They are likely to get help from family members who therefore work part-time and pay less taxes. There are a lot of indirect effects. Those not taking Vyvgart are taking old medication to flatten the immune system. That is good if you get an organ transplant, to avoid rejection symptoms, but if you take that as a myasthenia gravis patient for 10 or 20 years, your risk of cancer increases or you get severe osteoporosis with fractures in the pelvis and spine. If you calculate that through, you know that the discussion is often held too narrowly.”

## COOPERATION WITH THE ACADEMIC WORLD

In a separate interview, the CEO of Argenx has stressed how this life saving innovation was the result of intense cooperation between his company and academia: “Vyvgart is a unique

antibody fragment that has emerged from intense collaboration with academia. How exactly does that disease develop? That knowledge is often in universities. For Vyvgart, we collaborated with the research team of Sally Ward, affiliated with the University of Texas, who took ten years to unravel the biology of autoimmune diseases.”<sup>23</sup>

Over the years, Argenx was able to raise more than 3 billion USD venture capital and non-dilutive financing. There have been 2 IPO's (Euronext Brussels and Nasdaq), where the company is listed as “ARGX” and 5 follow on offerings.<sup>24</sup> The company has formed strategic alliances with Abbvie, LEO Pharma, Shire, and into research collaboration and license agreements with Bayer, Boehringer Ingelheim and Lilly, and into partnership with the Leukemia & Lymphoma Society.<sup>25</sup>

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<sup>23</sup>‘We schrijven pas geschiedenis als de verkoopcijfers goed zijn’, De Standaard, 24 December 2023 [https://www.standaard.be/cnt/dmf20211223\\_98013867](https://www.standaard.be/cnt/dmf20211223_98013867)

<sup>24</sup>Tim Van Hauwermeiren, Chief Executive Officer at argenx SE, LinkedIn Profile <https://www.linkedin.com/in/tim-van-hauwer-meiren-476a3521/?originalSubdomain=be>

<sup>25</sup>Tim Van Hauwermeiren, Chief Executive Officer at argenx SE, LinkedIn Profile <https://www.linkedin.com/in/tim-van-hauwer-meiren-476a3521/?originalSubdomain=be>

<sup>26</sup>Argenx Case study: ARGX-115 <https://www.argenx.com/case-studies/argx-115>





Apart from its success in coming up with innovative treatment of rare autoimmune disorders, the company has also made progress in treating cancer. It has therefore cooperated with academics, for example from the University of Leuven. The company notes that "it has (...) been clearly demonstrated that the immune system can recognize cancer cells as abnormal and can initiate a process to eliminate them. Simplified, this is the remarkable role the immune system can play in surveillance." Together with Argenx, academics have developed remedies that have the potential to reactivate the immune system to eliminate cancer cells.<sup>26</sup>

With the extra billion USD Argenx has received from investors, it is able to focus even more on innovation and delivering progress on treatment for all the diseases<sup>27</sup> it has targeted. At the end of March, the company was able to showcase a massive revenue growth of 629.86% over the

last year.<sup>28</sup> Apart from the success in July, more developments are upcoming. Later this year, new results on the performances of the company's remedies against blood disease ITP and the skin disease pemphigus will be announced<sup>29</sup>

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<sup>27</sup>Argenx Deep Antibody Pipeline of Differentiated Candidates 2023 [https://www.argenx.com/sites/default/files/media-documents/argenx\\_Pipeline\\_PDF\\_20230206.pdf](https://www.argenx.com/sites/default/files/media-documents/argenx_Pipeline_PDF_20230206.pdf).

<sup>28</sup>Argenx SE Revenue 2017-2023 ARGX, Macrotrends <https://www.macrotrends.net/stocks/charts/ARGX/argenx-se/revenue>.

<sup>29</sup>Argenx-CEO: 'Niet denken dat alles vanzelf zal gaan', De Tijd, 2 March 2023 <https://www.tijd.be/ondernemen/farma-biotech/argenx-ceo-niet-denken-dat-alles-vanzelf-zal-gaan/10450964.html>.

# THE IMPORTANCE OF IP IN THE RISE OF ARGENX

## PATENTS

CEO Tim Van Hauwermeiren has stressed how key innovation is for Argenx, saying: "Takeovers and deals are peculiar to the industry. Key drugs are seeing their patents expire, and companies need to find new revenue streams to survive. That is the business model of many big companies, because they do not innovate enough themselves. If we stop innovating, we will become like many others. That's why we keep investing."<sup>30</sup>

Already in 2016, Argenx stressed how "the company's main assets are intellectual property rights concerning technologies that have not led to the commercialization of any product."<sup>31</sup> Throughout its reporting, the company has repeated this regularly. Given the extremely long time span of 15 years in the life sciences industry, innovation and being able to rely on legal protection of innovation is perhaps more important there than in any other industry.

An example of the importance of IP protection for Argenx is the trademarking of the compa-

ny's proprietary SIMPLE Antibody platform.<sup>32</sup> This, according to Argenx in 2016, has "led to the discovery of ARGX115, the first antibody to show inhibitory activity on the immunosuppressive function of human Tregs. The IAP collaboration brings in the know-how of Argenx to validate the GARP protein as a target for cancer immunotherapy."<sup>33</sup>

For this discovery platform, Argenx owns a patent family containing six issued U.S. patents. These U.S. patents are expected to expire in 2029 to 2033. This patent family also contains patents that have been granted in Australia, Canada, Europe, the United Kingdom, Israel, India and Japan, and pending applications in China and Japan.

Typical assets used by Argenx that are only potentially profitable over time are its valuable data. In its cooperation with the AbbVie option deal, for example, a key part of the value provided by Argenx was delivering data.<sup>34</sup>

Apart from innovating itself, Argenx has throughout the years also bought IP rights from other

<sup>30</sup>Argenx-CEO Tim Van Hauwermeiren: 'We hebben het ondenkbare gedaan', De Tijd, 31 December 2022 <https://www.tijd.be/ondernemen/farma-biotech/argenx-ceo-tim-van-hauwermeiren-we-hebben-het-ondenkbare-gedaan/10437858.html>

<sup>31</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf)

<sup>32</sup>ARGEN-X SIMPLE ANTIBODY™ PLATFORM SET TO TRANSFORM THERAPEUTIC ANTIBODY DISCOVERY & DEVELOPMENT, Argenx press release, 8 March 2010 [https://forbion.com/server/multimediaserve/513/100315\\_argen-x\\_simple\\_antibody\\_platform\\_set\\_to\\_transform\\_therapeutic\\_antibody.pdf?hash=a02481e01b563f39bcaf8d4af5adb5a7f8044ea4e11cb660890258dca53ad901](https://forbion.com/server/multimediaserve/513/100315_argen-x_simple_antibody_platform_set_to_transform_therapeutic_antibody.pdf?hash=a02481e01b563f39bcaf8d4af5adb5a7f8044ea4e11cb660890258dca53ad901)

<sup>33</sup>"Creating value from highly differentiated antibody therapeutics", Argenx, 19 November 2016 <https://static.tijd.be/financeavenue/2016/Presentations/FR/argenx.pdf>

<sup>34</sup>"Creating value from highly differentiated antibody therapeutics", Argenx, 19 November 2016 <https://static.tijd.be/financeavenue/2016/Presentations/FR/argenx.pdf>



innovators, entering into license agreements under which the company licenses patents, patent applications and other intellectual property from third parties, just as it also licenses its own patents, patent applications and other intellectual property to those third parties.<sup>35</sup>

Several examples include: (1) April 2021, Argenx entered into a collaboration and license agreement with Elektrofi; (2) September 2020, it entered into a non-exclusive research license and option agreement with Chugai Pharmaceutical Co., Ltd.; and (3) October 2020, it entered into a non-exclusive research agreement with the Clayton Foundation.<sup>36</sup>

In addition to patent protection, Argenx also relies on trademarks and trade secrets to protect aspects of its business that are not amenable to, or that it does not consider appropriate for, patent protection. In 2021, it noted this includes "certain aspects of our llama immunization and antibody affinity maturation approaches".<sup>37</sup>

## LLAMAS

In this respect, it is important to know that llamas have been the new gold in biotech since some academics from the Free University of Brussels discovered in the late 1980s that camelids have powerful antibodies suitable for all kinds of therapeutic applications, from autoimmune diseases to cancer.<sup>38</sup> For Argenx in particular, llamas have been key, as the company is

developing potential therapeutic antibodies derived from these animals. As CEO Tim Van Hauwermeiren explained in 2021<sup>39</sup>, they have two special properties. First of all, they are small and, secondly, unlike other animals, their antibodies are almost identical to human antibodies, so they are not rejected by the body.

Van Hauwermeiren specified: "Antibodies can be 'trained' against diseases, so to speak, by making small changes. As a result, you can greatly improve their properties. This potential was the starting point for me, Hans De Haard and Torsten Dreier to establish Argenx in 2008. However, Vyvgart, [the leading medicine invented by Argenx] is an exception, and no longer has a link to llamas. The antibody fragment was developed in a unique way, though, so it could be used to knock down autoantibodies."

Importantly, Van Hauwermeiren thereby recalled that this molecule which has been developed by his company "has the potential to be used for numerous autoimmune diseases. This is also the reason for the company's current stock market value." In sum, if anyone would now be allowed to reproduce this molecule – to the extent that would be possible – there would not have been an incentive for Argenx to develop its life saving innovation.

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<sup>35</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>36</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>37</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>38</sup>"Tim Van Hauwermeiren, een 'Lucky Luke' van 14 miljard", De Tijd, 6 February 2021 <https://www.tijd.be/ondernemen/farma-biotech/tim-van-hauwermeiren-een-lucky-luke-van-14-miljard/10282506.html>.

<sup>39</sup>"We schrijven pas geschiedenis als de verkoopcijfers goed zijn", De Standaard, 24 December 2021 [https://www.standaard.be/cnt/dmf20211223\\_98013867](https://www.standaard.be/cnt/dmf20211223_98013867).

## LEGAL PROTECTION, COURT CASES AND LICENSING

It should be recalled that Argenx is a home-grown major European biopharma company and that it is rare to witness such companies survive in Europe. Not long ago, the company was still only a small start-up with just one thing: strong IP assets. There was hardly another reason for investors to stick with the company, given how central this was to its activity.

Argenx has stressed: "Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others."<sup>40</sup>

Thereby, the company has also highlighted how "issued patents could be found invalid or unenforceable if challenged in court." Also, there is the risk that despite efforts made by its licensors' or collaboration partners' efforts, it may not be possible to prevent third parties from infringing upon or misappropriating intellectual property rights it owns or controls, "particularly in countries where the laws may not protect those rights as fully as in the European Union and the U.S." Argenx adds that then, "we may fail in enforcing our rights, in which case our competitors

may be permitted to use our technology without being required to pay us any license fees and/or royalties."<sup>41</sup>

Furthermore, the company has described the great investment of time and energy its staff devotes to protecting its IP assets and how this undermines normal responsibilities, especially in the case of litigation:

"Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities.

"In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this may negatively impact us.

"Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litiga-

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<sup>40</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>41</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

<sup>42</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).





tion or other proceedings could have a material adverse effect on our ability to compete in the marketplace.”<sup>42</sup>

CEO Tim Van Hauwermeiren has furthermore pointed out how weaknesses in IP protection contributed to the very high price of the successful medicine produced by his company. When asked why his medicine “Vyvgart”, the commercial name of efgartigimod, cost 225,000 USD for one year of treatment, he explained: “You need to put that in perspective. In the past, the pharmaceutical industry did not develop drugs for so-called rare diseases, diseases from which only a very small group of people suffer but which have very serious consequences for them. To remedy that, the following arrangement was made between the pharma and biotech industry and society: develop innovative drugs for those rare diseases, and in return, we offer a fee which allows you to recover the high costs of research and clinical development. The development of efgartigimod involves as much as 1 billion euro. Moreover, the patent is only valid until the middle of the next decade, from then on you can counterfeit it for free and we won’t earn from it.

“So I think that 225,000 USD is a fair price for the 160,000 patients suffering from the disease in the U.S., Europe and Japan. Especially if you also take into account the huge gain in quality of life for the patients. These now have the prospect of a normal life again: being able to walk, go to school or work again. The patients don’t just receive an infusion of the drug either. There is also a whole follow-up provided by us.”<sup>43</sup>

At the beginning of last year, Argenx disclosed that its patent portfolio (which includes both proprietary and in-licensed patent families) comprises approximately 300 granted patents and approximately 308 pending patent applications, including approximately 35 issued U.S. patents, approximately 15 granted European patents and approximately 250 issued patents in other jurisdictions.<sup>44</sup>

In sum, a lot of the efforts of Argenx to develop life-saving remedies are devoted to legally protecting and legally enabling the cooperation to foster its innovations. Intellectual property protection is therefore truly at the heart of the company’s activity.

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<sup>43</sup>“We schrijven pas geschiedenis als de verkoopcijfers goed zijn”, De Standaard, 24 December 2021 [https://www.standaard.be/cnt/dmf20211223\\_98013867](https://www.standaard.be/cnt/dmf20211223_98013867)

<sup>44</sup>Argenx Annual Report 2021 [https://www.argenx.com/sites/default/files/report/argenx\\_report\\_march\\_21\\_2021.pdf](https://www.argenx.com/sites/default/files/report/argenx_report_march_21_2021.pdf).

# INTELLECTUAL PROPERTY PROTECTION IN EUROPE UNDER THREAT

## THE INTERNATIONAL PROPERTY RIGHTS INDEX

Most of the investment in today's innovation in biotech is not happening in Europe. According to *Nature*, "biotechnology companies based in the USA received more than five times the volume of total financing than companies based in Europe in 2021".<sup>45</sup> Clearly, the lack of deep financial markets are a challenge for Europe way behind the biotech sector. Non-economic, cultural aspects also play a role in this, but looking at the degree of intellectual property protection in Europe sheds some more light on this.

Instrumental in this regard is the International Property Rights Index (IPRI), which ranks the strength of both physical and intellectual property rights as well as the legal and political environments that contain them. It has been developed by the Property Rights Alliance in partnership with 128 think tanks in 74 countries to emphasize that property rights are the building blocks for a just, prosperous, and free society.

One of its components is the intellectual prop-

erty rights (IPR) category, apart from Legal and Political Environment (LP) and Physical Property Rights (PPR).<sup>46</sup> Notably, the IPRI correlated 0.899 remarkably with the Notre Dame Global Adaptation Index, highlighting the relevance of property rights systems for fostering social flexibility, enhancing readiness and lowering risks for global challenges.<sup>47</sup>

Western Europe is where most of Europe's biotech activity is based. McKinsey notes that France, Germany, and the United Kingdom (home to the largest biotech hub) stand out as the top three biotech centers in Europe, and together account for half of all European biotechs. It adds that France, Switzerland, and the United Kingdom have seen the fastest growth, accounting for 63 percent of the biotechs founded between 2018 and 2020.<sup>48</sup>

When looking at the metric "Intellectual Property Rights Protection" of the International Property Rights Index, a whopping 17 out of the 19 Western European economies surveyed had weaker intellectual property rights protection in 2022 as compared to 2021. Only in Finland and

<sup>45</sup> Jing Gong, Jean-Loup Romet-Lemonne & Brandy Houser, "Bridging the gap between innovation and later-stage financing for biotech in Europe", *Nature*, 1 June 2023 <https://www.nature.com/articles/d41573-023-00074-0>.

<sup>46</sup> International Property Rights Index (Property Rights Alliance) <https://www.internationalpropertyrightsindex.org/> <https://twitter.com/Euristic3000/status/1482397313322598414>.

<sup>47</sup> International Property Rights Index (Property Rights Alliance) <https://www.internationalpropertyrightsindex.org/>.

<sup>48</sup> "Biotech hot spots in a fragmented European landscape", McKinsey & Company, July 29, 2021 <https://www.mckinsey.com/industries/life-sciences/our-insights/infographic-biotech-hot-spots-in-a-fragmented-european-landscape?cid=soc-web>.



Germany, this improved. Things are not only bad in the EU. Also in non-EU member states, like the UK, Switzerland and Norway, protection weakened. Despite weakening IP protection, the United States offers stronger IP protection here than the brunt of its European counterparts, as only 8 European jurisdictions are ahead of the U.S.<sup>49</sup>

Weakening IP protection is quite a worrying sign, especially given the importance IP rights have played in developing life-saving vaccines during the Covid crisis, and the increasing importance of innovation in today's globalized economy.

The author of the study, Dr. Sary Levy-Carciente, considers a robust IP framework to include "knowledge-sharing, engaging in technology, licensing arrangements, demand for better contracts, clearly defining IP rights, promoting a common ecosystem, and sharing efforts and rewards."<sup>50</sup>

As discussed hereabove, these are precisely the kinds of activities Argenx is devoting itself to on a daily basis.

## CHANGING EUROPEAN UNION POLICIES

In recent years, the attitude of the European Union towards intellectual property rights protection has not evolved in a positive way.

In 2022, the European Commission for example announced to support overriding intellectual property (IP) protections for COVID-19 vaccines. This was criticized by the Life Sciences Acceleration Alliance (LSSA) e.V., a coalition of life science venture capital organizations focused on raising awareness of the critical role venture capital plays in the development of new therapies, medicines, devices, and technology, which stated the following:

"We are disappointed that after standing strong for innovation for so long, the European Commission has now changed their stance to support progressing conversations that will result in the abrogation of patent protections of COVID-19 technologies—an action that will simply do nothing to address the problem at hand. (...) As previously noted by life science investors, philanthropists, academics, policy-makers, stripping IP protections will not provide a solution in any way to this substantial issue. Instead, it suggests that decades of European commitment to innovation, which is the reason why the EU played such an integral role in the development of COVID-19 vaccines and therapeutics, cannot be relied upon."

The Alliance thereby highlighted the geostrategic dangers of the European Commission's stance, as well as the grave consequences for innovation, ultimately at the detriment of patients:

"There will be future crises, and it is our hope that the EU will lead the world in responding to them. However, the current path the EU is on will permit Russia and China to absorb European scientific prowess, only to the detriment of the citizens of the world."<sup>51</sup>

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<sup>49</sup>International Property Rights Index (Property Rights Alliance) <https://www.internationalpropertyrightsindex.org/>.

<sup>50</sup>"PRA Releases 2022 International Property Rights Index, Property Rights Alliance", 7 September 2022 <https://www.propertyrightsalliance.org/news/prareleases-2022-international-property-rights-index/>

<sup>51</sup>"LSAA raises concern about the European Commission's support of TRIPS waiver", Life Sciences Acceleration Alliance, 2 June 2022 <https://www.linkedin.com/pulse/ljaa-raises-concern-european-commissions-/>

"Finally, and perhaps most tragically, weakening IP protections in the face of 'extraordinary circumstances' sends two signals to the thousands of Europeans committed to the next generation of drugs. First, it says that IP and the rule of law is not universally guaranteed. Second, it disincentivizes the development of treatments, vaccines, and cures for the diseases prevalent in the developing world. Investors will resist efforts to develop innovations we are so close to having, like vaccines for HIV and malaria, and effective treatments for the grave threat of antimicrobial resistance (AMR). These are not crises within our own borders, but humanitarian challenges around the world."<sup>51</sup>

Furthermore, the European Commission has also come out against firm intellectual property rights protection as part of its proposed major overhaul of the European Union's 20-year-old pharmaceutical strategy. This reform includes rules for products that treat unmet medical needs, as well as measures to protect regulatory data and streamline administrative processes. It also aims to provide incentives to address antimicrobial resistance and to secure the EU's drug supply.<sup>52</sup>

Also here, the Life Sciences Acceleration Alliance (LSSA) e.V., issued a scathing judgement, lamenting that with regard to orphan drugs, the Commission's draft text aims to reduce the

period of market exclusivity from 10 to 5 years. It noted about this that "while the objective is to accelerate patient access to treatments, the end result could be quite different, as happened in the United States following the enactment of the Inflation Reduction Act, which reduced the market exclusivity of small molecules that are new chemical entities from 14 to 9 years. German MEPs and the Danish government have already alerted the Commission to the risks that these measures represent for therapeutic innovation in Europe and access to treatment for European patients."<sup>53</sup>

Furthermore, LSSA pointed out three negative consequences of the EU Commission's proposal:

"While the draft European regulation aims to accelerate the development and availability of orphan drugs to rare disease patients, the effects of reducing the exclusivity period could be counterproductive and present several risks:

- » A slowdown in innovation and the loss of Europe's leading position in orphan drugs.
- » Deterioration in access to new therapeutic solutions for patients.
- » Acceleration of the brain drain to Asia and the United States."<sup>54</sup>

<sup>51</sup>"LSAA raises concern about the European Commission's support of TRIPS waiver", Life Sciences Acceleration Alliance, 2 June 2022 <https://www.linkedin.com/pulse/lssa-raises-concern-european-commissions-/>.

<sup>52</sup>"Sofinnova and LSAA joint letter on the draft reform of the European Union's pharmaceutical strategy and orphan drugs", April 2023 <https://www.acceleratelifescience.org/resources> [https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG\\_Sofinnova\\_LSAA\\_Note\\_.pdf](https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG_Sofinnova_LSAA_Note_.pdf).

<sup>53</sup>"Sofinnova and LSAA joint letter on the draft reform of the European Union's pharmaceutical strategy and orphan drugs", April 2023 <https://www.acceleratelifescience.org/resources> [https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG\\_Sofinnova\\_LSAA\\_Note\\_.pdf](https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG_Sofinnova_LSAA_Note_.pdf).

<sup>54</sup>"Sofinnova and LSAA joint letter on the draft reform of the European Union's pharmaceutical strategy and orphan drugs", April 2023 <https://www.acceleratelifescience.org/resources> [https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG\\_Sofinnova\\_LSAA\\_Note\\_.pdf](https://static1.squarespace.com/static/60f1b323d27a3027d5f158e5/t/64555e74acdb172a5f049956/1683316340892/ENG_Sofinnova_LSAA_Note_.pdf).



## CONCLUSION

Argenx can serve as a true case story for the importance of IP protection for the growth of Europe's biotech sector and for innovation in Europe in general. This despite the fact that it is based in Europe, where companies have been struggling to scale, and despite the presence of a large domestic consumer market in Europe.

When looking at the activities of Argenx, it is evident how important the legal side of its activities is. Without IP protection, its life-saving innovations will not be protected and cooperation with partners is unlikely to materialize.

The International Property Rights Index demonstrates how IP protection in Europe is under threat, when looking at statistics. The European Commission's policy response to the questions on IP protection for Covid vaccines and on future patent protection for orphan drugs to rare disease patients is testimony of how also in practice, support for offering solid legal protection for innovation is no longer guaranteed even at the EU policy level, unlike what was the case previously.

Ultimately, those patients hoping for companies like Argenx to come up with solutions for rare autoimmune diseases are the victims of this.







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