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Lausanne, 30<sup>th</sup> January 2019

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## **Request for a compulsory licence on patents related to breast cancer medicine pertuzumab sold by Roche under the brand name Perjeta**

Dear Federal Councillor,

Public Eye hereby requests the Federal Council to enact a public non-commercial use (compulsory) licence on patents related to the breast cancer medicine pertuzumab sold by Roche under the brand name Perjeta. By virtue of Articles 40 and 40e of the Federal Act on Patents for Inventions (PatA) the Federal Council is empowered to exercise its right to any patent without prior authorisation of the patent holder when the public interest is at stake.

According to Article 26 of the Federal Act on the Federal Patent Court (PatCA), the latter has exclusive jurisdiction over actions for issuing licences in respect of patents. In order to help streamline such an unprecedented process in Switzerland, we have prepared for you a detailed model request to the Federal Patent Court (see attached), which the Federal Council can use in its entirety as a template. This document outlines the context and the arguments justifying the grant of a government-use licence to restore the balance between public and private interests in Switzerland.

The model request also entails a legal opinion written by pharmaceutical and anti-trust law expert Prof. Valérie Junod, which should remove all possible outstanding concerns regarding the applicability of a compulsory licence procedure in Switzerland. A public authority such as the Federal Council is entitled under Article 40 PatA to ask for a compulsory licence in the public interest on whatever grounds, including for public non-commercial purposes, and the holder of such a licence has various means to overcome data exclusivity for the subsequent registration of biosimilar products in Switzerland.

Approximately 1,200 new people are affected each year in our country by HER-2 positive breast cancer. They rely on the standard treatment that consists of a combination of pertuzumab (brand name Perjeta), trastuzumab (brand name Herceptin) and docetaxel (generic). An annual treatment with this combination therapy comes with a net public price tag of CHF 101,640 per patient.

As the owner of three out of the four medicines approved in Switzerland for the treatment of HER2-positive breast cancer, Roche occupies a dominant position in this market segment. This monopoly power has allowed Roche to obtain and maintain an excessive price, in particular for Perjeta, as witnessed by its turbulent regulatory history in Switzerland.

**Perjeta's excessive pricing undermines the Federal Council's constitutional mandate to ensure that the entire Swiss population benefits from affordable access to lifesaving treatments in a sustainable manner – and thus acts against the public interest.** At a time when the population is struggling to cope with already high insurance premiums and co-payment mechanisms, with some even foregoing treatments for financial reasons, further increases in out-of-pocket payments by the patients themselves, or rationing as in the recent case of new Hepatitis C treatments, would only cement a two-tiered system of access to medicines in Switzerland.

The Federal Council has just proposed a number of new cost-containment measures regarding the Swiss health system that are certainly useful for its financial viability. Unfortunately, none of them will have a significant impact on the inflationary trend of patent-protected medicines, which in 2017 accounted for three-quarters (74%, or over CHF 5 billion) of the total expenditure on medicines reimbursed by the mandatory health insurance scheme. Compulsory licensing would allow targeted and effective action on overpriced patented medicines, starting with those for which excessive pricing has been demonstrated.

As the Health Minister, you have a significant opportunity to demonstrate decisive leadership by advocating within the governmental college for a public non-commercial use (compulsory) licence in Switzerland on Perjeta. Such a decision would place the interests of the patients above the profits of pharmaceutical companies, and would in turn send a strong signal to the whole branch to adopt more reasonable pricing policies. Even a public commitment to explore a compulsory licence could tip the power balance in present and future negotiations on highly priced cancer drugs.

Consistent with national and international law, enacting a compulsory licence in Switzerland is not a legal issue, but ultimately a matter of political will.

We appreciate your consideration of this request and look forward to hearing from you.

Yours sincerely,



Patrick Durisch  
Health Policy Expert



Christa Luginbühl  
Joint Managing Director

Attachment: model request for a compulsory licence on patents related to breast cancer medicine pertuzumab sold by Roche under the brand name Perjeta

The Federal Patent Court  
P.O. Box  
CH – 9023 St. Gallen

Berne, dd/mm/2019

## REQUEST FOR JUDICIAL CONFIRMATION

regarding the grant of

a Public Non-Commercial Use Compulsory License (or government-use licence)  
(art. 40 and art. 40e of the Federal Act on Patents for Inventions)

over

patents held by F. Hoffmann-La Roche AG related to breast cancer medicine pertuzumab  
(brand name: Perjeta®)

Submitted by:  
The Federal Council  
Federal Chancellery  
Federal Palace West Wing  
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Represented by:  
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# Request for judicial confirmation regarding the grant of a public non-commercial use compulsory licence (or government-use licence) Articles 40 and 40e of the Federal Act on Patents for Inventions

## 1 Introduction

The Federal Council is the supreme governing and executive authority of the Swiss Confederation<sup>1</sup>. Its tasks are set out in the Federal Constitution, whose aim includes ensuring the greatest possible equality of opportunity among its citizens<sup>2</sup>.

Among the duties and powers of the Confederation listed in the Federal Constitution are the following:

- Respect and protect human dignity<sup>3</sup>
- Ensure non-discrimination and equality before the law<sup>4</sup>
- Ensure the right to life<sup>5</sup>
- Ensure the right to assistance and care for persons in need and unable to provide for themselves, and to the financial means required for a decent standard of living<sup>6</sup>
- Endeavour to ensure that every person has access to the health care that they require<sup>7</sup>
- Take measures to prevent abuses in price maintenance by dominant undertakings and private and public law organisations<sup>8</sup>
- Take measures against unfair competition<sup>9</sup>
- Take measures to protect consumers<sup>10</sup>
- Ensure the adequate provision of high quality primary medical care that is accessible to all<sup>11</sup>
- Take measures for the protection of health<sup>12</sup>

F. Hoffmann-La Roche AG (thereafter: Roche) is a Company Limited by Shares under the Swiss Code of Obligations (CC-220), and is registered in the Commercial Register.

By virtue of Articles 40 and 40e of the Federal Act on Patents for Inventions (Patents Act or PatA, CC 232.14)<sup>13</sup>, and based on the arguments set forth in the present request, the Federal Council has taken the political decision during its session of ..... 2019 to resort to a non-exclusive compulsory licence of public non-commercial use (or government-use licence) in order to exercise the rights under the patents related to breast cancer medicine pertuzumab (sold under the brand name Perjeta by Roche). The Federal Council hereby requests the Federal Patent Court of Switzerland to confirm the grant of this government-use licence.

<sup>1</sup> Article 174 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>2</sup> Article 2 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>3</sup> Article 7 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>4</sup> Article 8 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>5</sup> Article 10 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>6</sup> Article 12 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>7</sup> Article 41 al. b) of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>8</sup> Article 96 al. 2 let. a) of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>9</sup> Article 96 al. 2 let. b) of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>10</sup> Article 97 al. 1 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>11</sup> Article 117a al. 1 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>12</sup> Article 118 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>13</sup> Federal Act on Patents for Inventions of 25 June 1954 ([PatA, CC 232.14](#))

Pertuzumab was first authorised by Swissmedic on 13 August 2012<sup>14</sup>, and first included in the Swiss List of Specialties (LS)<sup>15</sup> by the Federal Office of Public Health (FOPH) on 1 March 2013<sup>16</sup>.

Pertuzumab is indicated in combination with trastuzumab (brand name Herceptin, also manufactured by Roche) and docetaxel (off-patent, produced by several generic manufacturers) for (1) the treatment of metastatic HER2-positive breast cancer and (2) the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory breast cancer or early-stage breast cancer with a high risk of recurrence for breast cancer at an early stage.

An application for the inclusion of pertuzumab on the World Health Organization Model List of Essential Medicines was submitted by Roche on 7 December 2018<sup>17</sup>. The WHO Model List of Essential Medicines includes medicines that should be available at all times in adequate amounts and in appropriate dosage forms, at a price affordable to communities<sup>18</sup>. The list is updated every two years by a dedicated Expert Committee, which should be discussing all new applications (including pertuzumab) at its next meeting of April 2019<sup>19</sup>.

## 2 Summary

The Federal Council is empowered to resort to compulsory licences according to international and national law, including for public non-commercial purposes (also called ‘government-use licence’). A compulsory licence refers to the practice by a government of authorising itself or a third party (e.g. a generic manufacturer) to use a patented product without the consent of the patent owner in order to safeguard the public interest, e.g. to promote access to medicines for all.

Having analysed the situation in Switzerland with regards to affordable and sustainable access to highly priced medicines, in particular for cancer, the **Federal Council has concluded that a public non-commercial compulsory licence is justified regarding the breast cancer drug pertuzumab (Brand name: Perjeta, manufactured by Roche)**, for the following reasons:

<sup>14</sup> [Swissmedic Journal 08/2012](#) (official publication of Swissmedic), pp 774-775. The authorisation was extended in 2017 for an additional five years, i.e. until 12.08.2022 – see [Swissmedic Journal 01/2017](#), p. 49. The extension for the neoadjuvant indication has not been published in the official Swissmedic Journal, but was mentioned for the first time in the [OFSP Bulletin 20/2018](#) of 14 May 2018, p. 12.

<sup>15</sup> In Switzerland, the mandatory health insurance system (or basic health package) only reimburses medicines that are registered on the List of Specialties (LS) and prescribed for authorised indications. The LS is established by the Federal Office of Public Health (FOPH). To be included in the LS, a medicine must be authorised by Swissmedic and must meet legal criteria, such as efficacy, adequacy and economic efficiency (EAE evaluation). Those conditions must be analysed by the FOPH for reimbursement and be reviewed every three years. In general, the FOPH decides to admit a medicine on the LS at the request of the holder of the market approval and after consultation with the Federal Commission of Medicines (FCM), which is composed of different interest groups – i.e. industry, insurers, patients, doctors, hospitals, pharmacists, federal and cantonal authorities. Inclusion in the LS is thus an important step as it sets the conditions and level of reimbursement for the product under the mandatory health insurance system. Reimbursement for a medicine on the LS is guaranteed, assuming all conditions spelt out in the so-called “limitatio” are met. Reimbursements for medicines not on the LS are considered under a separate legislative framework and are the sole decision of each health insurer. Therefore, the decision whether to include a drug in the LS has major implications for access to medicines in Switzerland (Excerpt from Public Eye, [Protect patients not patents: How medicine prices are leading to two-tiered healthcare in Switzerland](#), May 2018, Box 4.1 p. 20)

<sup>16</sup> [OFSP Bulletin 33/14](#) of 11 August 2014, p. 547, mentioning the first date of admission of pertuzumab on the LS (the OFSP Bulletins of 2013 are not available online anymore).

<sup>17</sup> World Health Organization (WHO) website, [page “Pertuzumab EML”](#).

<sup>18</sup> Union for International Cancer Control (UICC) website, [page “WHO Essential Medicines List”](#)

<sup>19</sup> World Health Organization (WHO) website, [page “22nd Expert Committee on the Selection and Use of Essential Medicines”](#)

- Roche owns three out of the four medicines approved in Switzerland for the treatment of HER2-positive breast cancer and occupies a dominant position in this market segment. **This dominant position allows Roche to charge an excessive public price for Perjeta (CHF 60,000 per patient per year).**
- Perjeta is not used alone but in combination with another expensive medicine, also owned by Roche (Herceptin), as well as an additional chemotherapy (docetaxel, generic). This brings the total cost of a yearly treatment to over CHF 100,000 (public price), with Perjeta and Herceptin accounting for 90% of these total costs (Perjeta alone: 54%). **Such excessive price levels undermine the Federal Council's constitutional mandate to guarantee universal access to healthcare in the long term to the whole Swiss population – and thus act against the public interest.**
- Roche, profiting from its monopoly position, has exerted intense pressure on the Federal Office of Public Health (FOPH) to obtain and maintain an excessive price for Perjeta, as **exemplified by Roche's decision to withdraw Perjeta from the List of Specialties (LS) from August 2014 to July 2015 in reaction to an FOPH request to reduce the price.** Not only did Roche's decision create uncertainty (each patient had to negotiate first with their insurance company to secure the reimbursement), but the **intimidation tactic resulted in a net price increase of 30% when Perjeta was reincluded in the LS (+CHF 670 per vial).** The FOPH had no real choice but to agree, given that its primary objective is to safeguard the availability and accessibility of Perjeta for all breast cancer patients in Switzerland who need it.
- In summary, the price charged by Roche for Perjeta is excessive because:
  - ⇒ Roche's exact profit margin on Perjeta is unknown, but is likely to be over 30%. **Such a profit margin is abusive when considering that Perjeta has to be taken in combination with Herceptin,** a blockbuster drug that enjoyed almost 20 years of monopoly and cumulative global sales of some CHF 90 billion. **This should have led to a more reasonable profit margin on Perjeta, a follow-on product of Herceptin.** Despite the expiry of the Herceptin patents, its price has not dropped significantly in Switzerland as there is still no competitor (trastuzumab bio-similar) in the Swiss market (contrary to the EU).
  - ⇒ EU case law holds that the difference between costs and price should help determine whether the price is higher than it should be ('excessive'). However, the FOPH has no access to all or parts of the R&D costs when setting the price of a medicine listed in the LS, leaving this process dependent on the bargaining power of each party. In the case of Perjeta, Roche clearly held the upper hand because of its monopoly position. **The price of Perjeta is not based on concrete Research & Development (R&D) costs.**
  - ⇒ **The current pricing of Perjeta does not adequately reflect public R&D investments.** Evidence shows that public funding and tax-funded research efforts have significantly contributed to the development of both Herceptin and Perjeta. **These public investments were not adequately considered in setting the initial public price of Perjeta in Switzerland.**

**Perjeta's excessive pricing is undermining the Federal Council's constitutional mandate to ensure that the entire Swiss population continues to benefit from affordable access to lifesaving treatments in a sustainable manner.** This universal coverage is only possible if the mandatory health insurance scheme is sustained, and the insurance premiums paid by the Swiss population continue to be affordable. **More restrictions on reimbursements, or rationing, would further cement a two-tiered system of access to medicines in Switzerland.**

Switzerland is not immune to rationing decisions in response to high prices, as witnessed between 2014 and 2017 following the entry onto the Swiss market of highly expensive antivirals for the treatment of Hepatitis C. It is possible that **even more expensive cancer treatments, such as the Perjeta combination therapy, will also have to be rationed.** FOPH experts have already warned that they

are dealing more often with situations in which medicines have to be listed in the LS in a targeted or staggered manner because of their very high prices.

The mandatory health insurance system already spends well over 20% of its budget on pharmaceuticals (almost 1 for each CHF 4 spent in 2017). Medicines are thus a major driver of the ever-increasing expenses of mandatory health insurance in Switzerland, in particular immunosuppressant and oncology drugs, whose share is constantly rising. The several new cost containment measures proposed by the Federal Council will have no effect on the high prices of patented medicines, which accounted in 2017 for 74% of all medicines reimbursed by the mandatory health insurance – or over CHF 5 billion. **For patented medicines, other measures such as compulsory licences will be needed as long as private interests prevail and unjustified, excessive prices are being demanded – or even imposed, due to the pricing power linked with monopolies.**

If CHF 100,000 per year were charged for all the 40,000 new cancer cases diagnosed annually in Switzerland, the total cost would be CHF 4 billion, for cancer patients alone. This represents 58% percent of the total pharmaceutical spending for all types of diseases by the mandatory health insurance system for 2017. The FOPH could never apply a price equivalent to Perjeta's to all other cancer medicines without jeopardising universal coverage of treatments for all types of pathologies (through rationing or inadequately serving certain disease areas or patient groups), or without drastically increasing insurance costs for patients (through premiums or co-payments). **The excessive price of Perjeta is unsustainable for the mandatory health insurance scheme and thus acts against the public interest.**

An independent legal analysis annexed to this request (appendix 2) confirms that data exclusivity does not represent an insurmountable obstacle for the registration of pertuzumab biosimilars following a compulsory licence granted in the public interest as various means exist to overcome it. Interpharma also states that data exclusivity should not constitute an obstacle to a compulsory licence issued for a legitimate public interest.

### **Conclusion:**

Considering the context of escalating health costs largely due to overpriced, newly approved medicines – in particular cancer drugs – and the increasing risk of rationing,

Considering that such excessive pricing places a disproportionate burden on the Swiss health insurance system, on HER2-positive breast cancer patients, and on the society as a whole,

Considering that it is of the utmost importance to restore the original objective of the patent system, which is to balance public and private interests,

The Federal Council has concluded in its session of .... 2019, based on the arguments laid out in the present document, that:

- 1) Because of its dominant position, Roche is charging an excessive price for Perjeta;
- 2) Such excessive pricing is financially unsustainable and acts against the public interest;
- 3) Therefore, a government-use licence to exercise the rights on the patents related to breast cancer medicine Perjeta® is justified under Articles 40 and 40e PatA.

**The Federal Council hereby requests the Federal Patent Court, as the competent authority having exclusive jurisdiction over actions for issuing a licence in respect of patents<sup>20</sup>, to confirm the grant of a public non-commercial use compulsory licence (government-use licence) in Switzerland for patents related to breast cancer medicine pertuzumab (sold under the brand name Perjeta® by Roche) according to the terms set forth in this document.**

<sup>20</sup> Federal Act on the Federal Patent Court of 20 March 2009 ([PatCA, CC 173.41](#))



### 3 Compulsory licensing under the Federal Patent Act (PatA)

#### 3.1 Applicable Law

The Paris Convention for the Protection of Industrial Property (1883), one of the first intellectual property treaties which is now administered by the World Intellectual Property Organisation (WIPO), included 'compulsory licensing' in its 1925 amendment (The Hague Act).

In the current text of the Paris Convention (1967), ratified by Switzerland in 1970, Article 5A(2) reads as follows<sup>21</sup>:

Article 5A Patents: *Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses*

[...]

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

[...]

The Paris Convention does not define precisely the term 'abuse of exclusive rights conferred by the patent', and neither limits licences as a result of abuses nor provides an exhaustive list of what constitutes an abuse, but explicitly cites 'excessive pricing' as one example of such abuse<sup>22</sup>. The Organisation for Economic Cooperation and Development (OECD) also cites on its website 'excessive pricing' among examples of the abuse of dominance and monopolisation<sup>23</sup>.

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS), which came into force in 1995<sup>24</sup>, mentions in article 2 al. 1 that "[WTO] *Members shall comply with Articles 1 through 12, and article 19 of the Paris Convention (1967)*". Since it introduces additional obligations in areas that were not addressed in earlier conventions, TRIPS is sometimes described as a 'Berne and Paris-plus' Agreement<sup>25</sup>.

The term 'non-voluntary' or 'compulsory' licensing refers to the practice by a government of authorising itself or third parties to use the subject matter of a patent without the authorisation of the patent holder for reasons of public policy. In these cases, the public interest of broader access to the invention is considered more important than the private interest of the right holder to fully exploit their exclusive rights<sup>26</sup>.

Article 8 TRIPS justifies a nation's use of the 'TRIPS flexibilities' to protect public health:

<sup>21</sup> World Intellectual Property Organization (WIPO), [Paris Convention for the Protection of Industrial Property](#), online version (accessed 7.1.2019)

<sup>22</sup> G. H. C. Bodenhausen, [Guide to the Application of the Paris Convention for The Protection of Industrial Property as Revised at Stockholm in 1967](#), United International Bureaux for the Protection of Intellectual Property (BIRPI), 1969, p. 71

<sup>23</sup> Organisation for Economic Cooperation and Development (OECD) website, page '[Abuse of dominance and monopolisation](#)' (accessed 9.1.2019)

<sup>24</sup> World Trade Organization, [Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex IC](#), 1994

<sup>25</sup> World Trade Organization's website, page '[Frequently-Asked Questions about TRIPS in the WTO](#)' (accessed 9.1.2019)

<sup>26</sup> J. Reichmann & C. Hasenzahl, [Non-Voluntary Licensing of Patented Inventions. UNCTAD-ICTSD Project on IPRs and Sustainable Development](#), Issue Paper No. 5, June 2003

## Article 8 Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The 2001 Doha Declaration on the TRIPS Agreement and Public Health – which, according to a recent report issued by a WTO Dispute Panel, is not merely a political statement but constitutes a subsequent “agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement” that “applies broadly to health issues”<sup>27</sup> – has clarified and reaffirmed the rights of all WTO members to grant compulsory licences and the freedom of each State to determine the grounds upon which such licences are granted<sup>28</sup>.

Switzerland adheres to both of these agreements and has transposed all the concerned provisions related to compulsory licensing into its own legislation. The PatA therefore accurately reflects the current rule of international law, and the legal interpretations of TRIPS and the Doha Declaration related to compulsory licensing therefore also apply to PatA and the Swiss context.

The Swiss Federal Patent Act (PatA) contains several provisions related to compulsory licensing that accurately reflect those of TRIPS, in particular those of Article 31 detailing the procedural requirements that must be satisfied for a TRIPS-compliant compulsory licence<sup>29</sup>.

Article 40 PatA addresses the general need to protect the public interest through compulsory licensing, and is applicable here. Moreover, Article 40e PatA, which acts as a common provision for all types of compulsory licences, and which transposes the TRIPS provision for licences for public non-commercial use (government-use licence) into national law, is also applicable.

Other provisions (Art. 36-38, 40a-40d PatA) that apply only in particular cases are not relevant for this judicial review.

Article 40 PatA provides:

### Art. 40 D. Licence in the interest of the public

- <sup>1</sup> Where public interest so dictates, the person to whom the proprietor of the patent has, without sufficient reason, refused to grant the license requested, may apply to the court for the grant of a license to use the invention.

<sup>27</sup> World Trade Organization, [Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging – Report of the Panels](#), WT/DS435/R ; WT/DS441/R ; WT/DS458/R ; WT/DS467/R, 28 June 2018 – see in particular paragraphs 7.2407 to 7.2411 (pp. 726-727)

<sup>28</sup> World Trade Organization, [Declaration on the TRIPS agreement and Public Health](#), Doha WTO Ministerial 2001, WT/MIN(01)/DEC/2, 20 November 2001

<sup>29</sup> Article 31 is entitled ‘Other Use Without Authorization of the Right Holder’, under Section 5 dedicated to patents

According to Article 40e PatA:

Art. 40 e I. Common provisions for Articles 36-40d

<sup>1</sup> The licenses provided for in Articles 36-40d are granted only if efforts by the applicant to obtain a contractual license on appropriate market terms within a reasonable period of time have been unsuccessful; in the case of a license in accordance with Article 40d, a period of 30 working days is regarded as reasonable. Such efforts are not required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

<sup>2</sup> The scope and term of the license are limited to the purpose for which it has been granted.

<sup>3</sup> The license may only be transferred with that part of the enterprise which uses the license. This also applies to sub-licenses

<sup>4</sup> The license is primarily granted for supplying the domestic market. Article 40d remains reserved.

<sup>5</sup> The proprietor of the patent has the right to appropriate remuneration. In assessing the remuneration, the circumstances of the individual case and the economic value of the license are taken into account. In the case of a license under Article 40d, the remuneration is determined by taking into account the economic value of the license in the importing country, its level of development and the urgency in public health and humanitarian terms. The Federal Council shall specify the method of calculation.

<sup>6</sup> The court shall decide on the grant and revocation of licenses, on their scope and duration as well as on the remuneration payable. In particular, it shall revoke an entitled person's license on request if the circumstances that led to its being granted no longer apply and it is not expected that they will arise again. Appropriate protection of the legal interests of the entitled person remains reserved. Where a license is granted under Article 40d, legal remedies have no suspensive effect.

In summary, TRIPS permits any member state to issue a compulsory licence for any patented invention, with no restrictions on the subject matter to be licensed. Rather than dictating specific inventions that may be licensed, TRIPS imposes procedural requirements<sup>30</sup>. Members have sovereign discretion to decide on the most effective method of utilising compulsory licences, either by permitting a government to use the patent subject matter itself or by issuing the licence to an authorised third party, such as a generic pharmaceutical company<sup>31</sup>.

In transposing the relevant TRIPS provisions almost verbatim into its own legislation, Switzerland can thus use this instrument at its own discretion in full compliance with international law, provided that the procedural requirements are respected.

<sup>30</sup> Cynthia M. Ho, [Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under TRIPS](#), North Carolina Journal of International Law and Commercial Regulation, Vol. 34, 2009; Loyola University Chicago School of Law Public Law and Legal Theory Research Paper Series No. 2009-003.

<sup>31</sup> Pier DeRoo, [Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Programs](#), Michigan Journal of International Law, Volume 32 Issue 2, 2011

### 3.2 Public non-commercial use licence (also referred to as “government-use licence”)

As explicitly indicated in the preamble of Article 31, the TRIPS Agreement permits nations to issue compulsory licences not only for government manufacturing of patented inventions, but also for a government authorised third party<sup>32</sup>.

In addition to compulsory licensing allowing for the use of a patented invention by a third party (e.g. a generic manufacturer) without the authorisation of the patent holder, most national laws also permit the government to make use of patented inventions for public purposes. The TRIPS refers to such use as “public non-commercial use”<sup>33</sup>.

While similar to a compulsory licence, the public non-commercial use of patents is a more direct, less restrictive method of authorising the non-voluntary use of a patent. For example, under 28 USC Sec 1498, the US government can use patents or authorise third parties to use patents for virtually any public use, without negotiation<sup>34</sup>.

The US government has always relied heavily on the non-voluntary licensing of patented inventions to facilitate public, non-commercial uses by the government and its agents, including with the intention of reducing the costs of certain medicines<sup>35</sup>. A closer analysis of the negotiating history of TRIPS suggests that the US attempted to distinguish between compulsory licences, which it disfavoured, and government-use licences, for which it wanted wide discretion in subject matter so as not to require any amendment to existing US laws<sup>36</sup>. This has been confirmed by a person involved in the TRIPS negotiations, who asserts that the phrase “public non-commercial use” was coined to reflect United States “government use” practice under 28 U.S.C. 1498<sup>37</sup>.

In Swiss law, the term “public non-commercial use” is found in Art. 40e PatA. The mere fact that it is present in PatA means that such “government use of patents” is also permitted in Switzerland and the Federal Council is empowered to resort to such public use of patents.

Neither TRIPS, nor the Doha Declaration nor any trade law have precisely defined the term “public non-commercial use”.

According to legal scholars, the term “public” could refer not only to use by a government but also to its purpose, i.e. use for the public benefit. A private entity could thus be charged by a government to exploit a patent for the benefit of the public<sup>38</sup>.

<sup>32</sup> Cynthia M. Ho, [Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under TRIPS](#), North Carolina Journal of International Law and Commercial Regulation, Vol. 34, 2009; Loyola University Chicago School of Law Public Law and Legal Theory Research Paper Series No. 2009-003.

<sup>33</sup> World Health Organization, [Public Health, Innovation and Intellectual Property Rights](#), Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 2006

<sup>34</sup> James Love, [Compulsory Licensing: Models for State Practices in Developing Countries. Access to Medicine and Compliance with the WTO TRIPS Accord](#), Intellectual Property Rights Series 6, Third World Network, 2004

<sup>35</sup> J. Reichmann & C. Hasenzahl, [Non-Voluntary Licensing of Patented Inventions, UNCTAD-ICTSD Project on IPRs and Sustainable Development](#), Issue Paper No. 5, June 2003

<sup>36</sup> Cynthia M. Ho, [Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under TRIPS](#), North Carolina Journal of International Law and Commercial Regulation, Vol. 34, 2009; Loyola University Chicago School of Law Public Law and Legal Theory Research Paper Series No. 2009-003.

<sup>37</sup> Pier DeRoo, [Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Programs](#), Michigan Journal of International Law, Volume 32 Issue 2, 2011

<sup>38</sup> UNCTAD-ICTSD Project on IPRs and Sustainable Development, [Resource Book on TRIPS and Development](#), Cambridge University Press, 2005

Similarly, “non-commercial use” may be defined either in relation to the nature of the transaction – i.e. “not-for-profit use” – or in relation to the purpose of the use. In the latter sense, the supply of public hospitals operating on a non-profit basis may be a “non-commercial” use of the patent<sup>39</sup>.

Legal scholars generally agree that any definition of public non-commercial use encompasses “government use” of the patented technology<sup>40</sup>.

Although Switzerland does not run a government, single-payer health care system, the existence of a statutory (mandatory) health insurance scheme rooted in federal law represents a single ‘public roof’ under which oncology treatments are financed. Further, oncology drugs such as Perjeta are typically provided by (public) university hospitals in the framework of their outpatient activities and are usually covered by mandatory health insurance. Therefore, channelling the pertuzumab biosimilar resulting from such a licence through the outpatient departments of the six university hospitals and a few other public cantonal hospitals in Switzerland – all operating on a non-profit basis – would comply fully with the purpose of “public non-commercial use” as described above.

One important feature of a compulsory licence for “public non-commercial use” is that it explicitly waives the obligation to engage in prior negotiations with the patent owner. Therefore, by not requiring commercial negotiations in advance, public non-commercial use is a concept that allows a government considerable flexibility in granting compulsory licences<sup>41</sup>.

### **3.3 Terms of the requested government use licence**

In this section, the Federal Council describes the scope of the compulsory licence of public non-commercial use it wants to resort to in order to supply the Swiss market (i.e., Swiss-based patients) with a biosimilar version of the original Perjeta medicine.

#### *3.3.1 Scope/Field of use*

The Federal Council requests the Federal Patent Court to grant a public non-commercial use compulsory licence for all relevant (current and pending) patents held by F. Hoffmann-La Roche AG and/or by members of the Roche Group related to the breast cancer medicine pertuzumab (Perjeta®) needed to produce, sell, supply and use the medicine for the treatment of HER2-positive breast cancer for all approved medical indications (thereafter: the pertuzumab patents).

At least 5 such pertuzumab patents have been identified as being enforced in Switzerland, the latest filed being valid until at least 28.01.2029 (see Appendix 1).

The Federal Council requests the Federal Patent Court to have Roche confirm which patents cover Perjeta and to state which additional patent must be included under this compulsory licence.

<sup>39</sup> Ibid

<sup>40</sup> Pier DeRoo, [Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Programs](#), Michigan Journal of International Law, Volume 32 Issue 2, 2011

<sup>41</sup> UNCTAD-ICTSD Project on IPRs and Sustainable Development, [Resource Book on TRIPS and Development](#), Cambridge University Press, 2005

### 3.3.2 Purpose

The Federal Council will rely on an established third-party manufacturer, with recognised production capacities and which applies proven quality compliance mechanisms, to manufacture and deliver the biosimilar product in Switzerland.

The Federal Council has identified, both in Switzerland and abroad, reputable companies with the capacity to develop a pertuzumab biosimilar. The grant of a compulsory licence in Switzerland would induce them to accelerate the development of a pertuzumab biosimilar.

If the selected manufacturer is based in Switzerland, it will secure from Swissmedic the necessary biosimilar marketing authorisation following the requirements set forth in Swissmedic's HD-Guidance document for the authorisation of biosimilars.<sup>42</sup>

Suppliers identified abroad are based in countries where no local patents create a barrier for the production of a pertuzumab biosimilar. Should the biosimilar manufacturer be based abroad, a Swiss-based entity duly accredited by Swissmedic will import, store, place on the market, and offer the biosimilar medicine under licence through official channels in Switzerland. This entity will be responsible for obtaining the Swiss marketing authorisation from Swissmedic, following the requirements set forth in Swissmedic's HD-Guidance document mentioned above.

### 3.3.3 Geographic Area

The licence shall be used to supply the domestic market in accordance with Article 40e let 4 PatA.

### 3.3.4 Royalties

Given that the purpose of the licence is to protect the public interest by reducing the price to a sustainable level, the amount of the royalty should not present a barrier to this end.

To comply with the requirement of adequate remuneration as provided in Article 40e al. 5 PatA, the Federal Council proposes the following royalty calculation:

- an amount equal to 4% of the ex-factory price of Perjeta (CHF 2'983.53 for the 420 mg/14ml vial, as of 1.5.2018), this method being consistent with the internationally recognised approach set by the 2005 World Health Organization (WHO) Tiered Royalty Method.<sup>43</sup>

This amount protects the public interest by allowing the sale of the biosimilar medicine at a price that is affordable for both patients and the health system in Switzerland.

### 3.3.5 Duration

The licence shall last until the latest patent filed related to pertuzumab (including its supplementary protection certificate or SPC) expires, or until the public interest reasons justifying the grant of the compulsory licence cease to exist.

<sup>42</sup> Swissmedic, 2018, [HD-Guidance document Authorisation Biosimilar](#), 1.1.2018 (accessed 1.5.2018)

<sup>43</sup> UNDP/WHO, [Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies](#), Health Economics and Drugs TCM Series No. 18, 2005 (accessed 14.03.2018)

According to the available information regarding the Perjeta patent landscape, the licence should remain valid until at least 28 January 2029 (see Appendix 1).

The final decision on the duration should, however, also consider any patents filed by Hoffmann-La Roche AG and/or by members of the Roche Group which the Federal Council is not aware of, i.e. patents that have not been yet granted (pending) and/or that may impede the proper use of the compulsory licence regarding pertuzumab.

### 3.3.6 Limitations

The Federal Council requests a non-exclusive licence. Roche and members of the Roche group remain thus free to use the patents and to market the medicine.

## 3.4 Procedural requirements

### 3.4.1 Admissibility

Article 26 al. 1 lit. a) of the Federal Act on the Federal Patent Court (Patent Court Act, PatCA, CC 173.41)<sup>44</sup> provides:

Chapter 4: Jurisdiction

Art. 26

<sup>1</sup> The Federal Patent Court has exclusive jurisdiction over:

- a. [...] actions for issuing a license in respect of patents;
- b. [...]
- c. the enforcement of decisions made under its exclusive jurisdiction.

This request for a public non-commercial use compulsory licence to the Federal Patent Court is therefore admissible.

### 3.4.2 Standing before the Court

As the supreme governing and executive authority of the Swiss Confederation, the Federal Council is entitled by international (TRIPS) as well as national (PatA) law to stand before the court to request the confirmation of the grant of a government-use licence for all patents related to pertuzumab (Perjeta).

<sup>44</sup> Federal Council, [Federal Act on the Federal Patent Court of 20 March 2009 \(status as of 1 December 2012\)](#), CC 173.41



### 3.4.3 Previous request for a contractual (or voluntary) licence

Neither TRIPS<sup>45</sup> nor PatA<sup>46</sup> require previous unsuccessful efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions, within a reasonable period of time, before a public non-commercial use licence can be issued.

This procedural requirement is therefore fulfilled.

## 3.5 The Public Interest

If individual interest is a core element of the patent system – by granting an inventor a monopoly – the ultimate goal of this system is to foster the public interest by encouraging innovation and promoting progress in society.

The public interest is also central to the notion of compulsory licensing<sup>47</sup>, as evidenced by the formulation of Art. 8 al. 1 TRIPS which justifies the introduction of a compulsory licence for public health / public interest: “[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest [...]”.

The concept of public interest cannot be defined in general terms. Rather, it is an indefinite legal concept which must be interpreted and made concrete in individual cases<sup>48</sup>.

The notion of public interest within the meaning of Article 40 PatA also covers the objective of effective competition pursued by the Federal Act on Cartels and other restraints of Competition (CC-251, Cartel Act, CartA). This opinion is put forward by the majority of the doctrine<sup>49</sup>.

Responding to a 2014 WIPO questionnaire on Exceptions and Limitations to Patent Rights, Switzerland ascertained that “Public health is in the public interest”<sup>50</sup>. It also stressed that “Articles 36 to 40 of LBI [PatA] indicate the legislator’s fear that a patentee might abuse the monopoly position provided by Article 8 of the LBI [...] to the detriment of the interests of the whole community”<sup>51</sup>.

Even in countries that have implemented a range of policy measures to manage medicine prices, such as Switzerland, the prices of newer cancer medicines have grown substantially over the past decades. WHO suggests that more measures may be needed to realign the prices of cancer medicines with a view to expanding patient access to cancer medicines and ensuring the long-term financial sustainability of health care systems<sup>52</sup>.

<sup>45</sup> Art. 31 TRIPS, let b): “[...] This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. [...]” [emphasis added]

<sup>46</sup> Art. 40<sup>e</sup> PatA al. 1: “[...] Such efforts are not required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. [...]” [emphasis added]

<sup>47</sup> Jean Marc Salamolard, [La Licence obligatoire en matière de brevet d'invention](#), Etude de droit comparé, Librairie Droz, Genève, 1978, pp. 215-216

<sup>48</sup> See Commentaire Romand, [Propriété Intellectuelle](#), De Werra-Gilliéron (ed.), Helbing Liechtenhahn, 2013, p. 1814

<sup>49</sup> Werner Stieger, “Kodak” – eine Momentaufnahme des Schnittbereichs von Immaterialgüter- und Kartellrecht aus helvetischer Sicht”, sic! 2001, p.100 ; Thierry Calame, SIWR IV Wirkung, p.498. See also the Commentaire romand on PatA, p.1814

<sup>50</sup> World Intellectual Property Organization (WIPO), [Questionnaire on Exceptions and Limitations to Patent Rights, Response of Switzerland \(Swiss Federal Institute of Intellectual Property\)](#), 2014

<sup>51</sup> Ibid

<sup>52</sup> World Health Organization (WHO), [Pricing of cancer medicines and its impacts](#), Technical Report, Geneva, December 2018



The notion of public interest under Article 40 PatA also covers the sustainability of the Swiss universal health coverage system. Indeed, the latter is supposed to guarantee all Swiss-based patients access to affordable, economically sustainable and quality healthcare<sup>53</sup>. The Federal Council has a constitutional duty to guarantee universal access to affordable, lifesaving medicines to all the Swiss population.

The financial resources of our health system are not infinite and the sustainability of the system requires that all stakeholders act in good faith and respect its spirit and purpose. The Federal Council is of the view that pharmaceutical companies should also strive towards more reasonable pricing to ensure the sustainability of the mandatory health insurance system, which represents one of their major sources of revenue<sup>54</sup>. Excessive prices may affect the sustainability of the system and lead to limited reimbursement options, or even rationing decisions, which ultimately harm patients. It is therefore in the public interest to use legally available tools to oppose such adverse consequences.

The Federal Council is of the opinion that the balance between public and private interests needs to be restored whenever such balance is disrupted, as in the Perjeta case. This can be done by reinstating competition and reducing prices to sustainable levels – a goal that can be achieved, as contemplated by the legislature, through compulsory licensing.

In view of the above, the Federal Council is of the opinion that a compulsory licence is justified in the case of Perjeta:

- As Roche has exploited its monopoly position to impose an excessive price;
- As this excessive price is threatening the fulfillment of the Federal Council's constitutional duty to guarantee affordable lifesaving medicines to all the Swiss population;

### **3.6 Perjeta's excessive pricing**

A careful analysis of both the regulatory history of Perjeta and market conditions show that Roche is charging an excessive price for Perjeta due to its dominant position in the HER2-positive breast cancer treatment market segment. Companies with market dominance are called price makers because they are able to set higher prices while maintaining market share. Economic theory suggests that a monopolist dictates the prices of their products as a price maker because there are no close substitutes<sup>55</sup>.

The Federal Act on Cartels (CartA) stipulates that dominant undertakings behave unlawfully if they abuse their position in the market by e.g. imposing unfair prices<sup>56</sup>.

Even in the context of patent-protected pharmaceuticals there is a notion of a "reasonable price" and, conversely, an "excessive price." A patent should not be the basis for charging excessive prices<sup>57</sup>.

<sup>53</sup> OECD/WHO, [OECD Reviews of Health Systems: Switzerland](#), OECD Publishing, 2011.

<sup>54</sup> In 2016, the medicines reimbursed by insurers accounted for 83.8% (CHF 4'689 million) of the turnover of the branch. Interpharma, [Le marché du médicament en Suisse](#), 2016, p. 20

<sup>55</sup> World Health Organization (WHO), [Pricing of cancer medicines and its impacts](#), Technical Report, Geneva, December 2018

<sup>56</sup> Article 7 of the [Federal Act on Cartels and other Restraints of Competition \(Cartel Act, CartA, CC 251](#) – status as of 1 December 2014)

### 3.6.1 Roche's dominant position in the HER2-positive breast cancer treatment market segment

The relevant market for HER2-positive breast cancer currently includes 4 products: Herceptin (trastuzumab), Perjeta (pertuzumab), Kadcylla (trastuzumab-emtansine) and Tyverb (lapatinib).

Roche holds three of the four drugs currently on the LS and on the Swiss market: Herceptin, Perjeta and Kadcylla. The three drugs totaled more than CHF 10 billion in global sales in 2017, including more than CHF 3 billion in Europe.<sup>58</sup> Tyverb (lapatinib) – sold by Novartis – is a third-line medicine which has been declining in sales for many years and in 2013 accounted for only 5% of the overall market share in the HER2-positive franchise, while Roche's other three drugs accounted for the remaining 95%.<sup>59</sup>

At the time of the inclusion of Perjeta in the LS (2013 and again in 2015, see section 3.6.2), Roche had thus a market share of over 90% in the HER2-positive breast cancer market in Switzerland.

The Court of Justice of the European Union has held in *Hoffmann-La Roche v Commission* (1979) that “very large market shares are highly significant evidence of the existence of a dominant position”<sup>60</sup>. In *AstraZeneca v Commission* (2010), the CJEU reiterates settled case law that “market shares of more than 50% constitute very large market shares and that a market share of between 70% and 80% is in itself a clear indication of the existence of a dominant position”<sup>61</sup>.

As a result, it can be inferred that Roche, through its three different products, enjoys a dominant position in the field of therapeutics indicated for the treatment of HER2-positive breast cancer.

### 3.6.2 The FOPH was under intense pressure to accept Roche's high price

The FOPH had to push the limits of the existing legal framework to allow the inclusion of Perjeta in the List of Specialties (LS), so that the medicine could be automatically reimbursed under the mandatory health insurance scheme. Roche, profiting from its monopoly position, has exerted intense pressure on the FOPH to obtain and maintain an excessive price for Perjeta<sup>62</sup>.

The inclusion history of Perjeta in the LS is summarized in Box 1 below.

In short, the whole negotiation process between Roche and the FOPH has resulted in a net increase of Perjeta's public price (+30%). As a consequence, the annual net costs of the standard combination therapy (Perjeta-Herceptin-Docetaxel) have only minimally decreased (-7%) between 2013 and 2018 – despite the fact that Herceptin lost its patent protection in July 2014. Herceptin's patent expiry should have resulted in significantly greater savings for the mandatory health insurance system<sup>63</sup>. These reduced savings work against the public interest.

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<sup>57</sup> Frederick M. Abbott, [Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health](#), UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016.

<sup>58</sup> Herceptin: CHF 7.014 billion; Perjeta: CHF 2.196 billion; Kadcylla: CHF 914 million – figures taken from : F. Hoffmann-La Roche Ltd, [Annual Report 2017](#), Basel, pp 32-33.

<sup>59</sup> GlobalData, [HER2-Positive Breast Cancer – Global Drug Forecast and Market Analysis to 2023](#), September 2014

<sup>60</sup> Case 85/76 [Hoffmann-La Roche v Commission](#) [1979] ECR 461, paragraph 41

<sup>61</sup> Case T-321/05, [AstraZeneca v Commission](#) ECLI:EU:T:2010:266, paragraph 23

<sup>62</sup> Several broadcasts from Swiss TV have reported about the regulatory history of Perjeta with regards to the LS, see e.g.: RTS, [Combien pour une année de vie de plus?](#), Temps présent, 21.09.2017 (forward to 34'30"), or RTS, [Roche impose le prix d'un médicament malgré la pression des autorités](#), 19:30, 01.02.2015. Another broadcast has just been announced regarding Roche's pressures around Perjeta's inclusion in the SL: SRF, [Poker um Medikamentenpreisen: Roche setzt Bundesamt unter Druck](#), Rundschau, 30 January 2019.

<sup>63</sup> See Art. 65e of the Ordinance on Health Insurance (OAMal, [RS 832.102](#) – only available in French, German or Italian) and Bundesamt für Gesundheit (BAG), [Handbuch betreffend die Spezialitätenliste \(SL\).2017](#), Chapter F, pp. 71-72 (document exists only in German and

### **Box 1: History of Perjeta's inclusion in the List of Specialties (LS)**

#### First temporary admission: March 2013-July 2014

Perjeta was provisionally included in the LS by the Federal Office of Public Health (FOPH) on 1 March 2013, pending a proper evaluation of the efficacy, adequacy and economic efficiency (EAE evaluation) as prescribed by federal law<sup>64</sup>. The **public price agreed upon by the FOPH was CHF 3,782.25 per 420mg-vial**. The listing included a "limitation" with a payback mechanism that was unusual for the LS, whereby Roche committed to pay back to the relevant health insurer CHF 1,600 per pack of Perjeta sold. The **net unit price was therefore CHF 2,182.25**.

#### Withdrawal from the LS: August 2014-June 2015

Negotiations went on between Roche and the FOPH during spring 2014 for the permanent inclusion of Perjeta in the LS. The FOPH considered the initial (2013) price of Perjeta not cost-effective<sup>65</sup> (hence the temporary admission) and requested a further price reduction. **Roche refused and chose to withdraw Perjeta from the LS as per August 2014**. This withdrawal resulted in several months of uncertainty for patients about the reimbursement, which they first had to negotiate with their insurance company.

#### Second temporary admission: July 2015-January 2018

In July 2015, following further negotiations, the FOPH agreed to temporarily re-admit Perjeta on the LS, with a **new public price of CHF 3,762.75 per 420mg-vial**. The payback mechanism was still present in the "limitation" but significantly reduced, from CHF 1,600 to CHF 737 per pack sold. The outcome of the negotiations for readmission was a **2015 net price of CHF 3,025.75, a net increase of CHF 843.50 (+39%)** compared to the previous 2013-2014 net price.

#### Third admission, with an extension of indication: May 2018-today

On 1 May 2018, a second indication of Perjeta (neoadjuvant treatment of HER-2 positive breast cancer, i.e. before surgery) was included in the LS, with a resulting decrease in price in accordance with the LS regulations. The **new public price (which is also the current one) is CHF 3,304.10 per 420mg-vial**, with a payback discount once more reduced to CHF 452.33 per pack sold. Hence a **current net price of CHF 2,851.77**, down CHF 173.98 (-12%) compared to the 2015 net price but **up CHF 669.52 (+30%)** compared with the 2013-2014 net price.

**Table 1: Evolution of the price of Perjeta in Switzerland**

Period	Public price (CHF)	Ex-factory price (CHF)	Amount payback / pack (CHF)	Net price per unit (CHF)	Annual public price (CHF)*	Annual net price (incl. payback) (CHF)*
03/2013 – 08/2014	3,782.25	3,450.00	1,600.00	2,182.25	68,080.50	39,281.00
07/2015 – 04/2018	3,762.75	3,430.97	737.00	3,025.75	67,729.50	54,463.50
05/2018 – today	3,304.10	2,983.53	452.33	2,851.77	59,473.80	51,331.86

\* Considering 17 treatment cycles/year (the first one double-dosed) for an average patient of 68kg bodyweight

<sup>64</sup> See Art 65 of the Ordinance on Health Insurance (OAMal, [RS 832.102](#) – only available in French, German or Italian)

<sup>65</sup> Bundesamt für Gesundheit (BAG), ([19972](#)) [Perjeta Roche Pharma \(Schweiz\) AG – Neuaufnahme in Spezialitätenliste per 1. Juli 2015](#), downloaded from the webpage [FOPH evaluations of drugs on the Specialties List](#): „Das BAG hatte das Arzneimittel nach einer Befristung nicht mehr als wirtschaftlich erachtet“ (only available in German)

**Table 2: Annual costs of the combination therapy Perjeta+Herceptin+Docetaxel in Switzerland**

Period	Annual public price Perjeta (CHF)*	Annual public price Herceptin (CHF) <sup>°</sup>	Annual public price Docetaxel Sandoz (CHF) <sup>+</sup>	Total <b>without</b> payback for Perjeta (CHF)	Total net <b>with</b> payback for Perjeta (CHF)
03/2013 - 08/2014	68,080.50	58,585.80	11,594.00	138,260.30	109,460.30
07/2015 - 12/2016	67,729.50	44,519.80	11,594.00	123,843.30	110,577.30
01/2017 - 04/2018	67,729.50	38,714.00	11,594.00	118,037.50	104,771.50
05/2018 - today	59,473.80	38,714.00	11,594.00	<b>109,781.80</b>	<b>101,639.86</b>

\*Considering 17 annual treatment cycles (the first one double-dosed) for an average patient of 68kg bodyweight (18 x 420mg vials/year)

<sup>°</sup> Considering an initial dose of 8mg/kg and a maintenance dose of 6mg/kg for an average patient of 68kg bodyweight (52 x 150mg vials/year)

<sup>+</sup> Considering a dose of 75mg/m<sup>2</sup> for an average patient with a body surface of 1.75m<sup>2</sup> (17 x 140mg pack/year)

The FOPH was not in a position to flatly deny Perjeta's re-entry on the LS, even though the price was higher. In theory, the FOPH can decide to refuse entry on the LS. However, in practice, the FOPH may be obliged to yield to pressure because a refusal runs contrary to the Federal Council's universal coverage mandate. In the field of cancer, where non-admission can have deadly consequences for patients, the refusal or withdrawal of a drug from the LS by the FOPH – on the grounds that it is too expensive – would not be understood by patients, nor by society at large. The absence of a therapeutic alternative (without compromising the outcome of the treatment) also reduced – possibly even negated – the FOPH's bargaining power.

Following are some of the concessions the FOPH had to make regarding the pricing of Perjeta as a result of pressure from Roche:

- When reinstated on the LS in July 2015, the price of Perjeta was higher than before Roche withdrew it – despite the fact that the FOPH considered the 2014 price no longer cost-effective, as outlined in an official document<sup>66</sup>. In other words, **a net price of about CHF 2,182.25 was found by the FOPH in 2014 to be excessive – in 2015 Perjeta was nevertheless reinstated on the LS at a net price of CHF 3,025.75 (+38.7%)**. The FOPH had no real choice but to yield to Roche's pressure regarding pricing, bearing in mind its primary objective of safeguarding the availability and accessibility of Perjeta for all breast cancer patients in Switzerland.
- **The FOPH accepted an unusual pay-back mechanism for Perjeta** despite the fact that such a mechanism is only admissible for medicines that are used for different approved therapeutic indications and/or in different combinations<sup>67</sup>. However, at the time of inclusion (2013) and re-admission (2015) onto the LS, Perjeta was only approved for one indication (metastatic HER2-

<sup>66</sup> Bundesamt für Gesundheit (BAG), [\(19972\) Perjeta Roche Pharma \(Schweiz\) AG – Neuaufnahme in Spezialitätenliste per 1. Juli 2015](#), downloaded from the webpage [FOPH evaluations of drugs on the specialities list](#): „Das BAG hatte das Arzneimittel nach einer Befristung nicht mehr als wirtschaftlich erachtet“ (only available in German)

<sup>67</sup> Conseil Fédéral, [Avis du Conseil fédéral sur le rapport de la CDG-E du 25 mars 2014 : Admission et réexamen des médicaments figurant sur la liste des spécialités \(LS\)](#), 27 août 2014, p. 7601 (document exists only in French or [German](#))

positive breast cancer) and in only one combination (with Herceptin and docetaxel). It was therefore, in theory, not appropriate in the case of Perjeta. In addition, it may have had negative repercussions on the mandatory health insurance expenses paid by Swiss patients<sup>68</sup>.

The Federal Council is aware that this payback mechanism has been criticised by various stakeholders<sup>69</sup> and is conscious of potential transparency issues arising from its use. The Federal Council has already given assurances that such a mechanism would be used only in exceptional circumstances and with the necessary caution by the FOPH – only with the aim of allowing certain costly drugs to be included in the LS, and thus ultimately to contribute to savings for the mandatory health insurance system<sup>70</sup>.

- **The FOPH accepted an exceptional innovation premium of 50%**, on Roche's demand, whereas the usual procedure caps the innovation premium at 20%<sup>71</sup>.

**Thus, Roche has taken advantage of its dominant position to obtain and maintain a high public price for Perjeta. Such a high public price acts against the public interest.**

### 3.6.3 *Perjeta's profit margin is abusive*

Roche's exact profit margin on Perjeta is unknown, but it is likely to be over 30%.

Following its launch, the price of Herceptin was reduced significantly, while maintaining a profit margin for Roche. Between 1 January 2009 and 1 January 2018 (9 years), the Swiss price of Roche's Herceptin was reduced by 42% (from CHF 1,290.20 to CHF 744.50 for a 150mg-vial). Given that Roche is still selling this product, it can be assumed that it is still earning a decent profit even at this lower price. By analogy, we can infer that if the price of Perjeta was reduced significantly, Roche would still make a profit.

The profit margins in the pharmaceutical industry are known to be very high – and are actually regularly cited as being among the highest across all industry sectors<sup>72</sup>.

Profit margins of the largest pharmaceutical companies regularly exceed 20%. Roche's 2017 annual report details a core operating profit margin of 42.7% for its pharmaceutical division and 35.7% for the whole Roche Group in relation to 2017 sales of CHF 53.299 billion<sup>73</sup>. This translated into a profit before taxes of CHF 18.268 billion (34.3%, core results) and a net income after taxes of CHF 13.404 billion (25.1%, core results) for the whole Roche Group<sup>74</sup>.

A profit margin of more than 30% for Perjeta has to be considered abusive in this context. Perjeta is taken in combination with Herceptin, another product manufactured by the same company that has

<sup>68</sup> Under the mandatory health insurance scheme, each patient must contribute with minimum 10% co-pay on the price of medicines being prescribed. It remains unclear whether the patients co-paid on the basis of the higher public price (not taking into account the payback discount) or on the lower net price (taking into account the payback discount). This financial impact may however be limited as the maximum amount of co-pay per patient per year is capped at CHF 700.

<sup>69</sup> Urs P. Gasche, [Preis-Deal mit Roche ist gesetzwidrig](#), Infosperber, 3 September 2013 (only available in German)

<sup>70</sup> [Avis du Conseil fédéral sur le rapport de la CDG-E du 25 mars 2014 « Admission et réexamen des médicaments figurant sur la liste des spécialités \(LS\)](#), Feuille Fédérale pp. 7600-7601, 27 August 2014 (available only in French, [German](#) and Italian)

<sup>71</sup> Bundesamt für Gesundheit (BAG), [Handbuch betreffend die Spezialitätenliste \(SL\), 2017](#), C.2.2., S. 44 (document exists only in German and [French](#))

<sup>72</sup> See e.g. Richard Anderson, [Pharmaceutical industry gets high on fat profits](#), BBC News, 26 November 2014 and Liyan Chen, [The most profitable industries in 2015](#), Forbes, 23 September 2015

<sup>73</sup> F. Hoffmann-La Roche Ltd, [Roche Financial Report 2017](#), Basel, Finance in Brief and p.3

<sup>74</sup> F. Hoffmann-La Roche Ltd, [Roche Financial Report 2017](#), Basel, p 4



been the market leader for HER2-positive breast cancer treatments for many years. Roche enjoyed almost 20 years of monopoly with Herceptin and has already earned generously with this product<sup>75</sup>. Roche has more than recouped its R&D investments for this product used in combination with Perjeta.

A recent article in JAMA mentioned cumulative sales of US\$ 88.2 billion for trastuzumab by the end of 2017, highlighting that Herceptin has earned Roche US\$31.20 for every risk-adjusted dollar that went into its R&D, and that the annual sales income for the same product were “in the hundreds of millions of US dollars for the originator company following expiry of its principal patents”<sup>76</sup>. The same article concludes by saying that returns from cancer drugs (including trastuzumab) “are much higher than what would be considered a justifiable return required for rewarding and incentivizing innovation, both in economic terms and by reasonableness”<sup>77</sup>.

Despite the expiry of the Herceptin patents in July 2014, Roche still holds a de facto market exclusivity over Herceptin in Switzerland as no biosimilar has yet been authorized in the country<sup>78</sup>, allowing for a higher price than in neighbouring countries<sup>79</sup>. Further, the public funding spent on the development of both Herceptin and Perjeta has been substantial and is not being duly considered (see next section).

All of this should have led to a more reasonable pricing of Perjeta, as a follow-on product of Herceptin. Six years after its first marketing approval, Perjeta has generated global sales of over US\$7 billion, with significant increases each year<sup>80</sup>.

Under the FOPH’s Instructions for the LS, the price of a biosimilar medicine must be at least 25% lower than the ex-factory price of the original preparation<sup>81</sup>. Even with a more significant price reduction, and assuming that Roche would lower its own price of Perjeta to the same level, it is safe to assume that Roche would still be realising a profit.

This shows that granting the requested public non-commercial use licence achieves a fair balance of interests, whereby patients’ access is facilitated, the costs of the mandatory health insurance scheme are contained and Roche’s financial interests are nonetheless safeguarded.

<sup>75</sup> James Love, [“Roche and the City of Hope claim biosimilar version of trastuzumab will infringe “at least” 40 patents”](#), Harvard Law Blog, 23 November 2017: *“Herceptin is a remarkable drug, but after enjoying 19 years as a monopoly and \$70 billion in sales, one might think enough is enough, as regards the rewards to the Roche shareholders”*

<sup>76</sup> Kiu Tay-Teo et al., [Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies](#), Jama Network Open 2019;2(1):e186875, 4 January 2019

<sup>77</sup> Ibid

<sup>78</sup> Contrary to the EU, where 4 trastuzumab biosimilars were approved between 2017 and 2018 from Samsung Bioepis (brand name: [Ontruzant, November 2017](#)), Amgen (brand name: [Kanjinti, May 2018](#)), Pfizer (brand name: [Trazimera, May 2018](#)) and Biocon-Mylan (brand name: [Ogivri, December 2018](#))

<sup>79</sup> For example in France, according to the Journal Officiel de la République Française ([Avis du 14.08.2018](#)), Herceptin was sold in 2018 (after patent expiry) at an ex-factory price of EUR 349.50 for a 150mg-vial (CHF 418.10 at the mean annual exchange rate), which corresponds to 34% less than the ex-factory price in Switzerland (CHF 634.22) at the same period.

<sup>80</sup> Kiu Tay-Teo et al., [Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies](#), Jama Network Open 2019;2(1):e186875, 4 January 2019 – supplemental content

<sup>81</sup> Bundesamt für Gesundheit (BAG), [Handbuch betreffend die Spezialitätenliste \(SL\),2017](#), C.6., S. 52 (available only in German and

### 3.6.4 The price of Perjeta is not based on concrete R&D costs

In *United Brands v. Commission* (1978), a lead case that establishes the current basis of the European doctrine regarding excessive pricing, the Court of Justice of the European Union (CJEU) held that:

“The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under Article 86 [now 102] of the Treaty.

It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.

In this case charging a price which is excessive because *it has no reasonable relation to the economic value of the product supplied* would be such an abuse.

This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a *comparison between the selling price of the product in question and its cost of production*, which would disclose the amount of the profit margin; [...]

The questions therefore to be determined are *whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*<sup>82</sup>

The logical starting point for determining whether the price of a product is unfair is therefore its R&D costs. Once these are determined, the difference between cost and price can be established and a determination made as to whether this difference is “excessive”. The cost/price methodology is the most direct way to determine the supplier’s profit, and therefore the most reasonable way to determine whether the price is higher than it should be<sup>83</sup>.

However, the cost of researching and developing originator pharmaceutical products is deliberately shrouded in mystery. The originator pharmaceutical industry has aggressively resisted providing data regarding its R&D costs<sup>84</sup>.

Prices in Switzerland are actually set by comparing foreign list prices and through a therapeutic comparison with the price of products that are used for the same or similar indications. Since March 2017, those two comparisons have equal importance<sup>85</sup>.

<sup>82</sup> Quotes from the CJEU judgment of [C-27/76 - United Brands v Commission](#) para 248-52, are excerpted (including added emphasis) from Frederick M. Abbott, [Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health](#), UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016.

<sup>83</sup> Frederick M. Abbott, [Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health](#), UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016.

<sup>84</sup> Frederick M. Abbott, [Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health](#), UC Irvine Law Review, Volume 6, Issue 3, pp. 281-320, Dec. 2016.

<sup>85</sup> Bundesamt für Gesundheit (BAG), [Die Preise von Medikamenten sollen auf neue Art und Weise überprüft werden](#), Medienmitteilung, 06.07.2016 (available only in German, [French](#) and [Italian](#))

Ideally, the FOPH should take R&D costs into account when evaluating cost effectiveness, in accordance with Article 65b al. 6 of the Ordinance on Health Insurance (OAMal, RS 832.102). However the FOPH has no access to all or parts of relevant R&D costs because they are considered commercially confidential by the originator company. The FOPH's director confirmed on several public occasions that he wished he could get the real R&D figures from the pharmaceutical companies<sup>86</sup>

This non-disclosure of concrete R&D costs, and the fact that these are considered confidential by the pharmaceutical industry, has been widely debated in the literature. The Council of Europe has also reported on this lack of transparency in R&D costs<sup>87</sup>, and passed a resolution in September 2015 calling on its member States, including Switzerland, to “oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion”<sup>88</sup>. This recommendation has not yet been acted upon.

In order to ascertain the magnitude of excessive pricing of the product, the Patent Court should therefore ask Roche to disclose the real R&D costs of Perjeta.

### 3.6.5 *Current pricing of Perjeta does not give due consideration to public R&D investment*

Evidence shows that public funding and tax-funded research efforts have significantly contributed to the development of both Herceptin and Perjeta. Drawing parallels between these two drugs is relevant because they both use the same technology (monoclonal antibody), share the same indication and are used in combination.

The technologies that allow the production of monoclonal antibodies (MABs) were developed at the UK Medical Research Council Laboratory of Molecular Biology (MRC LMB) in Cambridge, which is publicly funded via the UK Medical Research Council.<sup>89</sup>

For Herceptin, it was Dennis Slamon, a scientist from the University of California Los Angeles (UCLA), and a team at the National Cancer Institute (NCI) that discovered in 1987 that HER2 was amplified in human breast cancers. It was only after self-financed first clinical trials showed it could effectively be a promising drug that Genentech (now a member of the Roche Group) embarked on the development of this new monoclonal antibody alongside the UCLA<sup>90</sup>. The development of the product in the USA also benefited from more than half a billion US dollars in grants from the tax-funded National Institutes of Health (NIH), which mentions trastuzumab and tax credits associated with two orphan drug designations<sup>91</sup>.

Public contributions during the clinical development of trastuzumab were also particularly significant; almost half of the 641 trastuzumab clinical trials registered in Europe and the US from 2004 and 1998, respectively, were carried out for non-commercial purposes and with funding from uni-

<sup>86</sup> For example at the Health Care Summit, annual event co-organised by Le Temps and Politico, Geneva, 10 October 2017

<sup>87</sup> Liliane Maury-Pasquier, Rapporteur of the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly of the Council of Europe (PACE), Report [Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?](#), Doc. 13869, 14 September 2015

<sup>88</sup> Parliamentary Assembly of the Council of Europe (PACE), [Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?](#), Resolution 2071 (2015), 29 September 2015

<sup>89</sup> Just Treatment, [Enacting a Crown Use licence to secure access to affordable pertuzumab for Scottish breast cancer patients](#), Briefing document, 13 April 2018

<sup>90</sup> No es sano campaign (Spain), [Cancer drugs: high prices and inequity](#), case study of trastuzumab (pp. 28-32), April 2018

<sup>91</sup> James Love, [“Roche and the City of Hope claim biosimilar version of trastuzumab will infringe “at least” 40 patents”](#), Harvard Law Blog, 23 November 2017



versities, research centres and non-profit foundations<sup>92</sup>. Further, like many other oncology products, the initial approval of Herceptin in the USA was based upon evidence from a fairly small number of patients enrolled in clinical trials<sup>93</sup>.

The cost of production for a yearly supply of trastuzumab represents only a tiny fraction of the high prices charged; it has been estimated at \$242 (or less than \$16 per 600mg vial), which includes a 40% mark-up on the cost of the Pharmaceutical Active Ingredient (API) for formulation and quality assurance and a 50% increase for profit<sup>94</sup>.

For Perjeta, initial research builds on Slamon's et al. discovery regarding HER2 amplification in human breast cancers. Later in 1990, Brian Fendly et al. generated a panel of murine anti-HER2 antibodies by immunising mice with human HER2. By 2002, research led by Dr Agus at Cedars-Sinai Cancer Centre, in collaboration with Genentech, had evidenced that 2C4 (a mechanism which pertuzumab builds on) was effective in controlling tumour growth, and they hoped it would impact a wider range of tumours, not just HER2+. But pertuzumab failed trials in 2005 as a stand-alone treatment, before the 2012 CLEOPATRA trial results proved efficacy in combination with trastuzumab, leading to FDA and then European approval. Roche acquired a majority stake in Genentech in 1990, and took over full ownership in 2009<sup>95</sup>.

Even if the contribution of public funding for the development of pertuzumab cannot be quantified precisely, it has undoubtedly been significant – and highly unlikely to have been considered when setting the initial public price of the product.

**In conclusion, Roche, profiting from its dominant position, is charging an excessive price, which justifies the grant of a public non-commercial use licence under Articles 40 and 40e of the PatA.**

### **3.7 Perjeta's excessive price is undermining the Federal Council's health mandate**

According to the Federal Constitution, the Confederation and the Cantons shall ensure that every person has access to social security<sup>96</sup>, to the health care that they require<sup>97</sup> and an adequate provision of high quality primary medical care<sup>98</sup>. This includes access to lifesaving medicines.

Given that the regulation of pharmaceuticals – which also encompasses price control – is a federal prerogative in Switzerland, the Federal Council bears a specific duty to ensure that the entire Swiss population continues to benefit from affordable access to lifesaving treatments in a sustainable manner. This universal coverage is only possible if the mandatory health insurance scheme is sustained, and the insurance premiums paid by the Swiss population remain at an affordable level.

Despite that, the International Health Policy Survey 2016 showed that the proportion of people foregoing healthcare in Switzerland due to cost reasons (insurance premium & co-pay) has increased from 10.3% in 2010 to 22.5% in 2016 (1 in 5 individuals)<sup>99</sup>.

<sup>92</sup> No es sano campaign (Spain), , [Cancer drugs: high prices and inequity](#), case study of trastuzumab (pp. 28-32), April 2018

<sup>93</sup> James Love, "[Roche and the City of Hope claim biosimilar version of trastuzumab will infringe "at least" 40 patents](#)", Harvard Law Blog, 23 November 2017

<sup>94</sup> Cancer Alliance, [Cancer Alliance motivation for provision of trastuzumab in South Africa's public sector to women with HER2 positive breast cancer](#), November 2016

<sup>95</sup> Just Treatment, [Enacting a Crown Use licence to secure access to affordable pertuzumab for Scottish breast cancer patients](#), Briefing document, 13 April 2018

<sup>96</sup> Article 41 al. a) of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>97</sup> Article 41 al. b) of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

<sup>98</sup> Article 117a al. 1 of the Federal Constitution of the Swiss Confederation of 18 April 1999 ([CC 101](#))

The Federal Council is very concerned that the costs of the mandatory health insurance scheme have increased more rapidly than the average growth in expenses of the entire health system<sup>100</sup>. WHO stated in a recently released report that, on a global level, “the rate of growth of expenditure on cancer medicines greatly exceeds the rate of growth of newly diagnosed cancer cases and of overall health care expenditure”<sup>101</sup>. Switzerland is no exception to that.

Drug expenditure in 2017 by pharmacies, doctors and outpatient departments of hospitals was CHF 6.84 billion, out of a total expenditure of the mandatory health insurance scheme of CHF 32.3 billion (21.2%), according to FOPH statistics<sup>102</sup>. Alternative sources estimate that drug expenditure reached CHF 7.5 billion in 2017, resulting in an even higher ratio of over 23%<sup>103</sup>. Almost 85% of these drugs are covered by the mandatory health insurance scheme<sup>104</sup>.

Medicines are thus a major driver of the annually increasing costs of the mandatory health insurance scheme in Switzerland. The Federal Council has recently proposed several new cost-containment measures for the system, one of which is the introduction of a reference pricing system for medicines<sup>105</sup>. However, this will only address the overpricing of generic and off-patent drugs in Switzerland<sup>106</sup> and not those of **patented drugs, which accounted for 74% of all medicines reimbursed in 2017 by the mandatory health insurance scheme<sup>107</sup> - or over CHF 5 billion.**

To address the continuous rise in cancer drug prices, WHO clearly advises that “more measures [than the price-setting approaches in place, e.g. reference pricing] may be needed to realign the prices and expand access to cancer medicines” including by applying WTO/TRIPS flexibilities for patented medicines where appropriate<sup>108</sup>.

Immunosuppressant and oncology drugs are among the most expensive patented prescription medicines covered by the mandatory health insurance scheme, and their share of total drug expenditure is constantly rising<sup>109</sup>. From 2007 to 2017, the total costs of oncology drugs rose by 220% – more than a threefold increase due mainly to ever-increasing unit prices of those medicines<sup>110</sup>.

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<sup>99</sup> Observatoire suisse de la santé, [Expérience de la population âgée de 18 ans et plus avec le système de santé – Situation en Suisse et comparaison internationale](#), Obsan Dossier 56, 17 November 2016 (Executive summary also in German)

<sup>100</sup> Département fédéral de l'intérieur, [Rapport explicatif relatif à la révision partielle de la loi fédérale du 18 mars 1994 sur l'assurance-maladie : Mesures visant à freiner la hausse des coûts, 1er volet](#), 14 septembre 2018 (only in French, [German](#) or [Italian](#))

<sup>101</sup> World Health Organization (WHO), [Pricing of cancer medicines and its impacts](#), Technical Report, Geneva, December 2018

<sup>102</sup> Bundesamt für Gesundheit (BAG), [Statistik der obligatorischen Krankenversicherung 2017](#), Tabelle 217d (only in German or [French](#))

<sup>103</sup> Helsana, [Arzneimittelreport 2018](#), November 2018 (only in German with executive summary in French and English)

<sup>104</sup> Département fédéral de l'intérieur, [Rapport explicatif relatif à la révision partielle de la loi fédérale du 18 mars 1994 sur l'assurance-maladie : Mesures visant à freiner la hausse des coûts, 1er volet](#), 14 septembre 2018 (only in French, [German](#) or [Italian](#))

<sup>105</sup> Conseil fédéral, [Maîtrise des coûts de la santé : le Conseil fédéral appelle tous les acteurs à leur responsabilité](#), Communiqué, 14 septembre 2018 (exists only in French, [German](#) or [Italian](#))

<sup>106</sup> Département fédéral de l'intérieur, [Fiche d'information : Système de prix de référence pour les médicaments](#), 15.10.2018 (only in French, [German](#) and [Italian](#))

<sup>107</sup> Département fédéral de l'intérieur, [Rapport explicatif relatif à la révision partielle de la loi fédérale du 18 mars 1994 sur l'assurance-maladie : Mesures visant à freiner la hausse des coûts, 1er volet](#), 14 septembre 2018 (only in French, [German](#) or [Italian](#))

<sup>108</sup> World Health Organization (WHO), [Pricing of cancer medicines and its impacts](#), Technical Report, Geneva, December 2018

<sup>109</sup> Helsana, [Arzneimittelreport 2018](#), November 2018 (only in German with executive summary in French and English)

<sup>110</sup> Ibid

Today, many cancer drug treatments in Switzerland have exceeded the symbolic threshold of CHF 100'000 per year of treatment, and recent developments suggest that this upward trend will not be reversed any time soon. Kymriah, a new cancer treatment launched by Novartis and approved by Swissmedic in October 2018, is set to cost CHF 370'000 per injection<sup>111</sup> – LS admission modalities and final price setting are currently being negotiated with the FOPH. The same company has announced a treatment for a rare neuromuscular disorder in children set to cost CHF 4 million per injection<sup>112</sup>.

Perjeta is one of the excessively priced cancer drugs, as demonstrated in this document. The current public price of Perjeta (as of 1.5.2018) is CHF 3,304.10 per 420mg-vial, resulting in a treatment cost of about CHF 60,000 per year per patient (not including Herceptin and docetaxel). When Herceptin and Docetaxel are added to Perjeta, the annual cost of treatment reaches CHF 109,781.80 per patient (public price). As some patients require treatment cycles over several years, the price for treating one HER2-positive breast cancer patient can ultimately exceed CHF 750,000 (Perjeta + Herceptin + Docetaxel)<sup>113</sup>.

In a new report, WHO has calculated an affordability threshold of US\$ 40,600 per patient per year (average for high-income countries), above which pricing of cancer medicines might undermine universal coverage for all newly diagnosed cancer cases<sup>114</sup>. Using the same calculation method for Swiss health statistics<sup>115</sup>, the affordability threshold would theoretically be US\$ 33,149 per person per year. Even against the highest WHO benchmark, the Swiss health system cannot financially sustain Perjeta's present net price of over CHF 50,000, let alone costs above CHF 100,000 for the combination therapy with Herceptin. The FOPH could never apply an equivalent price to all cancer medicines without jeopardising universal coverage of medicines for all pathologies (through rationing or inadequately serving certain disease areas), or without drastically increasing the insurance costs for patients (through premiums and co-payments).

According to the Swiss Cancer League, 6,000 new breast cancer cases are diagnosed each year in Switzerland<sup>116</sup>, of which 1 in 5 is generally HER2-positive<sup>117</sup>. This means that on average 1,200 persons per year in Switzerland are diagnosed with a HER2-positive breast cancer that potentially requires this treatment. Every year, the mandatory health insurance scheme would therefore have to spend about CHF 130 million for the Perjeta + Herceptin + docetaxel combination only (at the present price) if all new patients were to be treated.

Such amounts are unsustainable when generalized. According to the Swiss Cancer League, 40,000 new patients are diagnosed with cancer each year in Switzerland<sup>118</sup>. If CHF 100'000 per year were spent for each of those patients, the mandatory health insurance costs would equal CHF 4 billion – for cancer patients alone – which contrasts with the CHF 605 million that was actually spent in

<sup>111</sup> Swissinfo, [Novartis leukaemia drug approved in Switzerland](#), 22 October 2018

<sup>112</sup> Tages Anzeiger, [4-Millionen-Franken-Geschäft mit der Hoffnung](#), 15 November 2018 (only available in German)

<sup>113</sup> Personal communication from one of the largest health insurance company in Switzerland

<sup>114</sup> World Health Organization (WHO), [Pricing of cancer medicines and its impacts](#), Technical Report, Geneva, December 2018, p. 76-77 & Appendix E

<sup>115</sup> Per capita health expenditure: (current) US\$ 9'836 ([WHO](#), 2016); population estimate: 8'373'338 ([World Bank](#), 2016); number of new cancer cases (incidence): 58'387 ([Global Health Data Exchange GHDx](#), 2016); pharmaceutical spending (total% of health spending): 13.8% ([OECD](#), 2016), Cancer burden (proportion of DALYs by disease area): 17% ([WHO](#), 2018, Appendix E). The same calculation with 2016 health data from the Federal Office of Statistics leads to an even lower affordability threshold of US\$ 28'212 per patient per year.

<sup>116</sup> Ligue suisse contre le cancer, [Le cancer en Suisse : les chiffres](#), Etat décembre 2018 (only available in French, [German](#) or [Italian](#))

<sup>117</sup> According to the scientific literature, 15-20% of breast cancer cases are HER2-positive

<sup>118</sup> Ligue suisse contre le cancer, [Le cancer en Suisse : les chiffres](#), Etat décembre 2018 (only available in French, [German](#) or [Italian](#))

2016. CHF 4 billion equals 57% of all drug expenditures in the mandatory health insurance scheme in 2016 (which then totaled CHF 7.09 billion). Of course, the same reasoning could be extended to other life-threatening diseases, thus pushing the pharmaceutical share of total healthcare costs even higher.

A mandatory health insurance scheme is not financially sustainable if each new drug, even if it extends survival by several months, costs CHF 100,000, or more when taken in combination, unless insurance premiums and/or public tax funding (i.e. public subsidies to those who cannot afford to pay the high premiums) are drastically increased or rationing is introduced. Indeed, as seen with the Swiss market entry of highly expensive antivirals for the treatment of Hepatitis C, Switzerland is not immune to rationing decisions when facing high prices<sup>119</sup>.

FOPH experts have warned the Federal Council that it will have to deal more and more with situations in which drugs must, because of their very high price, be included in the LS in a targeted or staggered manner<sup>120</sup>. In response to a parliamentary request from June 2018, the Federal Council publicly shared its concern that “pharmaceutical companies are increasingly asking for prices that would cause very high additional costs for the tax- and premiums-funded social insurance systems”<sup>121</sup>.

In order to guarantee affordable access to newer medicines for the entire population in the long run, further cost containment measures (in addition to those proposed in 2018<sup>122</sup>) need to be taken against excessively priced patented drugs. Public non-commercial use licences is one such measure.

There is no ‘blanket’ public non-commercial use licence that could simultaneously tackle all excessively priced drugs – this legal tool can only be applied to one specific product in a given market and for a given period of time.

The journey has to start somewhere. Therefore, the Federal Council chose to resort to a government-use licence for a medicine, Perjeta, that can provide considerable public health benefits (extending life) in the case of one of the deadliest and most common cancers in Switzerland (breast cancer), and for which there is sufficient evidence of excessive pricing resulting in a significant financial impact on mandatory health insurance costs.

<sup>119</sup> When first included in the LS in August 2014, the new antiviral sofosbuvir (sold by Gilead Sciences under the brand name Sovaldi) was only reimbursed for Hepatitis C patients with (late) Fibrosis stages 3 and 4 – those with (early) Fibrosis stages 1 and 2 had to wait until their situation worsen to get their treatment reimbursed under the mandatory health insurance scheme. This unprecedented rationing, essentially due to the high public price of the medicine (CHF 57,625 for a 3-months treatment at the time), has been gradually lifted over the years until it was totally removed in September 2017. See e.g. Office fédéral de la santé publique, [Bulletin 33/14](#), 11 August 2014, p. 545 (also available in [German](#)) or Office fédéral de la santé publique, [Hépatite C : remboursement sans restriction des nouveaux médicaments pour toutes les personnes concernées](#), Communiqué, 19 septembre 2017 (also available in [German](#) or [Italian](#))

<sup>120</sup> « *L’OFSP s’attend au cours des prochaines années à devoir face toujours plus souvent à des situations où des médicaments doivent, en raison de leur prix très élevé, être introduits de manière ciblée ou échelonnée dans la liste des spécialités pour obtenir la meilleure adéquation entre efficacité et coûts* » - from Conseil fédéral, [Médicaments contre l’hépatite C : conditions pour le remboursement élargies](#), Communiqué, 27 juillet 2015 (also available in [German](#) or [Italian](#))

<sup>121</sup> Excerpt of the reply of the Federal Council to the “interpellation” 18.3677 of National Council member Angelo Barrile, titled “[Agir contre les prix excessifs des médicaments brevetés](#)”, 14 September 2018 (only available in French, [German](#) or [Italian](#) – free translation). Original sentence: « *Le Conseil fédéral constate avec une certaine préoccupation que les entreprises pharmaceutiques demandent de plus en plus des prix qui engendreraient des coûts supplémentaires très élevés pour les systèmes d’assurance sociale financés par les impôts et les primes* ».

<sup>122</sup> Conseil fédéral, [Maîtrise des coûts de la santé : le Conseil fédéral appelle tous les acteurs à leur responsabilité](#), communiqué, 14 septembre 2018 (exists only in French, [German](#) or [Italian](#))

A government-use licence granted for Perjeta would considerably reduce the cost of the combination therapy (knowing that Herceptin's price will continue to decrease with the future entry of biosimilars) – and thus the expenses for the mandatory health insurance system. Assuming a price reduction of 25%<sup>123</sup> from the current public price of Perjeta, savings could amount to over CHF 15 million per year. International experience indicates that the competition generated by biosimilar products with the original biological product may reduce prices by around 80%<sup>124</sup> – this would provide annual savings of almost CHF 50 million. These estimates are conservative since they only consider the potential new HER2-positive breast cancer cases diagnosed each year and not those who are already under treatment.

The precedent of a public non-commercial licence in Switzerland would also restore the public interest by increasing the bargaining power of the FOPH in future price negotiations while, at the same time, encouraging the pharmaceutical industry to adopt more reasonable pricing policies that still provide sufficient profits. Even a public commitment to explore a compulsory licence could tip the power balance in present and future negotiations on highly priced cancer drugs.

**In view of the above, the Federal Council concludes that Roche is charging the mandatory health insurance system an unsustainable price for Perjeta. It is therefore in the public interest to grant a public non-commercial use licence (under Articles 40 and 40e PatA) that would lead to lower prices for the benefit of insured patients and public budgets.**

#### 4 Data Exclusivity

The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act or TPA, CC 812.21)<sup>125</sup> grants a protection period of 10 years – commonly called the data exclusivity period – during which a second applicant cannot refer to the results of the pharmacological, toxicological and clinical tests used for the marketing authorisation of the corresponding original preparation (Art 11a, 11b and 12 TPA). Although the current legislation does not specify a first applicant protection regarding biosimilars, Swissmedic applies the same protection rules by analogy.<sup>126</sup>

The Federal Council agrees with the conclusions of the attached legal opinion (see appendix 2) stating that various solutions exist to overcome data exclusivity should the registration procedure of a pertuzumab biosimilar occur before the end of the 10-year protection period (2022) after Perjeta's market approval. Indeed, if a non-voluntary licence were granted in the public interest, this same public interest would be contravened should data exclusivity impede the use of such a licence.

Interpharma, the trade association of research-based pharmaceutical companies in Switzerland, also shares the opinion that data exclusivity shall not be an obstacle to a compulsory licence issued in the public interest<sup>127</sup>.

<sup>123</sup> Under the FOPH's Instructions for the LS, a biosimilar medicine must be sold at least 25% lower than the ex-factory price of the original preparation – see footnote 72 for the reference

<sup>124</sup> Just Treatment, [Enacting a Crown Use licence to secure access to affordable pertuzumab for Scottish breast cancer patients](#), Briefing document, 13 April 2018

<sup>125</sup> Federal Council, [Federal Act on Medicinal Products and Medical Devices of 15 December 2000 \(status as of 1 January 2018\)](#), TPA, CC 812.21. The newly revised version of the TPA (as of 1 January 2019) has not yet been updated in English and is only available in [French](#), [German](#) or [Italian](#) (including the new articles 11a and 11b TPA related to data exclusivity)

<sup>126</sup> Swissmedic, 2018, [HD-Guidance document Authorisation Biosimilar](#), 1.1.2018, section 6.5 (accessed 1.5.2018)

<sup>127</sup> « *L'industrie pharmaceutique pratiquant la recherche admet que la protection des données tests ne doit pas faire obstacle à une licence obligatoire émise dans l'intérêt public justifié. Lorsqu'une licence obligatoire justifiée est émise, celle-ci a également la priorité sur la protection des données tests* », excerpt from the [Interpharma website](#) (only available in French and [German](#))



## 5 Conclusions

Considering the context of escalating health costs largely due to overpriced, newly approved medicines – in particular cancer drugs – and the increasing risk of rationing,

Considering that such excessive pricing places a disproportionate burden on the Swiss health insurance system, on HER2-positive breast cancer patients, and on the society as a whole,

Considering that it is of the utmost importance to restore the original objective of the patent system, which is to balance public and private interests,

The Federal Council has concluded in its session of ... 2019, based on the arguments laid out in the present document, that:

- 1) Because of its dominant position, Roche is charging an excessive price for Perjeta;
- 2) Such excessive pricing is financially unsustainable and acts against the public interest;
- 3) Therefore, a government-use licence to exercise the rights on the patents related to breast cancer medicine Perjeta® is justified under Articles 40 and 40e PatA.

The **Federal Council hereby requests the Federal Patent Court**, as the competent authority having exclusive jurisdiction over actions for issuing a licence in respect of patents<sup>128</sup>, **to confirm the grant of a public non-commercial use compulsory licence (government-use licence) in Switzerland for patents related to breast cancer medicine pertuzumab (sold under the brand name Perjeta® by Roche)** according to the terms set forth in this document.

<sup>128</sup> Federal Act on the Federal Patent Court of 20 March 2009 ([PatCA, CC 173.41](#))

## Appendix 1: The pertuzumab patents

<i>European patent Number</i>	<i>Title of invention</i>	<i>Filing date</i>	<i>Published on Swissreg on</i>	<i>Swiss SPC (number)</i>	<i>Protection until</i>
EP1189641	Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies	23.06.2000	29.07.2009	Yes (Co1189641/01)	22.06.2025
EP1585966	Treatment of Cancer with the Anti-ErbB2 Antibody rhu-MAB 2C4	11.07.2003	30.11.2011	Yes (Co1585966/01)	12.08.2027
EP1771482	HER2 Antibody Composition	15.07.2005	20.08.2014	No	15.07.2025
EP1802344	Antibody Formulation in Histidine-Acetate Buffer	19.10.2005	15.08.2012	No	19.10.2025
EP2238172	Composition comprising Antibody that binds to Domain II of HER2 and Acidic Variants thereof	28.01.2009	21.02.2018	No	28.01.2029

**Appendix 2: legal analysis on compulsory licensing and data exclusivity**



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## LEGAL ANALYSIS

### THE INTERFACE BETWEEN PATENT PROTECTION AND DATA EXCLUSIVITY

#### THE ISSUE OF COMPULSORY LICENSING IN THE PUBLIC INTEREST UNDER SWISS LAW

1. The Swiss Federal Act on Patents for Inventions (hereafter: Patents Act or PatA<sup>1</sup>) allows for the grant of compulsory licences. The requirements are found in Articles 40 to 40e PatA. In the present context, the key provision under consideration is Article 40<sup>2</sup>, which states that:

*"Licence in the interest of the public*

*<sup>1</sup> Where public interest so dictates, the person to whom the proprietor of the patent has, without sufficient reason, refused to grant the licence requested, may apply to the court for the grant of a licence to use the invention."*

This provision does not limit in any way the individuals or entities entitled to seek such a public interest licence. The requirement that the licence be dictated by the public interest is an indication that *public bodies* are among the entities that can request such a licence. Indeed, public interest is usually promoted and upheld by public bodies. This interpretation is further supported by Article 40e PatA, which is the common provision applicable to all compulsory licences (i.e., to the licences of Article 40, 40a, 40b, 40c and 40d PatA). Article 40e para.1 *in fine* PatA envisages a licence "*in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use*". In other words, certain situations of public interest (as per Article 40 PatA) may be held to be so serious as to qualify as situations of national emergency or extreme urgency as per Article 40e PatA. Similarly, a situation of public interest may call for "*public non-commercial use*" of the patented good or service.

Obviously, a public authority is best positioned to act in a situation of "national emergency [... or] extreme urgency" or even to pursue "non-commercial" objectives. One can think, for example, of an environmental disaster that would require the government to take immediate measures to protect an endangered area; it would make no sense if the government were banned from obtaining a PatA compulsory licence. Forcing the government to pursue a public taking (expropriation) as per

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<sup>1</sup> Federal Act on Patents for Inventions (Patents Act, PatA; RS 232.14) of 25 June 1954 (status as of 1 January 2017), unofficial English translation at <https://www.admin.ch/opc/en/classified-compilation/19540108/index.html>.

<sup>2</sup> This provision has remained unchanged since 1976. See DANIEL KRAUS / LEILA GHASSEMI, commentaire de l'art. 40 LBI, in: Commentaire romand PI, p. 1813.

Article 32 PatA – instead of just securing a compulsory licence - would be disproportionate and therefore against the law<sup>3</sup>.

Finally, in 2012 patent infringement affair<sup>4</sup>, the Federal Patent Court indicated that the Swiss government could have – and probably should have – requested a compulsory licence pursuant to Article 40 PatA<sup>5</sup>. This holding was confirmed by the Federal Tribunal in its 2013 judgment<sup>6</sup>. It was never claimed that legal obstacles prevent the government from filing such a request before the Federal Patent Court. Furthermore, nothing in the reasoning of the two judgments suggests that the right of the government to seek a compulsory licence depends on the kind of patent or on the kind of technology.

In conclusion, a public authority is entitled to seek a compulsory licence under Article 40 PatA, on whatever grounds, provided that its request and action are dictated by the public interest. This licence is, of course, not limited to urgent situations of emergency, since the decisive criteria as per the PatA is the assessment of public interest.

2. There is no inherent conflict between the Patent Act and the Therapeutic Products Act (TPA<sup>7</sup>). Each legislation covers a different subject matter. Each confers a type of protection relevant to its subject matter. Data exclusivity (as per Article 11a, 11b and 12 TPA) is unique to pharmaceuticals, and more precisely to certain pharmaceuticals, mostly those approved under an ordinary marketing authorisation procedure<sup>8</sup>. Data exclusivity and patent protection operate independently<sup>9</sup>. Thus, a drug can be patented without ever having benefitted from data exclusivity – and vice versa (a drug with data exclusivity, which has never had patent protection).

There is no loophole in the Patent Act, in the sense that its compulsory licences are meant to apply only to patents, and were never intended to be extended to other types of protection conferred by other laws. Indeed, compulsory licences under the PatA (potentially) apply to an extremely broad range of products and services, the commercialisation of which may run into various types of barriers, depending on the subject matter. It would not be practical to include in the Patent Act (section 5) derogations or exceptions to other laws because the range of exceptions to be added would be too extensive and would call for a specific assessment which might be beyond the scope of expertise of the patent authorities. In other words, the Patent Act is not designed to anticipate the possible subsequent *marketing problems* of patented products/services, including therapeutic products, regardless of whether or not a compulsory patent licence has been granted.

On the other hand, the TPA can be said to be incomplete (i.e., legal loophole), in the sense that it hardly regulates the exceptions or limitations to its data exclusivity provisions (see points 3 and 4

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<sup>3</sup> Commentaire romand de la PI, au commentaire de l'art. 32 LBI par DANIEL KRAUSS / LEILA GHASSEMI, p. 1755.

<sup>4</sup> Judgment O2012\_021.

<sup>5</sup> In this affair, the Swiss Federal government had allegedly used a patent-protected technology, without seeking a voluntary nor a compulsory license. The patent-holder sued for infringement and for damages. The legal issue was whether the Federal Patent Court had jurisdiction over the patent holder's various claims.

<sup>6</sup> Following the appeal by the government, the Federal Tribunal mostly confirmed the judgment of the Federal Patent Court. See Judgment of February 5, 2013, ATF 139 III 110.

<sup>7</sup> Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; RS 812.21) of 15 December 2000 (status as of 1 January 2019), unofficial and not-yet-updated English translation at <https://www.admin.ch/opc/en/classified-compilation/20002716/index.html>.

<sup>8</sup> See further Swissmedic's guideline, Guide complémentaire, Exclusivité des données, HMV4, January 1, 2019.

<sup>9</sup> See, e.g., PETER MOSIMANN / MARKUS SCHOTT, Heilmittelgesetz, Basler Kommentar, Helbing & Lichtenhahn, 2006, p. 140.



below)<sup>10</sup>. The TPA does not provide an answer to the question that arises once a compulsory licence on a patent has been granted in the public interest.

3. Data exclusivity is not necessarily an insurmountable obstacle for the party having secured a compulsory licence under Article 40 PatA. There are various pathways to overcome data exclusivity under the TPA. For example, this party can produce its own test data<sup>11</sup>; it can rely on publicly available data (i.e., published literature); it can apply for an authorisation under Article 13 or Article 14 para. 2 TPA (if a generic or biosimilar has been approved abroad); it can wait for the data exclusivity to lapse.

Moreover, if a patent compulsory licence has been granted because the Patent Court recognised a public interest in launching a product incorporating the patented invention, it is very likely that the refusal of the data exclusivity holder to grant consent to the use of the data (as per Article 12 para.1 letter e TPA) would amount to an abuse of dominant position under the Cartel Act<sup>12</sup>. Indeed, the data exclusivity holder is very likely to occupy a dominant position<sup>13</sup>, because if there had been many independent parties offering that product, there would probably not have been a public interest as required by Article 40 PatA. Moreover, for that company holding a dominant position to deny access to the Swissmedic-held data is likely to be viewed as abusive (Article 7 CartA<sup>14</sup>), since a court has already considered that "public interest" requires an additional product on the market.

4. If the data exclusivity holder refuses its consent in breach of Article 7 CartA, the holder of the compulsory licence under Article 40 PatA will have to begin an independent civil action to have the abuse established and corrected (Articles 12 and 13 CartA). The Swiss Competition Commission may want to investigate the suspicion of a CartA violation (Articles 26 and 27 CartA). The civil tribunal may also want to refer the issue of CartA conformity to the Competition Commission (Article 15 para.1 CartA). These civil and administrative actions might unduly postpone the launch of the "public-interest" product. In a context of urgency, whether for the population at large or for certain individuals at risk, such delays could have dangerous, or even lethal, consequences.

There may therefore be a public interest in avoiding undue delay in the commercialisation of the product once Article 40 PatA has been deemed applicable. Currently, the absence of provisions

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<sup>10</sup> There is since 2019 one limitation to the scope of data exclusivity in Article 16a para. 5 TPA; it applies only to pediatric medicines that the marketing authorisation holder plans to "abandon".

<sup>11</sup> In the case of a biosimilar medicine, the applicant has to submit its own test data. The extent to which the applicant relies on the data already submitted by the holder of the original medicine varies. This issue is not directly addressed in Swissmedic's guideline, Guide complémentaire, Autorisation d'un produit biosimilaire HVM4, January 1, 2019.

<sup>12</sup> Federal Act on Cartels and other Restraints of Competition (Cartel Act, CartA; RS 251) of 6 October 1995 (Status as of 1 December 2014), unofficial English translation at <https://www.admin.ch/opc/en/classified-compilation/19950278/index.html>. Discussing the possibility to use the Cartel Act to obtain a patent licence, see ANDRI HESS-BLUMER, Patent Trolls – eine Analyse nach Schweizer Recht, sic ! 2009, p. 851 ss; MAX WALLOT, Massnahmen gegen Patenttrolle: Zwangslizenzen, Rechtsmissbrauchsverbot oder doch Verhältnismässigkeitsprüfung? Sic ! 2011, p. 157 ss; RETO M HILTY / ALFRED FRÜH, Lizenzkartellrecht, Stämpfli, 2017, pp. 177-194; FRANÇOIS DESSEMONTET, La propriété intellectuelle et les contrats de licence, CEDIDAC, 2011, p. 296; GEORG RAUBER, Verhältnis des neuen Rechts zum Immaterialgüterrecht, Schulthess 2004, p. 209-211. Most authors consider that PatA compulsory licences and CartA licences operate independently, in the sense that an applicant can seek one and/or the other, depending on the circumstances.

<sup>13</sup> Article 4 para. 2 CartA ("*Dominant undertakings are one or more undertakings in a specific market that are able, as suppliers or consumers, to behave to an appreciable extent independently of the other participants (competitors, suppliers or consumers) in the market.*")

<sup>14</sup> According to this provision, "*Dominant undertakings behave unlawfully if they, by abusing their position in the market, hinder other undertakings from starting or continuing to compete, or disadvantage trading partners.*" Refusals to deal are mentioned as examples of possible abusive conduct at Article 7, para. 2 letter a CartA. On this issue, see RUTH ARNET, Freiheit und Zwang beim Vertragsabschluss, Kapitel 2: Die Kartellrechtliche Kontrahierungspflicht, Stämpfli, 2008, pp. 171-203.

limiting the scope of data exclusivity in the TPA makes delays likely. The legislature should therefore act to correct this problem. A revision of the TPA to include data exclusivity limitations akin to those currently found in the PatA is needed.

Interestingly, this is what has been decided by the European Union in the context of compulsory licences granted to permit the commercialisation of a patented drug for export purposes<sup>15</sup>. When the EU authorities decide that public interest calls for the grant of such a patent compulsory licence, data exclusivity is automatically waived (i.e. does not apply), allowing for the medicinal product to be authorised in the EU without undue delay<sup>16</sup>.

In that regard, Interpharma in Switzerland has written "*L'industrie pharmaceutique pratiquant la recherche admet que la protection des données tests ne doit pas faire obstacle à une licence obligatoire émise dans l'intérêt public justifié. Lorsqu'une licence obligatoire justifiée est émise, celle-ci a également la priorité sur la protection des données tests*"<sup>17</sup>. In other words, the trade association of the Swiss research-based pharmaceutical industry has recognised that data exclusivity should not prevent the commercialisation of medicines, once a public interest in their commercialisation has been recognised.

Up to now, the legal literature in Switzerland has not seized upon the issue of data exclusivity limitations<sup>18</sup>. Courts have never had to deal with such a topic. No solution has therefore been proposed. Only recently was the matter briefly mentioned by the authorities, in response to a 2018 parliamentary interpellation<sup>19</sup>.

Solutions must therefore be identified to achieve coherence between the PatA system of compulsory licences and the TPA system of data exclusivity.

When revising the TPA, the Swiss legislature could choose between a regime where a compulsory licence under Article 40 PatA automatically leads to a waiver of pharmaceutical data exclusivity under the TPA or a regime whereby the Federal Patent Court decides, at the same time as it decides on the application of Article 40 PatA, whether and how data exclusivity should be limited<sup>20</sup>.

Alternatively, the Federal Patent Court could apply by analogy Articles 40 and 40e PatA to the regime of data exclusivity of the TPA. Such reasoning by analogy is admitted in situations where courts hold the law to be incomplete (i.e., legal loophole). A true loophole is admitted if the legislature has, by inadvertence, failed to address an issue that requires a legal answer, and for

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<sup>15</sup> Such compulsory licences are called for by Articles 31 and 31bis of the WTO's TRIPS Agreement.

<sup>16</sup> Article 18 para. 2 Regulation 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. According to this provision, "*If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply.*" Article 14(1) and Article 10 confer data exclusivity.

<sup>17</sup> interpharma, web page titled "Accords de libre-échange", at <https://www.interpharma.ch/fr/place-pharmaceutique/2626-accords-de-libre-echange>. In English, this would translate as "*The research-based pharmaceutical industry acknowledges that data exclusivity must not constitute an obstacle to a compulsory licence issued for a legitimate public interest. If a legitimate compulsory license is issued, this license has priority over test data protection*".

<sup>18</sup> See the Commentaire romand de la PI, (Helbing & Lichtenhahn, 2013), en particulier les commentaires des art. 40 à 40e LBI par DANIEL KRAUS / LEILA GHASSEMI; le commentaire bâlois Heilmittelgesetz (Helbing & Lichtenhahn, 2006), en particulier le commentaire de l'art. 12 LPTh (ancienne version), par PETER MOSIMANN / MARKUS SCHOTT; STEFAN KOHLER / CHRISTA PFISTER, Erstanmelderschutz für Arzneimittel in der Schweiz, sic ! 5/2008, p. 395ss; DOMINIK BACHMANN, Der Erstanmelderschutz in der Schweiz und in der EU, Schweizerische Zeitschrift für Gesundheitsrecht 2004 Nr. 3, p. 31ss.

<sup>19</sup> Point 3 of the reply of the Federal Council of September 14, 2018 to the "interpellation" 18.3677 of National Council member Angelo Barrile, titled "Agir contre les prix excessifs des médicaments brevetés".

<sup>20</sup> Discussing a somewhat similar issue related to the jurisdiction of the Federal Patent Court, see PASCAL FEHLBAUM, La jurisprudence du Tribunal fédéral des brevets, sic! 2014, p. 316-317.



which none is available by interpretation<sup>21</sup>. The solution ultimately selected in order to close the loophole must be in harmony with the overall legal regime<sup>22</sup>. This would be the case here, as it would require the Federal Patent Court to assess all aspects of the given case, to decide what lies in the public interest

5. In conclusion, patent protection and data exclusivity operate independently from each other. When public interest dictates that a compulsory licence be granted, the holder of such a licence has various means to overcome data exclusivity. As recognised by interpharma, data exclusivity should not be an obstacle to the launch of a product held by to be in the public interest. A pharmaceutical company that nonetheless objects to the use of its data would likely violate Article 7 of the Cartel Act, which prohibits the abuse of a dominant position. Denying access to regulatory data is abusive when it undermines the attainment of a public interest duly recognised by the courts.

Prof. Valérie Junod



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<sup>21</sup> True legal loopholes are to be distinguished from cases where the legislature deliberately remained silent. In that latter hypothesis, where the legislature knowingly decided not to legislate, courts cannot in principle correct or complete the statute, even if its solution is perceived as unsatisfactory. On the contrary, if the regulation is held to have a true legal loophole ("lacune proprement dite" ou "lacune véritable" ou encore "lacune authentique"), the court must enact the proper solution to answer the legal question (art. 1 para.2 Civil Code). See for example the judgment of the Federal Tribunal (ATF), 125 III 425; see also ATF 126 III 129 and 129 III 656.

<sup>22</sup> Federal Tribunal's judgment of December 7, 2018, 6B\_822/2018.