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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[1]) 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[2], which states that:

> "*Licence in the interest of the public*
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> [1] *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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[1] 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.

[2] 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[3].

Finally, in 2012 patent infringement affair[4], the Federal Patent Court indicated that the Swiss government could have – and probably should have – requested a compulsory licence pursuant to Article 40 PatA[5]. This holding was confirmed by the Federal Tribunal in its 2013 judgment[6]. 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[7]). 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[8]. Data exclusivity and patent protection operate independently[9]. 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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[3] Commentaire romand de la PI, au commentaire de l'art. 32 LBI par DANIEL KRAUSS / LEILA GHASSEMI, p. 1755.
[4] Judgment 02012_021.
[5] 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.
[6] 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.
[7] 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.
[8] See further Swissmedic's guideline, Guide complémentaire, Exclusivité des données, HMV4, January 1, 2019.
[9] See, e.g., PETER MOSIMANN / MARKUS SCHOTT, Heilmittelgesetz, Basler Kommentar, Helbing & Lichtenhahn, 2006, p. 140.

below)[10]. 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 license 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[11]; 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[12]. Indeed, the data exclusivity holder is very likely to occupy a dominant position[13], 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[14]), 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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[10] 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".

[11] 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 HMV4, January 1, 2019.

[12] 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.

[13] 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.*")

[14] 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[15]. 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[16].

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*"[17]. 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[18]. 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[19].

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[20].

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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[15] Such compulsory licences are called for by Articles 31 and 31bis of the WTO's TRIPS Agreement.

[16] 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.

[17] 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*".

[18] 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.

[19] 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".

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

which none is available by interpretation[21]. The solution ultimately selected in order to close the loophole must be in harmony with the overall legal regime[22]. 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.

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[21] 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.

[22] Federal Tribunal's judgment of December 7, 2018, 6B_822/2018.