

A Licence! And Quick! Recent Developments Concerning Compulsory Licences For Patented Pharmaceuticals In The European Union

By Patricia Cappuyens and Jozefien Vanherpe

Almost sixty years ago, the renowned economist Edith Tilton Penrose described compulsory licensing as the most effective and flexible method to reduce the cost of the patent monopoly.¹ Over half a century later, the examples of compulsory licences in practice are, globally speaking, still quite scarce, and in the European Union practically non-existent. However, the times might be changing. Last July, the German Federal Court of Justice confirmed a compulsory licence granted for the AIDS drug “Isentress” in preliminary injunction proceedings. In the fall of 2017, the Minister for Health of the Netherlands announced his intention to extensively explore the use of compulsory licencing of patents of highly expensive medicines. These evolutions seem to point towards a renewed interest in implementing the international, European and national legislative provisions on compulsory licencing, with real, practical consequences. Food for thought and, therefore, a Scoop of the theory and recent practice of compulsory licencing in the European Union, with a focus on pharmaceutical products.

Compulsory Licences: the Basics

1. A compulsory licence is an authorisation granted by a government, to a party which is not the patentee, to use a certain invention without the patentee’s consent.² The effect of such a licence is a limitation of the private power that comes with the grant of a patent. Its goal is to further the public interest, often to counteract the absence of exploitation of a patented invention by a patentee in the face of demonstrable domestic demand. Similarly, applicants for a compulsory licence may find themselves unable to exploit an invention for which they have obtained patent protection because they would otherwise infringe a patent of an earlier date.

1. E. Tilton Penrose, “The Economics of the International Patent System,” Baltimore (USA), *Johns Hopkins Press*, p. 231.

2. See e.g. D.J. Brennan, “The first compulsory licensing of patents and copyright,” *Legal History* 2017, vol. 17, 1, available online at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3012345 and UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, Chapter 25: Patents: Non-Voluntary Uses (Compulsory Licenses), 2004, p. 461, available online at <https://www.iprsonline.org/>.

2. Legislative provisions that authorise the grant of compulsory licences for public interest reasons have been around for years.³ Such reasons have included non-working of the patent on the national level (*i.e.* insufficient exploitation of the invention) and failure to meet demand on reasonable terms, but also certain anticompetitive practices⁴ or the right to health. While patentees might not welcome their exclusive rights being curtailed by the government, it goes without saying that compulsory licences offer significant opportunities when it comes to public health and access to medicines.

3. Historically, there has been a great deal of controversy about the appropriate scope of compulsory licencing schemes. This was even one of the reasons for the initiation of negotiations for an IP-specific agreement within the World Trade Organisation (WTO),⁵ which eventually led to the TRIPS Agreement.⁶

Legislative Action

4. Almost all European countries have provisions regarding compulsory licences in their patent legislation. While these national provisions are not identical, they

3. See e.g. Article 5A of the Paris Convention, which dates from 1883 and recognises the right of its state parties to remedy abuses of patent rights, including failure to work the patent. See also D.J. Brennan, “The first compulsory licensing of patents and copyright,” *Legal History* 2017, vol. 17, 4, in which reference is made to a discussion about the compulsory licencing of intellectual property as early as 1829. In 1995, the national laws of approximately 100 countries already provided some form of compulsory licensing, see E. Bond and K. Saggi, “Compulsory licensing, price controls, and access to patented foreign products,” April 2012, p. 3, available online at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf.

4. C.M. Correa, “Intellectual Property Rights and the use of Compulsory Licenses: Options for Developing Countries,” South Centre T.R.A.D.E. Working Paper, October 1999, 10-21 and UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, Chapter 25: Patents: Non-Voluntary Uses (Compulsory Licenses), 2004, p. 462.

5. See <https://www.wto.org/>.

6. UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, Chapter 25: Patents: Non-Voluntary Uses (Compulsory Licenses), 2004, p. 463 and references cited there.

must all comply with the twelve conditions for compulsory licencing schemes set forth in Article 31 of the TRIPs Agreement.⁷ We describe the main conditions in this provision below.⁸

5. First and most importantly, each compulsory licence must be considered on its individual merits.⁹ This implies that the government is not allowed to provide blanket authorisations of compulsory licences in relation to certain categories of technologies or companies. Instead, each licence application must undergo a review process to check whether all of the criteria are met.¹⁰

6. Prior to the grant of a compulsory licence, the proposed user must have made reasonable efforts to obtain a licence from the patentee.¹¹ The use of the term ‘reasonable’ indicates the flexibility of this requirement, the practical implementation of which depends on factual circumstances. Moreover, the prior negotiations requirement is waived in three cases: when there is a national urgency or other circumstances of extreme urgency or in case of public non-commercial use. Here again, the language of Article 31 TRIPs leaves substantial room for interpretation and is flexible in nature.

7. In any case, the patentee must receive an ‘adequate’ remuneration for the licence.¹² Moreover, any compulsory licence must be limited in scope and duration¹³ and will be terminated “*if and when the circumstances which led to it cease to exist and are unlikely to recur.*”¹⁴ Further, such a licence is non-assignable¹⁵ and

7. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C to the Agreement establishing the World Trade Organisation, effective as of 1 January 1995, available online at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

8. See for the full list of conditions: Article 31 TRIPs. See for great detail on the interpretation of these conditions UNCTAD and ICTSD, *Resource Book on TRIPs and Development*, Chapter 25: Patents: Non-Voluntary Uses (Compulsory Licenses), 2004, p. 468-480.

9. Article 31, a) TRIPs.

10. This process must subsequently be subject to independent review, see Article 31, j) TRIPs.

11. Article 31, b) TRIPs.

12. Article 31, h) TRIPs. Further, any decision relating to such remuneration must be subject to independent review within the country at issue (Article 31, j) TRIPs). For the sake of completeness, we note that a country that has granted a compulsory licence in relation to a certain patent is not obliged to ensure injunctive relief against the licensee. In such a case, the country may limit the remedies available to the payment of an adequate remuneration, pursuant to Article 44.2 TRIPs.

13. Article 31, c) TRIPs.

14. Article 31, g) TRIPs.

15. Article 31, e) TRIPs.

non-exclusive.¹⁶ The latter implies that the licensee will not be able to stop the patentee from also producing the product at issue.

8. An interesting additional condition is that the compulsory licence must predominantly regard supply of the domestic market of the country granting such a licence.¹⁷ This condition does not apply in case a compulsory licence is granted to remedy an anti-competitive practice.¹⁸ In that case, the abovementioned requirements regarding prior negotiation and/or notification mentioned also do not apply.

9. Following the entry into force of the TRIPs Agreement in 1995, there was uncertainty among public interest groups as to whether the compulsory licencing system as described above was sufficient to ensure support of public health, especially in promoting access to existing medicines while also promoting R&D of new drugs. In a bid to quell these concerns, further negotiations between WTO member states led to the Doha Declaration¹⁹ in November 2001. This Declaration reaffirms the right of WTO member states to take measures to protect public health and, in particular, promote access to medicines for all. In this regard, it is agreed that member states may use the flexibilities built into TRIPs to the fullest extent, including the compulsory licence system in Article 31 TRIPs.

Further, in order to cater for developing countries that lack the manufacturing capacity to supply their own domestic market,²⁰ the General Council of the WTO decided in 2003 that the abovementioned condition of ‘predominantly domestic supply’ can be

16. Article 31, d) TRIPs.

17. Article 31, f) TRIPs.

18. Article 31, k) TRIPs.

19. Declaration on the TRIPs Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2, available online at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

20. See in this regard e.g. O. Ayodeji Owwoeye, “Compulsory patent licensing and local drug manufacturing capacity in Africa,” *Bull World Health Organ* 2014, n° 92, 214-219.

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waived under specific circumstances.²¹ As a result, generic copies made under compulsory licences may in some cases be exported to countries that lack production capacity.

10. This idea was translated into EU law by means of Regulation No 816/2006,²² which establishes a procedure allowing EU companies that wish to manufacture generic medicines for use in the developing world to apply for a compulsory licence to this end. This legislation and another, earlier Regulation²³ aimed at encouraging companies to sell medicines at a lower, tiered price in poor countries, were considered important steps in the EU's wider development strategy.²⁴

Implementation in Practice—Outside the EU

11. However, the practical implementation of the big ideas described above remained limited for quite some time, within the EU and throughout the world.

There have been a number of instances whereby a compulsory licence was granted on the government's initiative, such as the compulsory licence issued for AIDS drugs in Rwanda, Thailand and Brazil in 2007.²⁵

However, the first market-initiated compulsory licence for a pharmaceutical product was granted only quite recently, more specifically by a decision of the

21. Decision of the General Council of 30 August 2003, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health," WT/L/540 and Corr.1, available online at https://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm.

22. Regulation (EC) No 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, OJ L 9 June 2006, n° 157, 1-7.

23. Council Regulation (EC) 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ L 3 June 2003, n° 135, 5-11, recently repealed and replaced by Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines, OJ 24 May 2016, n° 135, 39-52.

24. See in relation to the policy of the European Commission in this context e.g. European Commission, "Access to Medicines, EU global health actions for low-and middle-income countries," Fact sheet, April 2016, available online at http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154443.pdf.

25. See in this regard E. Bond and K. Saggi, "Compulsory licensing, price controls, and access to patented foreign products," April 2012, p. 4-5, available online at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf; J.P. Love, "Recent examples of the use of compulsory licenses on patent," KEI Research Note 2007/2, available online at <https://www.keionline.org/>; and J.H. Reichman, "Compulsory licensing of patented pharmaceutical inventions: evaluating the options," 2010, available online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2893582/>.

Indian Controller of Patents dating from March 2012.²⁶ More specifically, the company Natco Pharma Ltd. was granted authorisation to produce a generic version of Bayer Corporation's patented anti-cancer medicine Nexavar, in view of the high price of this drug and its insufficient availability.²⁷ This decision was later upheld by the Bombay High Court.²⁸ In December 2014, the Supreme Court of India dismissed Bayer's special leave for appeal against this decision, rendering it final.²⁹

Implementation in Practice—Within the EU?

12. Notwithstanding the extensive legislative provisions described above, compulsory licensing within the European Union was very slow to take off. Subject to a number of notable exceptions, such as the compulsory licences announced by the Italian Competition Authority in the course of 2005-2007, almost no compulsory licences saw the EU light of day.³⁰ However, there are several elements indicating that change might be underway.

Indeed, while the use of compulsory licences has traditionally been considered as a mechanism to ca-

26. *Natco vs. Bayer*, Controller of Patents, Compulsory License Application No.1 of 2011, 9 March 2012. See in this regard F. Ali, "Nexavar: The First Market Initiated Compulsory Licence," *Nuis Law Review* 2016, Vol. 9, 229-257; E. Bonadio, "Compulsory Licensing of Patents: The Bayer/Natco Case," *EIPR* 2012, 719-728; and A. Kaur and R. Chaturvedi, "Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma," *J Intellect Prop Rights* 2015, 284.

27. See in this regard e.g. V. Bajaj and A. Pollack, "India Orders Bayer to License a Patented Drug," *The New York Times* 12 March 2012, available online at <http://www.nytimes.com/2012/03/13/business/global/india-overrules-bayer-allowing-generic-drug.html> and A. Jha, M. Antanl and G. Gokhale, "First compulsory license likely to impact the pharmaceutical industry in India," *Pharma Focus Asia* 2012, n° 16, 20-23.

28. See *Natco v. Bayer*, OA/35/2012/PT/MUM; *Bayer v. Union of India*, W.P. Number 1323 of 2013, available at <http://bombayhighcourt.nic.in>.

29. See e.g. Reuters, "Bayer fails to block generic cancer drug in India's top court," 12 December 2014, available online at <https://www.reuters.com/article/us-bayer-india-ruling/bayer-fails-to-block-generic-cancer-drug-in-indias-top-court-idUSKBN0JQ1XA20141212>. See also S. Basheer and R. Samuel, "Bayer's Nexavar and the "working" of compulsory licensing: mind the patent (information) gap!," April 2015, 16 pages, available online at <https://spicyip.com/wp-content/uploads/2015/04/Report-on-Bayer-for-writ-Finalized.pdf>.

30. See more information at https://www.keionline.org/wp-content/uploads/Annex_B_European_Union_Compulsory_Licenses_1Mar2014_8_5x11_0.pdf. See also extensively from the perspective of health management and health economics N.G. Cherian, "Using Compulsory Licenses to access pharmaceuticals: A Cross Case Analysis on Outcomes," 2016, available online at https://www.duo.uio.no/bitstream/handle/10852/54054/Cherian_Thesis_Nov2016.pdf?sequence=1.

ter to the needs of developing countries (often not without criticism from the West),³¹ more and more upper-income countries in the European Union and elsewhere are now also showing an interest in making the compulsory licencing system work to their advantage.³²

Germany: the Raltegravir Judgment of the Federal Court of Justice

13. On 31 August 2016, the Federal Patent Court (*Bundespatentgericht* or “BPG”) granted a compulsory licence to Merck by means of a preliminary injunction, thereby authorising Merck to continue the commercialisation of its antiretroviral drug “Isentress” (with active ingredient raltegravir) on the German market.³³

In August 2015, patentee Shionogi had filed infringement proceedings before the Regional Court of Düsseldorf (*Landgericht* or “LG”) against Merck, requesting injunctive relief. However, at the beginning of 2016, Merck filed a request with the BPG to grant a compulsory licence by way of a preliminary injunction. The BPG granted this request and, in July 2017, this decision was affirmed by the Federal Court of Justice (*Bundesgerichtshof* or “BGH”).³⁴ The BGH’s decision was hailed by many as a breakthrough, potentially opening up the way for more compulsory licences in Germany.³⁵

31. See in this regard e.g. J. Tudor, “Compulsory licensing in the European Union,” *Geo. Mason J. International Com. Law* 2012, Vol. 4, 226-227.

32. See e.g. E.F.M. ‘T Hoen, P. Boulet and B.K. Baker, “Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation,” *Journal of Pharmaceutical Policy and Practice* 2017, 2-3, available online at <https://doi.org/10.1186/s40545-017-0107-9> and P.R. Slowinski, “Comment on the German Federal Supreme Court Decision “Raltegravir.” *Patent Act*, Secs. 24, 85(1), IIC 2018, 129. See for a less than enthusiastic observation in this regard A. Houldsworth, “Compulsory licensing threat in Europe requires vigilance from pharma patent owners,” 15 December 2017, available online at www.lexology.com.

33. See for an extensive review of the state of the law in Germany before this judgment P. Maume, “Compulsory Licensing in Germany,” in R.M. Hilty and K. C. Liu, *Compulsory Licensing, MPI Studies on Intellectual Property and Competition Law 22*, Berlin-Heidelberg, Springer-Verlag, 2015, 95-120.

34. Decision of the Federal Supreme Court (Bundesgerichtshof) 11 July 2017—Case No. X ZB 2/17.

35. See e.g. P.R. Slowinski, “Comment on the German Federal Supreme Court Decision “Raltegravir.” *Patent Act*, Secs. 24, 85(1), IIC 2018, 130; R. Teschemacher, “German Federal Court of Justice confirms the compulsory license granted by way of a preliminary injunction for the AIDS drug Isentress; the EPO Board of Appeal then revokes the European patent,” IP Report Patent Law by Bardehle Pagenberg, 2017, p. 6 and J. Wild, quoting J. Pitz, in “Recent decision opens up the possibility of more compulsory licensing in Germany,” 13 November 2017, <http://www.iam-media.com>.

The question arises whether the BGH’s decision would pass the test of the Federal Constitutional Court (*Bundesverfassungsgericht* or “BVG”). However, subsequent to the BGH’s decision, the EPO Board of Appeal revoked³⁶ the patent at issue, thereby precluding a further constitutional appeal by Shionogi. The BGH’s decision has therefore become final.

14. In relation to the required public interest, the BGH ruled that the meaning of this concept is in constant flux. In accordance with the principle of proportionality, the public interest at issue must be weighed against the protected interests of the patentee. If the public interest may be met by way of another measure, no compulsory licence may be granted. However, according to the BGH, a public interest in the grant of a compulsory licence for a medical product can exist even when only a relatively small group of patients is affected. This is the case in particular when this group would be exposed to an especially high risk if the medicament in question were no longer available.

15. The decision of the BGH is the first to lay down clear rules regarding the prerequisites for the grant of a compulsory licence in the EU. Importantly, it shows that the applicability of compulsory licences is not limited to developing countries.³⁷ Further, it clarifies that a FRAND offer is not required for a compulsory licence to be granted.³⁸ It may serve as a precedent, inciting other companies to request a compulsory licence when they are confronted with infringement claims.

Legislative Initiatives and Regulatory Hurdles

16. The German decision might have even spurred on the new Dutch Minister for Health, Mr. Bruno Buins, who announced on 22 November 2017 that he would take all necessary action to tackle high pricing of pharmaceutical drugs. In this regard, Mr Buins expressly informed the Dutch parliament that his

36. EPO, Technical Board of Appeal 3.3.01, T 1150/15, decision of October 11, 2017.

37. Cf. P.R. Slowinski, “Comment on the German Federal Supreme Court Decision “Raltegravir.” *Patent Act*, Secs. 24, 85(1), IIC 2018, 129.

38. See in relation to the meaning of “FRAND terms” and a “FRAND offer” one of our previous Scoops from Europe, with reference P. Cappuyns and J. Vanherpe, “Europe Takes on FRAND Licensing—Again,” *les Nouvelles—Journal of the Licensing Executives Society*, LII 2017, n° 3, 122-126.

39. See for online media coverage in Dutch e.g. <https://www.zorgvisie.nl/bruins-onderzoekt-mogelijkheden-dwanglicentie/>; <https://www.nrc.nl/nieuws/2017/11/23/minister-grens-opzoeken-om-farmaceut-onder-druk-te-zetten-14171115-a1582199>; and <https://fd.nl/economie-politiek/1228784/minister-ziet-dwanglicenties-als-serieuze-optie-in-strijd-tegen-dure-geneesmiddelen>. See in English e.g. <https://medicineslawandpolicy.org/2017/11/medicines-excitement-in-the-netherlands-new-health-minister-announces-firm-action-on-absurd-medicines-pricing-and-gets-the-european-medicines-agency/>.

Ministry would extensively explore the possibilities of compulsory licensing of patents for drugs that are considered to be too expensive.³⁹ The Minister presumably got this idea from the Dutch Council for Public Health and Society, which published a report on the development of new medicines at the beginning of November 2017.⁴⁰ In its report, the Council outlined a number of possibilities to tackle high pricing of medicines, including the grant of compulsory licences.⁴¹

17. It is as yet uncertain where the plans of the Dutch Minister will lead. His ambitious objectives might be thwarted by EU medicines regulations, more specifically the rules on data and market exclusivity.⁴² These rules can prevent the registration of a generic, even when a compulsory licence to produce is granted.

18. EU law⁴³ grants a period of data exclusivity to innovator companies, during which the data they gathered in the course of pre-clinical and clinical trials may not be referenced in the regulatory filings of another company for the same drug substance.

In order to obtain regulatory approval for drugs, the applicant(s) must provide the regulatory authority with a substantial body of data proving that their product is efficacious and safe. Generic companies that wish to subsequently enter the market usually rely on the information initially filed by the innovator company. However, as a result of data exclusivity, the generic company has to wait for a substantial period before being able to file for regulatory approval of their prod-

uct themselves, namely eight years following the initial market authorisation for the originator product. Moreover, in view of the additional market exclusivity, the generic product may not be commercialised for ten years after grant of this marketing authorisation. In certain circumstances, the originator's exclusivity may be extended by another year, *e.g.* if the market authorisation was granted for a significant new indication for the relevant medicinal product. Therefore, for a period of maximum eleven years after grant of the initial market authorisation—even if a compulsory licence is granted—an alternative to the originator product cannot be marketed within the European Union, unless the originator's data and market exclusivity is waived.⁴⁴ Such a waiver already exists in abovementioned Regulation No 816/2006 (paragraph 10).⁴⁵

Conclusion

19. Recent developments indicate that the use of compulsory licences in developed countries and in the European Union is gathering momentum. However, in view of the current EU rules on data and market exclusivity we do not believe that the grant of compulsory licences for patent-protected pharmaceuticals will soon become commonplace. It remains to be seen what recent legislative initiatives, such as the plans of the Dutch Minister for Health, will achieve in this regard. ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=3166254>

40. Raad voor Volksgezondheid en Samenleving, "Ontwikkeling nieuwe geneesmiddelen. Beter, sneller, goedkoper," November 2017, 88 pages, available online at https://www.raadrsv.nl/uploads/docs/RVS_Advies_Ontwikkeling_nieuwe_geneesmiddelen.pdf.

41. See in particular pages 41 through 45 of this document.

42. See for a convincing argument for greater coherence in this regard E.F.M. 'T Hoen, P. Boulet and B.K. Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation," *Journal of Pharmaceutical Policy and Practice* 2017, 9 pages, available online at <https://doi.org/10.1186/s40545-017-0107-9>.

43. Article 14, §11 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 30 April 2004, 1-33 and Articles 10, §1 and §5 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 30 April 2004, n° 136, 34-57 (as implemented in the national law of the EU member states).

44. Cf. E.F.M. 'T Hoen, P. Boulet and B.K. Baker, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation," *Journal of Pharmaceutical Policy and Practice* 2017, p. 4-6, available online at <https://doi.org/10.1186/s40545-017-0107-9>.

45. See Article 18 of this Regulation.