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ON COMPULSORY LICENSING OF TRADE SECRETS TO SAFEGUARD PUBLIC HEALTH

OLGA GURGULA* AND LUKE MCDONAGH**

ABSTRACT. *In the pharmaceutical sector an increasing number of new medicines are large-molecule products, namely biologics derived from living organisms, rather than small-molecule drugs synthesised from chemicals. Unlike small-molecule medicines, which are relatively easy to manufacture, large-molecule products are less stable and harder to produce. We investigate whether the current UK legal system provides an appropriate balance between the protection provided to technology owners and the public interest in accessing medical technologies, especially in times of emergencies. At present, UK law facilitates compulsory licensing of patents but has no equivalent scheme for trade secrets. Our analysis of the legal constraints on potential reforms suggests that a mechanism for compulsory licensing of trade secrets would be compatible with UK domestic law, the European Convention on Human Rights, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, provided appropriate safeguards are put in place to balance the rights of intellectual property holders with the public interest. The article contributes a detailed framework for the compulsory licensing of trade secrets, drawing parallels with voluntary technology transfer agreements, including provisions for defining the scope of transfer, maintaining confidentiality, restricting future use, providing fair compensation and ensuring enforceability.*

KEYWORDS: *trade secrets, patents, medicines, compulsory licensing, technology transfer.*

I. INTRODUCTION

In the pharmaceutical sector an increasing number of new medicines are large-molecule products, namely biologics derived from living organisms,

*Senior Lecturer, Brunel University London. Address for correspondence: Email: Olga.gurgula@brunel.ac.uk.
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**Associate Professor, LSE Law School, London School of Economics. Email: L.t.mcdonagh@lse.ac.uk.

rather than small-molecule drugs synthesised from chemicals. Six out of 10 of the bestselling medicines in 2022 were large-molecule products, including two vaccines and four treatments.[1] Unlike small-molecule medicines, which have a stable structure and are relatively easy to manufacture, large-molecule products are more complex, less stable and harder to produce. As the complexity of pharmaceutical innovation has increased, so has the protection of pharmaceutical products. In addition to patents, companies rely on trade secrets.[2] While patent documents are accessible to the public through databases operated by patent offices, the law of trade secrets protects confidential knowledge that gives an economic advantage to the holder precisely because such information is not known by competitors.[3] The combination of (disclosed) patents and (undisclosed) trade secrets provides a significant level of legal protection. Given the growing importance of large-molecule products, we investigate whether the current UK legal system provides an appropriate balance between the protection provided to technology owners and the public interest in accessing medical technologies.

The traditional justification of a patent's 20-year exclusionary right is to create incentives to invest in research and development, while simultaneously operating as a "bargain" – with the patent granted in return for disclosing the invention on the public database at the patent office.[4] Nevertheless, the patent disclosure requirement underperforms in the case of multifaceted medical products such as large-molecules, which are typically covered by dozens of patents.[5] The problem is not that every patented invention that makes up the large-molecule product may be insufficiently disclosed. Rather, the challenge is that where there are multiple patents covering different "inventions" within the large-molecule product, even if each individual invention is sufficiently disclosed, the various individual patent specifications may not explain how to combine the numerous inventions to manufacture the final product.[6] Instead, some technical know-how and manufacturing processes are retained by originator firms as trade secrets and, as we explain below, unlike patents, there is no obligation imposed on the pharmaceutical company to disclose information protected by trade secrets. For large-molecule products trade secrets may include information on the process of

[1] L. Urquhart, "Top Companies and Drugs by Sales in 2022" (2023) 22 Nature Reviews Drug Discovery 260. The two vaccines were for COVID-19 but the four bestselling treatments were unrelated to COVID-19.
[2] S. Thambisetty et al., "Addressing Vaccine Inequity during the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond" [2022] C.L.J. 384.
[3] M. Risch, "Why Do We Have Trade Secrets?" (2007) 11 Marquette Intellectual Property Law Review 1.
[4] A. Devlin, "The Misunderstood Function of Disclosure in Patent Law" (2010) 23 Harvard Journal of Law & Technology 401.
[5] J.C. Fromer, "Dynamic Patent Disclosure" (2015) 69 Vanderbilt Law Review 1715, 1727–28.
[6] R. Feldman, "Trade Secrets in Biologic Medicine: The Boundary with Patents" (2022) 24 Columbia Science and Technology Law Review 1, 33–38.

manufacture, specific (unpatented) medical formulae, cell lines, genomic information and other biological materials and samples.[7] In addition, pharmaceutical companies consider certain manufacturing and clinical data submitted to regulatory authorities, such as the UK Medicines and Health products Regulatory Agency ("MHRA"), as their trade secrets.[8]

Without access to the relevant trade secrets, it may be difficult, if not impossible, for any firm other than the originator to manufacture the exact large-molecule product. This marks a distinction from older technologies such as small-molecule drugs, which can be reverse engineered, or replicated relatively easily using available patent information, without the need to access trade secrets. This distinction has real consequences. As we note below, the problem came to light during the COVID-19 pandemic, when several potential producers of vaccines found trade secrecy to be a considerable barrier to their efforts to boost production of needed vaccines.[9]

A normative question arises: does the current system provide an appropriate balance between the rights of the originator firm and the public interest in accessing a specific technology? One way the existing system seeks to strike this balance is through voluntary licensing of patents and trade secrets via technology transfer agreements. While this may be a preferred option, given that voluntary agreements aim to satisfy both parties, there are certain circumstances, such as a health emergency, where reliance on voluntary negotiations may not be effective, namely when an owner refuses to license. An alternative option is via compulsory licensing. A compulsory licence is a permission granted by a state authority that authorises a third party to use a patented invention without the holder's consent, but with compensation provided.[10] At present, although the UK legal system provides for compulsory licensing of patents, there is no equivalent provision for trade secrets. The result is that if there were an urgent need to access a specific large-molecule medicine and the UK Government decided to issue a compulsory patent licence to an alternative producer to make that exact product, without voluntary sharing of trade secrets by the originator, it is unlikely that such a licence would be sufficient to facilitate alternative production. By refusing to transfer the relevant trade secrets, the originator could block the effect of the UK Government's action during a crisis.

Recent scholarly literature highlights these concerns. Dreyfuss remarks that the increased use of trade secrets in the pharmaceutical industry raises access

[7] O. Gurgula and J. Hull, "Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer" (2021) 16 Journal of Intellectual Property Law & Practice 1242.
[8] Human Medicines Regulations 2012, SI 2012/1916, reg. 332.
[9] Thambisetty et al., "Addressing Vaccine Inequity", 398–404.
[10] C.M. Correa, "Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents" (2020) South Centre Research Paper No. 107.

and welfare issues that the intellectual property ("IP") system has yet to come to terms with.[11] Aplin and Liddicoat note that an originator's refusal to disclose trade secrets could impede the usefulness of compulsory licensing of patents on a vaccine, concluding that there is no obvious way to mitigate this problem under the current law in the UK or EU.[12] Li-Dar Wang suggests that an ancillary order, granted by a court, could compel trade secret transfers to ensure the effectiveness of compulsory licensing of patents, but admits this method is untested.[13] Gurgula and Hull suggest that an additional mechanism in international law to facilitate compulsory licensing of trade secrets would add much-needed legal clarity.[14]

Additionally, the literature indicates that the UK legal system has shortcomings compared with other jurisdictions.[15] For instance, US law offers several non-voluntary, government use options that go beyond what UK law allows.[16] Levine and Sarnoff show the US possesses a mixture of formal and informal means to mandate trade secret transfers,[17] with the US making use of some of these options in the context of the COVID-19 vaccine accelerator Operation Warp Speed, which we discuss further below.[18] To clarify the extent of the US Government's powers, they recommend creating a new "emergency powers" exception within federal trade secret law to authorise compelled trade secret transfers. Meanwhile, Morten and Kapczynski argue that the US Food and Drug Administration has the authority to disclose the confidential regulatory data it holds.[19] In EU law, Aplin explains that the Data Act recently implemented a mechanism akin to a compulsory licence of trade secrets, requiring a data holder to transfer trade secret data to a recipient who can demonstrate they will maintain data secrecy.[20]

[11] R.C. Dreyfuss, "Trade Secrets and Deep Secrets" (2024) NYU Law and Economics Research Paper No. 24–37.

[12] T. Aplin and J. Liddicoat, "Discussion Paper on the Interplay between Patents and Trade Secrets in Medical Technologies", available at https://www.wipo.int/edocs/mdocs/scp/en/wipo_ip_covid_ge_2_22/wipo_ip_covid_ge_2_22_paper.pdf (last accessed 27 August 2025).

[13] R. Li-Dar Wang, "Ancillary Orders of Compulsory Licensing and their Compatibility with the TRIPS Agreement" in R. Hilty and L. Kung-Chung (eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (Heidelberg 2015).

[14] Gurgula and Hull, "Compulsory Licensing".

[15] C.J. Morten and C. Duan, "Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises" (2020) 23 Yale Journal of Law & Technology 1.

[16] US Defense Production Act of 1950. See also US "march in" rights over technologies that were developed using public funds: The Trademark Law Amendments Act of 1980 (The Bayh-Dole Act).

[17] D.S. Levine and J.D. Sarnoff, "Compelling Trade Secret Sharing" (2023) 74 Hastings Law Journal 987.

[18] J. Love, "KEI Review of 62 COVID 19 Contracts Reveals 59 Authorizations for Non-Voluntary Use of Third Party Patents under 28 USC 1498", available at https://www.keionline.org/37987 (last accessed 27 August 2025).

[19] C.J. Morten and A. Kapczynski, "The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines" (2021) 109 California Law Review 493.

[20] See Commission Regulation (EU) No 2023/2854, art. 5(9), as discussed by T. Aplin, "The Data Act and Trade Secrets: An Experiment in Compulsory Licensing" in A. Sattler and H. Zech (eds.), *The Data Act: First Assessments* (Trier 2024).

This issue is timely. Several legal systems are grappling with pandemic preparedness and reform. From 2023 to 2025, the EU considered a new compulsory licensing regime that, in the European Commission's initial proposal, sought to facilitate transfer of "necessary" pharmaceutical information on products needed in a crisis.[21] Developing an international approach to compelling transfer of knowledge on manufacture of medical products was a relevant issue during the 2021–25 negotiations over the World Health Organization ("WHO") Pandemic Agreement.[22] However, despite extensive EU[23] and WHO[24] discussions on the need to implement an additional mechanism for the involuntary transfer of trade secrets, the eventual texts of both documents – the EU provisional agreement on a Regulation[25] and the WHO Pandemic Agreement[26] – lack such a mechanism. This is unfortunate because, as noted above, compulsory licensing of patents is inadequate for producing large-molecule medicines without a corresponding method of compelling disclosure of essential manufacturing knowledge, a gap that we argue necessitates a targeted legislative response.

In this regard, our paper offers a novel contribution by focusing on doctrinal and normative aspects of the protection of trade secrets in the UK jurisdiction and providing a detailed proposal for legislative reform. We begin by reviewing the nature and purpose of compulsory licensing of patents in the context of medicines, noting that current UK law does not provide a mechanism for compulsory licensing of trade secrets from an originator to an alternative producer. This leads us to ask: should the UK have an equivalent compulsory licensing regime for trade secrets as for patents? Specifically, we consider whether there are cogent reasons for why we might allow patents to be licensed on a compulsory basis, but not allow the same for trade secrets. Answering this requires us to

[21] Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, "Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006", available at https://single-market-economy.ec.europa.eu/document/download/95b319e8-e594-4ad2-97e0-7340d9adfc6c_en?filename=COM_2023_224_1_EN_ACT_part1_v11.pdf (last accessed 27 August 2025). See also O. Gurgula, "On the European Commission's Proposal to Create a New EU-Wide Compulsory Licensing Regime" (2024) 46 European Intellectual Property Review 70.

[22] A. Hampton et al., "Equity in the Pandemic Treaty: Access and Benefit-Sharing as a Policy Device or a Rhetorical Device?" (2023) 51 Journal of Law, Medicine & Ethics 217.

[23] "Report on the Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006 (COM(2023) 0224)", available at https://www.europarl.europa.eu/doceo/document/A-9-2024-0042_EN.html (accessed 27 August 2025).

[24] O. Gurgula and L. McDonagh, "Proposal for a New Article 11bis in the WHO Pandemic Accord: A Pandemic Technology Transfer Mechanism", Southviews No. 261, available at https://www.southcentre.int/southviews-no-261-23-april-2024/ (last accessed 27 August 2025).

[25] Council of the European Union, "Provisional Agreement on a New Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006, ST 10213/2025 INIT", available at https://data.consilium.europa.eu/doc/document/ST-10213-2025-INIT/en/pdf (accessed 27 August 2025).

[26] World Health Organization, "WHO Pandemic Agreement, WHA78.1 (20 May 2025)", available at https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf (accessed 27 August 2025).

examine the various doctrinal and political constraints on potential reform. We emphasise that patents and trade secrets have important variances that suggest that limitations to trade secret protection would need to operate differently from those related to patents. Our analysis focuses on the relevant laws in the UK – the English doctrine of breach of confidence, medical regulation law and freedom of information law. We also assess the right to property under the European Convention on Human Rights ("ECHR") and the UK's international obligations under the World Trade Organization ("WTO") Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and other free trade agreements and bilateral treaties.[27] TRIPS is of particular significance because it is the pre-eminent international IP agreement, adhered to by 166 WTO members as of 2025.

Having outlined the constraints, we offer a proposal on how compulsory licensing of trade secrets could work within the UK legal system, both to complement a compulsory patent licence and, potentially, as a standalone measure when, for example, patents have expired, but manufacturing know-how remains secret. We specify that the relevant trade secrets to be licensed should encompass both the necessary manufacturing information and any sample(s) of the product (e.g. vaccine) needed for analysis/comparison purposes. We do not limit this proposal to health emergencies, but we note that a pandemic would be an example of when such a scheme could prove useful. Although our focus is on compulsory licensing and medicines, we do not rule out that our analysis could be relevant to future debates about other forms, such as climate-related technologies.

Finally, we conclude that to make the system fully functional, additional reforms of the IP system would be required. Although a full assessment of these is beyond the scope of our paper, we suggest directions for future scholarly consideration, including making amendments to the Patents Act 1977 to streamline compulsory licensing of patents, as well as to facilitate the suspension of regulatory exclusivities.

II. Is the Framework for Compulsory Licensing of Patents Fit for Purpose?

Given the function of intellectual property is to prevent others from making the protected product, it is no surprise that the need to balance strong patent protection with access provisions has long been acknowledged at the national and international levels. Yet, as we shall see, until recently the role of trade secrets has been overlooked in legislation and in the academic literature.

[27] TRIPS, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994) (in force since 1995, as amended on 23 January 2017).

Article 31 TRIPS contains flexibilities, such as compulsory licences and government use, that can restrict patent rights.[28] This capability was bolstered in November 2001 when the Doha Declaration on the TRIPS Agreement and Public Health confirmed that the granting of compulsory licences to safeguard health is a TRIPS flexibility which all WTO members have the right to use.[29] Although emergencies are the primary scenario in which the use of such flexibilities may be required, compulsory licensing of patents is not limited to crises. Since the coming into force of TRIPS in 1995 most compulsory licences on patents have been granted by developing countries on small-molecule treatments for such diseases as HIV and hepatitis C, in contexts such as the unavailability of the product in that market, or the high prices charged by the patent owners.[30]

The TRIPS compulsory licensing system attracted scrutiny during the COVID-19 pandemic in the context of large-molecule products, namely vaccines.[31] Several COVID-19 vaccines were developed in 2020 via the public–private voluntary licensing model, such as the Oxford-AstraZeneca vaccine and the National Institutes of Health-Moderna vaccine. However, production and distribution inequities became apparent during the pandemic, with many lower and middle-income countries ("LMICs") unable to secure vaccine supplies.[32] Despite this, pharmaceutical companies rejected requests for voluntary licensing of vaccine technologies to WHO initiatives such as the COVID-19 Technology Access Pool ("C-TAP") and the WHO mRNA hub.[33] Firms also refused several offers to take voluntary licences from LMIC manufacturers with production capacities.[34] Greater technology transfer to such LMIC manufacturers would have encouraged more distributed production of vaccines worldwide, thereby assisting in attaining global

[28] TRIPS, art. 31.

[29] Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial (WT/MIN(01)/DEC/2, adopted 14 November 2001).

[30] See The TRIPS Flexibilities Database, available at http://tripsflexibilities.medicineslawandpolicy.org/ (last accessed 27 August 2025).

[31] J. Crombie, "Intellectual Property Rights Trump the Right to Health: Canada's Access to Medicines Regime and TRIPS Flexibilities in the Context of Bolivia's Quest for Vaccines" (2021) 17 Journal of Global Ethics 353.

[32] Thambisetty et al., "Addressing Vaccine Inequity", 388–92.

[33] See M. Safi, "WHO Platform for Pharmaceutical Firms Unused since Pandemic Began", *The Guardian*, available at https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began (last accessed 27 August 2025); and A. Maxmen, "The Radical Plan for Vaccine Equity", *Nature*, available at https://www.nature.com/immersive/d41586-022-01898-3/index.html (last accessed 27 August 2025).

[34] See A. Furlong, "Big Vaccine Makers Reject Offers to Help Produce More Jabs", *Politico*, available at https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/ (last accessed 27 August 2025). See also A. Prabhala and A. Alsalhani, "Pharmaceutical Manufacturers across Asia, Africa and Latin America with the Technical Requirements and Quality Standards to Manufacture mRNA Vaccines", available at https://msfaccess.org/sites/default/files/2021-12/COVID19_TechBrief_Manufacturing-mRNA-Report-10DEC2021_ENG_0.pdf (last accessed 27 August 2025).

coverage.[35] Yet, when the voluntary model fell short, LMICs lacked the legal mechanisms to compel trade secret transfer.[36]

Meanwhile, certain high-income states contemplated or utilised involuntary IP mechanisms.[37] In relation to patents, the US granted 59 "authorisations for non-voluntary use" to private companies, including Moderna, as part of Operation Warp Speed.[38] Simultaneously, the US Government facilitated the National Institutes of Health ("NIH"), the Biomedical Advanced Research and Development Authority ("BARDA") and Moderna to share mutual expertise, including know-how.[39] This led to the creation of the NIH-Moderna vaccine.

Although Moderna pledged voluntarily not to enforce its vaccine patents during the pandemic, the firm refused to license its trade secrets to the WHO mRNA hub, located at the firm Afrigen in South Africa, that sought to produce a mRNA vaccine for African use. This delayed the work of the hub, showing how a refusal to share trade secrets can block production of a vaccine in a scenario where the patents were not at issue. As we detail below, eventually the NIH stepped in to assist Afrigen by sharing mRNA know-how.[40] For present purposes, the above highlights the limits of the voluntary licensing model and the problem that can arise when there is no mechanism to compel trade secret licensing.

A. UK Law: Compulsory Licensing in the Patents Act 1977

In the UK, government authorised use of patents has a statutory history that long predates TRIPS.[41] In the late-nineteenth and early-twentieth centuries, government authorisation facilitated unlicensed military usage of patented technologies, for which the UK Government would decide the amount of compensation given.[42] During World War I, the UK passed legislation to allow the expropriation of foreign IP, including over medical technologies,

[35] P. Ranjan and P. Gour, "The TRIPS Waiver Decision at the World Trade Organization: Too Little Too Late!", (2023) 13 Asian Journal of International Law 10.

[36] See Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19, Communications from India and South Africa, 2 October 2020 (IP/CW/669). For the final WTO Ministerial Decision on these proposals, see Draft Ministerial Decision on the TRIPS Agreement, 12th Ministerial Conference, 17 June 2022 (WT/MIN(22)/W/15/Rev.2).

[37] T. Musmann, "German Government Plans Possibilities to Limit Patents in View of Corona Pandemic", available at https://patentblog.kluweriplaw.com/2020/03/24/german-government-plans-possibilities-to-limit-patents-in-view-of-corona-pandemic/ (last accessed 27 August 2025).

[38] Love, "KEI Review".

[39] "Statement from NIH and BARDA on the FDA Emergency Use Authorization of the Moderna COVID-19 Vaccine", available at https://www.nih.gov/news-events/news-releases/statement-nih-barda-fda-emergency-use-authorization-moderna-covid-19-vaccine (last accessed 27 August 2025).

[40] Maxmen, "Radical Plan".

[41] P. Johnson, "Scoping Crown Use: Authorizing Infringement for the Services of the Crown" (2020) 15 Journal of Intellectual Property Law & Practice 594, 599.

[42] See e.g. Patents, Designs, and Trade Marks Act 1883, s. 22; and Patents and Designs Act 1919, s. 8.

such as Salvarsan, a German-originated syphilis treatment.[43] In the 1960s, the UK Ministry of Health utilised Crown use – government-ordered authorisation – to obtain low cost pharmaceutical products.[44] Yet, since the 1960s there has been little use of involuntary mechanisms. One reason is that for much of this period NHS procurement has occurred successfully on commercial terms with firms, with the NHS purchasing and/or importing medicines in bulk as a single-payer. Nonetheless, this relationship may now be fraying. Concerns over access to expensive medicines are increasingly prevalent in the UK.[45] In 2018–19, delays in securing NHS procurement of a cystic fibrosis treatment (Orkambi) led to calls for the Government to utilise Crown use of the relevant Vertex-owned patents for local production for UK needs.[46]

Currently, involuntary use of patents is regulated by sections 46–59 of the Patents Act 1977. There are two options: (1) compulsory licensing; and (2) the aforementioned Crown use. For the first, the key provision is in section 48, requiring an application to the Comptroller of Patents at the UK Intellectual Property Office ("IPO") for a compulsory licence, or for a licence to be available "as of right". This would amount to an authorisation, granted by the UK IPO, to allow the recipient to use the invention without the consent of the patent holder. Such applications are usually made by a private producer who wishes to manufacture the patented product (though a government department can apply).[47] The second option, Crown use, is regulated by section 55 of the Patents Act 1977. As noted above, government use involves the state authority granting an authorisation on patents for its own use, either by a state agency or department, or by a private entity that aims to supply the needs of the Government.[48]

Although seldom used, the patent aspect of the UK's compulsory licensing/Crown use system appears to be operable. This is not to say that the system has no flaws[49] – indeed, we return to the topic of minor reforms to compulsory licensing of patents later in this article.

[43] Trading with the Enemy Act 1916, ss. 5, 6. See P. Johnson, "Access to Medicine: The Rise of the British Pharmaceutical Industry" in G. Dinwoodie (ed.), *Methods and Perspectives in Intellectual Property* (Cheltenham 2013).

[44] *Pfizer Corporation v Ministry of Health* [1965] A.C. 512 (H.L.).

[45] H. Thomas, "A Tussle over Medicines Pricing Is Looming in Britain", *Financial Times*, available at https://www.ft.com/content/20e235da-f9bb-45cc-98c2-ec2c1640b618 (last accessed 27 August 2025).

[46] S. Boseley, "Calls for Action on Patients Denied £100,000 Cystic Fibrosis Drug", *The Guardian*, available at https://www.theguardian.com/science/2019/feb/03/nhs-cystic-fibrosis-drug-orkambi-vertex (last accessed 27 August 2025). See also the relevant debate in the House of Commons at HC Deb. vol. 654 cols. 135–44 (4 February 2019), available at https://hansard.parliament.uk/Commons/2019-02-04/debates/12C071ED-9463-4502-8625-89B910AD12F5/Orkambi?highlight=care (last accessed 27 August 2025).

[47] *Swansea Imports Limited v Carver Technology Limited* [2004] UK IPO (O/170/04).

[48] Patents Act 1977, ss. 55, 59. For a discussion on whether such authorisation must be express, see *IPCom GmbH & Co. KG v Vodafone Group Plc* [2021] EWCA Civ 205, [2021] Bus. L.R. 813, at [155] (Arnold L.J.).

[49] J.E. Liddicoat and J. Parish, "Ironing Out the Wrinkles: Reforms to Crown Use and Compulsory Licensing to Help Prepare the Patents Acts 1977 for the Next Health Crises" (2021) 4 Intellectual Property Quarterly 245.

Nevertheless, even under the current law, in a crisis involving a shortage of a small-molecule drug which is relatively easy to produce using the formula provided in the patent information, the UK system should facilitate compulsory production. This is because even if a process of manufacture were kept as a trade secret, once the alternative manufacturer has obtained the compulsory licence for the patent(s), the firm should be able to develop a substitute process for making the small-molecule product without them needing to access the specific confidential method developed by the originator.

There is one other option. In a case of a shortage of a small-molecule drug, in theory an alternative producer could decide to go ahead and manufacture even without obtaining a compulsory patent licence or a Crown use authorisation. The producer could utilise a combination of reverse engineering and public patent information to make the drug.[50] This would be a kind of strategic infringement by the producer to serve the public need. If this strategic infringement by the producer were challenged by the patent holder, a UK court would have discretion to decide that the best way to remedy the infringement would be to refuse injunctive relief (given the emergency) and to require reasonable damages or royalties.[51] This would effectively operate as a compulsory licence granted under conditions by the court.[52] Nonetheless, the risk of an injunction being granted is high and so the option of the upfront compulsory licence remains preferable to strategic infringement.[53]

In contrast, with a large-molecule medicine that cannot be produced using patent information alone, in the absence of voluntary licensing of trade secrets by the originator, current UK law would be ineffective at facilitating access. Although the Patents Act 1977 provides for compulsory licensing of patents, there is no comparable mechanism for compulsory licensing of trade secrets.[54] For example, if the UK Government were to offer an IP-holder a monetary inducement to encourage voluntary technology transfer of know-how to an alternative producer and this offer were refused, UK law provides no clear route to compel this transfer, by sanction or otherwise. Unlike the US Government's powers under the Defense Production Act, there is no evident UK executive power that would enable the Government to

[50] T. Aplin, "Reverse Engineering and Commercial Secrets" (2013) 66 Current Legal Problems 341.
[51] Sarnoff relates that in the US this ability to infringe applies both to patent rights and to trade secrets already in the Government's possession; see J.D. Sarnoff, "TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection" (2020) South Centre Research Paper No. 119.
[52] J.L. Contreras and J. Maupin, "Unenjoined Infringement and Compulsory Licensing" (2023) 37 Berkeley Technology Law Journal 662.
[53] A stay of injunction was refused, for example, in *Evalve Inc v Edwards Lifesciences Ltd.* [2020] EWHC 513 (Pat), [2020] R.P.C. 13, at [54]–[55] (Birss J.).
[54] Patents Act 1977, ss. 46–59.

compel a private company to transfer trade secrets.[55] It is possible that the UK Government might try to assert such an executive power or pass emergency legislation. Yet, it is uncertain what the Government might do and what the legal consequences would be, for example, whether a specific executive action would be challenged via judicial review.[56] Amid this uncertainty, without access to trade secrets – namely manufacturing information and a sample – the alternative producer would not be able to manufacture the exact large-molecule product.

B. Does the UK Legal System Provide Any Route to Accessing Trade Secret Information?

One possible route to obtaining additional information on the manufacture of a large-molecule product is via accessing the regulatory data held by the MHRA. The marketing authorisation dossier supplied to the MHRA by a pharmaceutical company does not only include data on pharmacological tests and clinical trials;[57] it also includes detailed manufacturing information such as descriptions of manufacturing processes and data on composition of the drug product.[58] The opaque nature of the dossiers means it is not possible to be certain, but it is feasible that an alternative producer seeking to make a large-molecule product would be able to combine the existing patent documents with the dossier to learn how to manufacture it.[59]

Nevertheless, obtaining disclosure via this route is untested. The MHRA has a policy whereby if the applicant has claimed certain data as confidential information the agency will typically redact this from any disclosure.[60] The information classed as confidential is likely to include detailed descriptions of manufacturing processes, namely the exact information an alternative producer would need. Therefore, the MHRA could conclude that it should refuse to disclose the unredacted dossier.

[55] US Defense Production Act of 1950. The respective UK statute – the Defence Contracts Act 1958 – refers only to "defence", not other types of emergencies. Hence, the Defence Contracts Act 1958 was not relevant to the UK's development and procurement of COVID-19 vaccines, which fell under procurement legislation: Public Contracts Regulations 2015, SI 2015/102.

[56] An unusually broad or unprecedented assertion of executive power could be nullified via judicial review, as occurred in relation to prorogation in e.g. *R (on the application of Miller) v Prime Minister* [2019] UKSC 41, [2020] A.C. 373.

[57] See Human Medicines Regulations 2012, SI 2012/1916, para. 11, schd. 8 and para. 5, schd. 8.

[58] The MHRA confirmed to us by email that for confidential information such as manufacturing processes, applicants may clearly mark any data as commercially confidential in their submission and this will be "handled appropriately" in line with the law. The UK Public Assessment Report templates detailing how much info on method of manufacture must be provided are available at https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk#uk-public-assessment-report-ukpar-templates (last accessed 27 August 2025).

[59] The MHRA confirmed to us by email that submissions are standardised via the application documents, but it is not possible to estimate what each one contains in terms of manufacturing information.

[60] For example, the Scottish Medicines Consortium provides guidance to companies on how to complete the commercial info checklist on the New Product Assessment Form, available at https://scottishmedicines.org.uk/making-a-submission/ (last accessed 27 August 2025).

Even if a third-party manufacturer were to make a request under the Freedom of Information Act 2000 ("FOIA"), this route runs into the same problem. Although the FOIA provides that public authorities, such as the MHRA, are obliged to publish certain information about their activities upon request, there are exemptions.[61] Section 41 of the FOIA sets out an absolute exemption from the "right to know" where the information was provided to the public authority in confidence,[62] whereas section 43(1) FOIA provides a specific qualified exemption from disclosure for information which is a trade secret and section 43(2) provides a qualified exemption for information for which disclosure would be likely to prejudice the commercial interests of any legal person. As the section 43 exemptions are qualified exemptions, not absolute ones, a public interest test is applied.[63] This means that the MHRA must consider whether maintaining the section 43 exemption outweighs the public interest in disclosure of the information.[64] The question of whether the information sought was truly imparted in confidence and thus is covered by the absolute exemption in section 41, or whether it is a trade secret/commercially valuable covered only by the qualified exemptions in section 43, is assessed on a case-by-case basis.[65] To analyse how the MHRA would consider this issue, we must assess the doctrinal constraints of the law of breach of confidence, which we turn to below.

To summarise, we have outlined a problem: the lack of an operative legal mechanism to provide access to trade secrets renders the compulsory licensing system in the Patents Act 1977 unworkable in the context of large-molecule medicines. This raises the prospect of reform, but before this is considered, it is necessary to analyse whether the system can and should be reformed given the relevant constraints.

III. Should the UK Have an Equivalent Compulsory Licensing System for Trade Secrets to that for Patents? What Constraints Exist?

In this section, we outline what makes trade secrets unique within the IP system, assessing the factors – doctrinal or political – that might

[61] Information Commissioner's Office, "The Guide to Freedom of Information", available at https://ico.org.uk/media2/migrated/4020010/guide-to-freedom-of-information-4-9.pdf (last accessed 27 August 2025).

[62] See Information Commissioner's Office, "Section 41 (Information provided in confidence): Freedom of Information Act", available at https://ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/section-41-information-provided-in-confidence/ (last accessed 27 August 2025).

[63] See Information Commissioner's Office, "Section 43 (Commercial Interests): Freedom of Information Act", available at https://ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/section-43-commercial-interests/ (last accessed 27 August 2025).

[64] For a case in which the section 41 and 43 exemptions were relevant to the release of anonymised clinical trial data, see *Queen Mary University of London v Information Commissioner and Matthees* [2016] UKFTT 2015_0269 (GRC) 1, 10–11.

[65] For a case in which the tribunal held the requested information was not covered by the section 41 exemption, see *Mattha Busby v The Information Commissioner* [2023] UKFTT 305 (GRC), at [41]–[47].

constrain any proposal for compulsory licensing. Specifically, we consider whether there are cogent reasons for why we might allow patents to be licensed on a compulsory basis, but not allow the same for trade secrets. We explain that trade secrets and patents have important variances that suggest any limitations on trade secret protection may need to operate differently from those relevant to patents. We analyse UK domestic law, the ECHR, TRIPS, and free trade agreements.

A. The Rationale of Trade Secret Use

Why use secrecy rather than apply for a patent? There are several reasons.[66] First, in the period before the inventor applies for a patent, trade secrecy is used (temporarily) to protect the novelty of the invention. This is critical because if the invention is disclosed to the public before the patent application's filing date (or priority date), the patent could be denied for lack of novelty. Second, patent protection and trade secrecy can be complementary, protecting different aspects of products. Today, many firms opt for both: patents for some features of the product (discrete "inventions" such as active pharmaceutical ingredients, biological molecules, formulations, etc.), while other information, such as manufacturing know-how, is kept secret within the firm.[67] Third, for some new products trade secrets may be the only option because such products may be made up of elements, such as software or algorithms, which are difficult to patent as such due to rules on patentable subject matter.[68] As a corollary, for some products patents may be the only option, such as for information that cannot be kept secret because it is easy to reverse engineer, or where there is a risk that competitors will arrive at the same knowledge independently.[69]

Both types of protection have their advantages and drawbacks. While patents require a formal application and payment of renewal fees, trade secrets provide protection with low upfront costs. Patents require disclosing the details of an invention to the public (including competitors), whereas trade secrets allow firms to keep critical information from rivals. A patent prevents third parties from using the invention without permission, even if the third party produced the invention independently, namely without copying;[70] however, in most situations, a trade secret holder cannot prevent reverse engineering or

[66] D.S. Almeling, "Seven Reasons Why Trade Secrets Are Increasingly Important" (2012) 27 Berkeley Technology Law Journal 1091; and T. Aplin et al., *Gurry on Breach of Confidence*, 2nd ed. (Oxford 2012), at [1.08]–[1.15].
[67] A. Arundel, "The Relative Effectiveness of Patents and Secrecy for Appropriation" (2013) 30 Research Policy 611, 613.
[68] Patents Act 1977, s. 1(2).
[69] W. van Caenegem, *Trade Secrets and Intellectual Property: Breach of Confidence, Misappropriation and Unfair Competition* (Alphen aan den Rijn 2014), 4.
[70] Patents Act 1977, s. 60.

independent creation of the relevant know-how.[71] Patents are perceived as secure rights but are limited to 20 years, while trade secrets are potentially perpetual, but only so long as the knowledge is kept secret. Crucially, as we analyse below, there is much more conceptual ambiguity over the status of trade secrets within the legal system than there is over patents.

B. How Does Trade Secret Protection Fit into the IP System?

As mentioned above, the essence of a trade secret, and indeed its unique value, is in knowledge that is deliberately kept undisclosed. Yet, when we examine trade secrets from a conceptual perspective, the foundation of this type of protection appears unclear.[72] As noted above, trade secrets are not registered rights comparable to patents, trade marks or registered designs, all of which require applications, grants and renewals (and time limits, in the case of patents and designs). Trade secrets are not entirely aligned with copyright or unregistered designs either, given that unlike trade secrets, these rights expire at the end of their duration. Hence, it is not clear whether to consider trade secrets as part of the IP system, and thus afford them the features of a property right, or to view them as part of non-proprietary regimes (such as equity or unfair competition).[73]

In the literature, some scholars argue that trade secrets are not IP rights due to the way trade secrets are often linked to misappropriation and unfair competition (as in Article 39 TRIPS, analysed below), whereas other scholars consider that trade secrets share enough similarities to IP rights – such as control over information – that they should be understood as akin to IP.[74] Some argue that trade secret protection is a hybrid right sharing traits of both IP and unfair competition.[75] As outlined below, the UK legal system has not provided a definitive answer.

The purpose of this article is not to take a stance on what the "correct" foundation is. We argue that the conceptual opaqueness of trade secret protection is relevant because it affects our understanding of the place trade secret protection occupies within various legal regimes and thus our analysis of reform. Indeed, to answer our central question on whether, and to what extent, we can place limitations on the protection of trade secrets via compulsory licensing, we must assess the various doctrinal constraints to this reform. Examining the equitable basis of English trade

[71] L. Bently and T. Aplin, "Patents and Trade Secrets" in N. Wilkof, I. Calboli and S. Basheer (eds.), *Overlapping Intellectual Property Rights*, 2nd ed. (Oxford 2023), 65, 72.
[72] Dreyfuss, "Trade Secrets".
[73] L. Bently, "Trade Secrets: 'Intellectual Property' But Not 'Property'?" in H.R. Howe and J. Griffiths (eds.), *Concepts of Property in Intellectual Property Law* (Cambridge 2013).
[74] M.A. Lemley, "The Surprising Virtues of Treating Trade Secrets as IP Rights" in R.C. Dreyfuss and K.J. Strandburg (eds.), *The Law and Theory of Trade Secrecy* (Cheltenham 2011).
[75] A. Ohly, "Germany: The Trade Secrets Protection Act of 2019" in J. Schovsbo, T. Minssen and T. Riis (eds.), *The Harmonization and Protection of Trade Secrets in the EU: An Appraisal of the EU Directive* (Cheltenham 2020).

secret protection helps to assess the extent to which trade secrets can be licensed compulsorily in this jurisdiction. Moreover, if trade secrets are "property" rights under the ECHR, to which the UK is a party, then a compulsory licence should be viewed as a certain "exception" to the exclusive rights provided by trade secrets, requiring striking a proportionate balance between the rights of a trade secret holder and the public interest. By contrast, if trade secrets relate to unfair competition, as is the case under TRIPS and other free trade agreements, then the assessment should focus on whether an act of compulsory licensing is contrary to honest practices in industrial or commercial matters. A compulsory licence in the latter scenario would not be an exception to an exclusive right, it would be a determination of what the scope of protection is in a particular circumstance such as a crisis.[76]

As the following analysis demonstrates, whichever comparative conceptual basis is examined – whether based on breach of confidence, or as a property right under the ECHR, or under the unfair competition regime under TRIPS – none prevents the possibility of compulsory licensing of trade secrets.

C. Trade Secrets under English Law: Breach of Confidence

The English approach, rooted in equity, arises from a personal obligation of confidence, rather than an obligation not to compete unfairly.[77] The framework for the protection of confidential information was provided in *Coco v A.N. Clark (Engineers) Ltd.*[78] and subsequent case law.[79] There are three requirements. The first is that the information must have the quality of confidence, meaning it must not be trivial and thus must be sufficiently detailed, and, crucially, it must be kept secret. The second requirement is that there must be an obligation of confidence between the parties. This is an objective test judged from the perspective of the reasonable recipient of the information.[80] The duty arises where such a recipient of information has actual or constructive knowledge either that the information is confidential, or that it has been disclosed in breach of an obligation of confidence.[81] The third element is that there must be a breach causing detriment.[82] The wrongful act – a breach – lies in non-

[76] T. Aplin, "The Limits of Trade Secret Protection in the EU" in S.K. Sandeen, C. Rademacher and A. Ohly (eds.), *Research Handbook on Information Law and Governance* (Cheltenham 2021), 174–75.
[77] *Saltman Engineering Co. Ltd. and others v Campbell Engineering Co. Ltd.* (1948) 65 R.P.C. 203, 215 (C.A.) (Lord Greene).
[78] *Coco v A.N. Clark (Engineers) Ltd.* [1969] R.P.C. 41, 47 (Megarry J.).
[79] See e.g. *Lion Laboratories Ltd. v Evans and others* [1985] Q.B. 526 (C.A.); and *Vestergaard Frandsen S/A (now called MVF3 APS) v Bestnet Europe Ltd.* [2013] UKSC 31, [2013] 1 W.L.R. 1556, at [22]–[23] (Lord Neuberger (with whom Lord Clarke, Lord Sumption, Lord Reed and Lord Carnwath agree)).
[80] *Primary Group v Royal Bank of Scotland* [2014] EWHC 1082 (Ch), [2014] R.P.C. 26, at [211] (Arnold J.).
[81] R. Arnold, "Accessory Liability for Breach of Confidence" (2014) European Intellectual Property Review 554, 554–56.
[82] *Faccenda Chicken Ltd. v Fowler* [1987] Ch. 117 (C.A.). at [120]–[122].

compliance with the obligation(s), namely via unauthorised use or disclosure. Critically, the holder of a trade secret is more vulnerable than the holder of a patent because once the secrecy is lost, a court cannot order it to be regained.[83] In fact, if a secret is made public, the information no longer qualifies for trade secret protection. In such circumstances, the only remedy will be damages (or an accounting of profits), rather than an injunction. That said, as Aplin points out, "widespread circulation or publication of information is required to destroy confidentiality".[84] If disclosure is more limited, so the information maintains its "relative secrecy", an injunction may still be granted.[85]

Breach of confidence covers not only commercially tradeable industrial trade secrets but also the privacy rights of individuals who may be concerned about unlawful surveillance, whether from state or private actors.[86] We draw a clear distinction between the two on the basis that, unlike rights to privacy or freedom from surveillance, industrial trade secrets are commonly licensed/transferred to other private firms via technology transfer agreements. For our purposes the relevant doctrinal constraints relate to equitable conduct in the industrial setting, rather than to issues of individual privacy or surveillance. Our reform proposal, outlined below, focuses solely on industrial trade secrets and maps onto established practices of technology transfer as far as possible.

In light of this, we ask: how would any limitation on trade secrets, such as via a compulsory licensing system, be constrained by the law of breach of confidence? To answer this, we consider three potential scenarios of compelled disclosure of trade secrets. The first concerns the possibility raised above, that the MHRA may disclose an originator's trade secrets (as contained in a marketing authorisation dossier). The second would be an application to a court for an order to compel an originator firm to share trade secrets with an alternative manufacturer. The third, our favoured option, would be a new legislative mechanism for compulsory licensing of trade secrets.

Regarding the first scenario, in theory the MHRA could decide to disclose trade secret information to an alternative producer, such as following a FOIA request. Would this be acceptable under the doctrine of breach of

[83] Bently and Aplin, "Patents and Trade Secrets", 72.
[84] Aplin, "Reverse Engineering", 355.
[85] Pre-Brexit, the UK implemented Directive (EU) 2016/943 (OJ 2016 L 157 p.1) via the Trade Secrets (Enforcement, etc.) Regulations, SI 2018/597. See also M. Malone, "Do the Trade Secrets (Enforcement, etc.) Regulations Contain New Principles for the Breach of Confidence?" (2021) 43 European Intellectual Property Review 759.
[86] T. Aplin and R. Arnold, "UK Implementation of the Trade Secrets Directive" in Schovsbo, Minssen and Riis (eds.), *Harmonization and Protection*, 68.

confidence? Such a disclosure could be considered a "breach" under the principles of *Coco*.[87] Nevertheless, the MHRA could raise a public interest defence.[88]

The public interest defence against an action for breach of confidence acknowledges that there are circumstances that may enable the recipient/holder of confidential information to disclose that information to an appropriate person (e.g. a regulator) or, in some circumstances to other third parties (e.g. to the media), when this is in the public interest.[89] In *Lion Laboratories Ltd. v Evans* the Court of Appeal stated that "there's a balancing exercise between two competing public interests: the public interest in maintaining the secrecy of confidential information and the public interest in disclosing matters 'which are of real public concern'".[90] Though untested, it is feasible that the disclosure by the MHRA of the marketing authorisation dossier to an alternative manufacturer may be justifiable based on this public interest defence, namely the need to address a public health emergency.

This brings us to a key limitation of this approach – it is not suited for limited transfer of trade secrets. The MHRA would have no authority to attach any conditions to the third-party usage of the information disclosed. The default position under the FOIA is disclosure to the public, which would destroy confidentiality entirely. Hence, this route is not well-suited for the more limited disclosure needed, namely to enable production while preventing destruction of confidentiality. Furthermore, the FOIA route would only provide information – it would not enable an alternative producer to obtain a sample of the product, as the MHRA does not hold biologic samples.

On the second scenario, would it be possible to justify a new route of equitable action? Since the protection of confidential information is rooted in equity, one of its strengths is flexibility, including new types of action based on the public interest. A party, such as the alternative producer or the Government, could apply to the English court for compelled disclosure of the relevant trade secrets (manufacturing information and a sample) needed to facilitate production of the large-molecule product. Would a court be willing to order this?

English courts have ordered disclosure of confidential information in patent proceedings, albeit only in a limited way, and not for the

[87] See e.g. *Anderson v Information Commissioner* [2008] UKIT EA/2007/0103, at [12]; and *North Western and North Wales Sea Fisheries Committee v Information Commissioner* [2008] UKIT EA/2007/0133, at [69], noting that *Coco* is not the only test to determine exemptions.

[88] C.M. Phipps, S. Teasdale and W. Harman, *Toulson and Phipps on Confidentiality*, 4th ed. (London 2020), at [5.057]–[5.087].

[89] The "iniquity defence" in *Gartside v Outram* (1856) L.J. Ch 113 grew into a more expansive defence based on public interest grounds in e.g. *Initial Services v Putterill* [1968] 1 Q.B. 396 (C.A.) and *Lion Laboratories Ltd. v Evans* [1985] Q.B. 526 (C.A.).

[90] *Lion Laboratories v Evans* [1985] Q.B. 526, 536 (Stephenson L.J.).

purpose of aiding manufacture of a product.[91] These cases involved restricted groups of people and narrow sets of information. Could the judicial line of thinking be expanded? It is not impossible. A court could decide to grant a disclosure order with the aim of balancing the interest in protecting confidential information with the need to facilitate production of life-saving medicines. This approach requires some speculation, as we do not have exact case law that indicates this route exists. It may also involve a lengthy court process. Nonetheless, while perhaps not the optimal approach, the above discussion highlights that confidential information is not protected absolutely and in all circumstances.

Overall, we favour the third option: legislative reform to allow the UK Government to issue a compulsory licence of trade secrets. We outline the specifics of this proposal in the next section, but for present purposes it is important that we analyse whether and how the doctrinal constraints of breach of confidence could affect any such proposal.

Breach of confidence focuses on protection against unauthorised disclosure and use of information. In our compulsory licensing scenario, it is relevant that, while the disclosure would not be authorised by the trade secrets holder, it would be authorised by the Government, under statute, acting in the public interest. Indeed, in this compulsory licensing situation it would be the originator who would disclose their own trade secrets to an alternative producer – there would not be a party who had acquired the trade secrets illicitly. Moreover, as we explain below, in our proposal the use by the alternative producer would arguably not cause undue detriment to the holder, since compensation would be provided and strict licence terms on future use would secure confidentiality. Here, a critical consideration would be to focus less on the mandatory nature of the licence, and instead to ask whether trade secrecy over the knowledge would still "work" as a form of legal protection after the compulsory licence has come to an end. As explained in the next section, in our proposed compulsory licensing model, trade secrecy would still "work", similar to how trade secrecy can still work over knowledge shared between two firms in a voluntary technology transfer agreement, even after the end of their commercial partnership.

The details of the proposed mechanism are explained in the next section. Prior to that, we must consider other doctrinal constraints, including the ECHR.

[91] Confidential business secrets can be disclosed where necessary for patent litigation proceedings, e.g. with only external parties (solicitors) viewing secrets documents, as in *IPCom GmbH & Co. Kg v HTC Europe Co. Ltd. and others* [2013] EWHC 2880 (Ch), at [44]–[50] (Roth J.). See also *Warner-Lambert Co. v Glaxo Laboratories Ltd.* [1975] R.P.C. 354, 360 (C.A.) (Buckley L.J.).

D. Trade Secrets: An Intellectual Property Right under the ECHR?

If trade secrets are a form of property, what constraints does this engender? Certainly, intellectual property rights, such as patents, copyrights and trade marks, are considered "possessions" within the scope of Article 1 Protocol 1 ECHR, to which the UK is a party.[92] There are, however, no such decisions about trade secrets and, in fact, this brings us back to the debate as to whether a trade secret should qualify as a "possession", namely as property.[93] In the UK, although some courts have considered confidential information to be akin to intellectual property, there is no definitive statement as yet.[94] For present purposes we do not make a determination on this, but we proceed as if the right to property is relevant.[95]

Given this, a holder of trade secrets might object to compelled transfer as an interference with their "possessions" under Article 1 Protocol 1. Like patents, rights to trade secrets would be qualified rights, not absolute rights, under the ECHR.[96] In ECHR jurisprudence qualified rights can be limited as long as the legal measures are proportionate, namely that they are taken pursuant to a legitimate aim, such as public health, and that limits to the right do not go further than necessary to achieve that aim, with adequate compensation an important factor.[97] The leading UK Supreme Court judgment on interpreting the ECHR proportionality standard in UK law emphasises four aspects: (1) whether its objective is sufficiently important to justify the limitation; (2) whether it is rationally connected to the objective; (3) whether a less intrusive measure could have been used; and (4) whether a fair balance has been struck between the rights of the individual and the interests of the community.[98] As long as an IP limitation abides by these factors, it will be proportionate.

On proportionality, it is also worth taking account of EU-derived UK case law on the similar IP provision in Article 17(2) in the EU Charter of Fundamental Rights, which although it is no longer binding on the UK, remains relevant to UK jurisprudence,[99] even considering the Retained

[92] *Anheuser-Busch Inc. v Portugal* (2007) 44 E.H.R.R. 42.

[93] T. Aplin, "Right to Property and Trade Secrets" in C. Geiger (ed.), *Research Handbook on Human Rights and Intellectual Property* (Cheltenham 2011).

[94] *Vestergaard Frandsen v Bestnet Europe* [2013] UKSC 31, [2013] 1 W.L.R. 1556, at [56] (Lord Neuberger (with whom Lord Clarke, Lord Sumption, Lord Reed and Lord Carnwath agree)). See also *Veolia ES Nottinghamshire Ltd. v Nottinghamshire County Council and others* [2010] EWCA Civ 1214, [2012] P.T.S.R. 185, at [120]–[121] (Rix L.J.).

[95] The right to privacy under Article 8 of the ECHR should not apply to commercial secrets: see Aplin and Arnold, "UK Implementation", 72–73.

[96] *Anheuser-Busch v Portugal* (2007) 44 E.H.R.R. 42, where "no interference" to an IP right was found, at [79]–[87].

[97] As in a case involving real property; see *James and Others v United Kingdom* (1986) 8 E.H.R.R. 123, at [47]–[54].

[98] *Bank Mellat v Her Majesty's Treasury (No. 2)* [2013] UKSC 39, [2014] A.C. 700, at [20] (Lord Sumption (with whom Lady Hale, Lord Kerr and Lord Clarke agree in whole; Lord Neuberger and Lord Dyson agree only on the procedural grounds, Lord Carnwath only on the substantive grounds).

[99] *R (on the application of Lumsdon) v Legal Services Board* [2015] UKSC 41, [2016] A.C. 697, at [23]–[26] (Lord Reed and Lord Toulson (with whom Lord Neuberger, Lady Hale and Lord Clarke agree)).

EU Law (Revocation and Reform) Act 2023. The UK's interpretation of ECHR case law and EU-related jurisprudence follows the same formula, meaning that the UK can intervene and limit IP rights where the legitimate aim of the protection of a public interest is pursued in a proportionate manner, such as in the case of the removal of trade marks from packaging of cigarettes to safeguard health.[100] This suggests that, in accordance with proportionality, it is feasible to legislate to allow compulsory licensing of trade secrets.

While we support taking proportionality into account when introducing a compulsory licensing mechanism into statute, we caution against the use of proportionality on a case-by-case scenario. The Government should not be obliged to go through individual proportionality assessments – weighing both interests – each time it seeks to use the mechanism. On this, compulsory licensing of patents offers a model for our mechanism that integrates proportionality in a way that does not require engagement in individual cases. Neither TRIPS nor the Patents Act 1977 requires a proportionality test in the context of the specific issuance of a compulsory licence for a patent. Instead, Article 31 TRIPS and section 48 of the Patents Act 1977 embed a balance between strong patent protection and the public interest in accessing patent protected technologies via compulsory licensing. This balance is reflected in the various elements of the mechanism aimed at protecting both the IP rights holder and the public interest. On the one hand, this involves the requirement of prior negotiations, non-exclusivity of the licence and provision of adequate compensation to the rights holder; on the other hand, it gives the state the ability to craft grounds for granting a compulsory licence and even to waive the requirements of negotiations during national emergencies and for public non-commercial use.

To summarise, if trade secrets are "possessions" under the ECHR, a limitation, such as creating a compulsory licensing mechanism, should be proportionate to the legitimate aim pursued. In our view, a targeted compulsory mechanism for transfer of trade secrets when needed in the public interest, that provides for limited scope, maintenance of confidentiality and compensation, is likely to be viewed as proportionate to the aim of protecting public health.

E. Trade Secrets: Obligations under TRIPS

As noted above, the Article 31 TRIPS compulsory licensing system focuses on patents. Meanwhile, Article 39 of TRIPS is silent on compulsory licensing of trade secrets. Is there a reason for this? Specific to

[100] *R (on the application of British American Tobacco UK Ltd.) v Secretary of State for Health* [2016] EWHC 1169 (Admin), [2016] R.P.C. 22, at [427]–[432] (Green J.) and on appeal [2016] EWCA Civ 1182, [2018] Q.B. 149, at [91]–[115], [116]–[124] (Lewison L.J.).

medicines, a relevant consideration is how patent protection was used by the pharmaceutical industry when TRIPS was negotiated in the late 1980s until its final agreement in 1994. In the 1980s, pharmaceutical companies mostly produced small-molecule drugs and typically tended to protect these products using one patent or a small number of patents.[101] At the time of its negotiation, it was plausible that the Article 31 mechanism would provide an adequate flexibility to ensure access to patented technologies on small-molecule medicines. This raises a question: if the Article 31 mechanism was tailored to the pharmaceutical field of 1994, does it remain appropriate today? As discussed above, in the context of the now prevalent large-molecule medicines, the Article 31 mechanism cannot be said to be effective. Does TRIPS allow space for domestic reform? As we argue below, our analysis indicates that Article 39 of TRIPS does provide sufficient room for UK implementation of compulsory licensing of trade secrets.

Article 39(2) of TRIPS requires members to protect undisclosed information against unfair competition, with an express link to Article 10bis of the Paris Convention for the Protection of Industrial Property, which defines unfair competition as "[a]ny act of competition contrary to honest practices in industrial or commercial matters".[102] Thus, it protects against misappropriation, which is actionable if the trade secrets were acquired improperly, such as via theft or espionage, and used/or disclosed in violation of a duty to maintain confidentiality.[103] The emphasis on unfair competition implies that there are two or more market actors competing against each other and that those "unfairly" competing would benefit, including financially, from their unfair acts.

In the compulsory licensing scenario, while there may be an element of competition between the trade secrets holder and the compulsory licensee, the element of "unfair acts" by the latter would be missing. A licensee recipient of trade secrets would be acting based on the authorisation from the Government in pursuit of a public interest in a situation when, for example, the normal market conditions had not provided sufficient access to the product. The licensed information could not be said to have been acquired improperly, and the element of "unfair acts" would not be present. The purpose of the compulsorily licensed production would be to cover an urgent need, not to compete with an originator. Even in a different scenario, such as excessive pricing of an original product, a compulsory licence would be granted not to compete with an originator,

[101] European Commission, "Pharmaceutical Sector Inquiry: Final Report" (Brussels 2009), paragraph 486.

[102] Paris Convention for the Protection of Industrial Property 1883 (adopted on 20 March 1883, as amended on 28 September 1979), art. 10^{bis}. See also N. Pires de Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information* (The Hague 2008), at [39.1.33].

[103] K.F. Jorda, "Trade Secrets and Trade-Secret Licensing" in A. Krattiger et al. (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, vol. 2 (Oxford 2007), 1047.

but to satisfy an urgent need for an otherwise unaffordable medicine. Thus, in the public health context, even if production of a needed product had an impact on competition, it is unlikely to be perceived by a court as "unfair". It is rational to conclude that a compulsory licence granted by a government authority compelling a trade secret holder to transfer information necessary to produce a needed medicine would not be considered as unfair competition per se under Article 39(2) of TRIPS. Nevertheless, there may still be a risk of unfair use of confidential information by the compulsory licensee if the use of such information were to go beyond the scope of the compulsory authorisation. This could include continuing to sell the product after the expiry of the compulsory licence, or future use, such as using the confidential information to develop a competing commercial product. As we argue below, setting strict terms within the compulsory licence can mitigate such risks of unfair competition.

Finally, Article 39(3) of TRIPS is relevant to the option discussed above, of disclosure by the MHRA of the confidential information contained in a marketing authorisation dossier. While we consider this a second order option, it is useful to ask whether TRIPS prevents such data disclosure. Article 39(3) of TRIPS mandates members to protect regulatory data against disclosure, but it contains two exceptions when disclosure is allowed: 39(3)(a) where it is necessary to protect the public or 39(3)(b) when steps are taken to ensure that the data are protected against unfair commercial use. Regarding Article 39(3)(a), we consider that where the disclosure by the MHRA of a regulatory dossier to an alternative producer would be undertaken to protect public health, such as where there is a severe shortage, or where no equivalent health product is available on the market, it would satisfy this condition.[104] Concerning Article 39(3)(b), the interpretation of "unfairness" and "commerciality" must be considered, as above, in the context of this public health scenario. Therefore, we argue that the disclosure of a dossier by MHRA to a third-party producer to accelerate the production and/or trialling of a needed medicine would satisfy Article 39(3)(a–b) of TRIPS.[105]

Furthermore, it is worth highlighting that there is no specific prohibition on compulsory licensing of trade secrets in Article 39 of TRIPS, which can be contrasted with Article 21 of TRIPS, which expressly prohibits compulsory licensing of trade marks. Additionally, when we read Article 39 in light of the importance given to public health in the Doha Declaration, it bolsters our argument that TRIPS gives sufficient space to

[104] S. Basheer, "Protection of Regulatory Data Under Article 39.3 of TRIPS: The Indian Context", available at https://ssrn.com/abstract = 934269 (last accessed 27 August 2025), 24–28, noting that even with commercial use of regulatory data, only compensatory liability would apply.

[105] Pires de Carvalho, *The TRIPS Regime*, at [39.2.102]–[39.3.115], [39.3.195]–[39.3.207]; see also G.S. Ali, "TRIPS and Disclosure of Clinical Information: An Intellectual Property Perspective on Data Sharing" (2017) 20 The Journal of World Intellectual Property 24.

members to implement a provision in their national IP laws to facilitate compulsory licensing of trade secrets with the aim of safeguarding public health during a crisis.[106] That Article 66.2 of TRIPS encourages technology transfer should also be taken into account.[107] Finally, it is notable that during the COVID-19 pandemic the UK was a principal defender of the existing TRIPS system, arguing that TRIPS already has adequate space for domestic flexibilities, and that the broad TRIPS waiver proposed by India and South Africa was unnecessary.[108] The view that there was merit in India and South Africa's waiver proposal, not least that it would have provided greater legal certainty, is not wholly inconsistent with the UK's position. Indeed, taking the UK's own argument seriously gives weight to an interpretation that there is flexibility within the terms of TRIPS to reform the UK compulsory licensing system to make it workable for future pandemics.

F. Trade Secrets: The UK's Obligations under Other Free Trade Agreements and Bilateral Investment Treaties

The impact of the UK's obligations under international free trade agreements on trade secrets has only received academic attention recently.[109] Since the UK has ratified more than 30 separate free trade agreements ("FTAs") a full examination of all of these is beyond this article. We cover a sample of six, including the post-Brexit agreements with (1) the EU, (2) Australia, (3) New Zealand, (4) Japan, and (5) Iceland, Liechtenstein and Norway, and (6) the recent "continuity" agreement with Ukraine. On analysing these, we find no reason why a compulsory licensing mechanism of trade secrets would contradict the UK's obligations. The protection of trade secrets under such agreements follows a typical formula. First, trade secrets are protected against unfair competition – a type of protection that, as argued above regarding TRIPS, would allow compulsory licensing of trade secrets provided safeguards are in place. For example, Article 252(1) of the most stringent agreement – the EU-UK Trade and Cooperation Agreement – mandates that parties shall provide protection to a trade secrets holder when "the acquisition, use or disclosure of a trade secret" is carried out "in a manner contrary to honest commercial practices".[110] This emphasises the

[106] The WTO decision on limiting trademarks, considering the right to health, is instructive; see Panel Report, Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging (WT/DS467/R, adopted on 27 August 2018).

[107] TRIPS, art. 66.2

[108] P. Loft, "Research Briefing: Waiving Intellectual Property Rights for Covid-19", available at https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf (last accessed 27 August 2025).

[109] A. Ferguson, "Trade Secrets at Risk" (2024) 40 Arbitration International 337, 338.

[110] *Trade and Cooperation Agreement between the United Kingdom of Great Britain and the EU*, CP 426 (London and Brussels 2021).

protection is not absolute but centres on unfair competition. Second, some agreements contain an exception to allow the UK to impose certain restrictions on trade secret protection. For example, Article 252(4) of the EU-UK agreement provides that "[n]othing in this Section shall be understood as requiring either Party to consider any of the following conducts as contrary to honest commercial practices: … (c) the acquisition, use or disclosure of a trade secret required or allowed by the law of each Party".[111] These agreements also take account of the Doha Declaration, stating that nothing should prevent the parties from taking measures to protect public health.[112]

The above FTAs with New Zealand, Australia and the EU include provisions on investments. However, the UK also has separate bilateral investment treaties with some states, including Colombia, Turkey, Moldova and Egypt. Taking these four as a sample of the UK's bilateral treaties, we find the same pattern of language on "expropriation" is repeated.[113] If a trade secret holder claims that a compulsory licence amounts to an expropriation of investment under a bilateral investment agreement (and it is not certain that trade secrets would be classed as such), as long as this is undertaken with due process, for a legitimate public purpose, and with compensation, this would not breach the bilateral obligation.[114]

G. Trade Secrets: Political Constraints

It is worth considering the political constraints in the UK by asking whether the absence of compulsory licensing of trade secrets in the Patents Act 1977 is a "gap" in the legislation, or whether it is justifiable as a deliberate

[111] *Free Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and Australia*, CP 689 vol. V (London and Adelaide 2022), art. 15.69 (hereafter "UK-Australia FTA"); *Free Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and New Zealand*, CP 750 vol. IV (London 2022), art. 17.63 (hereafter "UK-New Zealand FTA"); *Political, Free Trade and Strategic Partnership Agreement between the United Kingdom of Great Britain and Northern Ireland and Ukraine*, CP 312 (London 2020), art. 148 (hereafter "UK-Ukraine FTA"); *Agreement between the United Kingdom of Great Britain and Northern Ireland and Japan for a Comprehensive Economic Partnership*, CP 311 vol. 1 (Tokyo 2020), Article 14.41 (hereafter "UK-Tokyo FTA"); *Free Trade Agreement between Iceland, the Principality of Liechtenstein and the Kingdom of Norway and the United Kingdom of Great Britain and Northern Ireland*, CP 498 vol. 1 (London 2021), art. 7.46.

[112] See also UK-Australia FTA, art. 15.6; UK-New Zealand FTA, art. 17.6; UK-Ukraine FTA, art. 209; UK-Japan FTA, art. 14.39.

[113] *Bilateral Agreement for the Promotion and Protection of Investments between the Government of the United Kingdom of Great Britain and Northern Ireland and Republic of Colombia*, Cm 8973 (Bogota 2010), art. 6(1); *Agreement between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the Republic of Moldova for the Promotion and Protection of Investments*, Cm 4260 (London 1996), art 5(1); *Agreement between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the Republic of Turkey for the Promotion and Protection of Investments*, Cm 1600 (London 1991), art. 5(1); *Agreement between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the Arab Republic of Egypt for the Promotion and Protection of Investments*, Cmnd 6638 (London 1976), art. 5(1).

[114] Ferguson, "Trade Secrets at Risk", 354–57.

political decision. We find no evidence that there has been an explicit political determination to exclude trade secrets from compulsory licensing. Examining the 1977 parliamentary debates in Hansard reveals that the issue of compulsory licensing of trade secrets was simply not contemplated.[115] This is unsurprising given that, as stated above, at the time most medicines were small-molecule drugs that did not involve complicated processes. It is plausible that Parliament did not foresee how significant trade secrets would come to be with respect to large-molecule pharmaceuticals.

There may be another reason why trade secrets were not on the agenda during parliamentary debates over compulsory licensing. Given the link between trade secrets and sensitive issues such as privacy and surveillance, is it possible that the UK legislature deliberately excluded trade secrets from compulsory licensing because it decided that ordering their disclosure would be inappropriate in all circumstances? We consider this unlikely. As we state above, a clear distinction can be drawn between commercially tradeable industrial trade secrets and the privacy rights of individuals. Our approach applies only to commercially tradeable secrets, not individual privacy.

Did Parliament avoid legislating for a compulsory licence to transfer secrets because of the concern that legislating might provide an overbroad mandate? This question brings us back to the essential vulnerability of a trade secret – that is, the risk of a "leak" or disclosure and consequent loss of value. This is a relevant concern – but one that applies only if the proposed compulsory licence would in fact create such an unjustifiably broad mandate in practice. As we detail below, our suggested approach to compelled disclosure is akin to the precise model of the voluntary transfer of trade secrets between two firms via a technology transfer agreement. This limited model would enable the trade secret to still "work" after the compulsory licence has come to an end. As such, we can minimise the risk of an overbroad mandate.

Nonetheless, if reform were adopted, its utility would depend on the Government's willingness to use it. This is a political decision: it cannot be guaranteed that the new provisions would be used. On this we make two points. First, as part of its role in a democracy the elected Government would need to be responsive to the health needs of the electorate, especially in a crisis. In our view, it is better to have a well-ordered legislative framework in place rather than the current patchwork, which is unworkable in the context of large-molecule medicines. This would be a positive even if a future Government were unwilling to issue

[115] An early legislative draft had some unintentionally ambiguous language about whether provisions regarding employee inventions may enable employees to reveal secrets, but this was removed; see HC Deb. vol. 932 cols. 1452–54 (25 May 1977).

the licence, calculating that it would prefer not to interfere with market-based innovation incentives or national trade advantages, for example.

Second, reform could provide a communicative vehicle for aspirational norms capable of changing behaviour of actors in the pharmaceutical market. The existence of strong governmental powers might have a "push" factor leading to greater voluntary disclosure and licensing arrangements. The legitimate threat of a compulsory patent licence helped to compel private companies to improve global access in the context of HIV/AIDS drugs in the late 1990s/2000s.[116]

Representatives of pharmaceutical companies are likely to raise their voices against this proposal, as they do when the current flexibilities are used.[117] It is notable that pharmaceutical organisations often make statements to the effect that they will stop investing if laws are passed that potentially limit their IP rights or market power. For example, the prominent lobby group, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), is on record as opposing all forms of state healthcare that involve price moderation – from the UK's NHS to South Korea's system – on the basis that such systems allegedly weaken investment in innovation.[118] Just as the presence of such claims is not a reason to depart from the idea of state healthcare, there is no reason to abandon the idea of reforming the compulsory licensing system. This does not mean that there is no risk of backlash from private firms, but neither is the risk so great that a new legislative framework should be avoided. Instead, it is incumbent upon the UK Government to consider whether the long-standing mechanism for compulsory licensing should be made fit for purpose in the era of large-molecule medicines. If the answer is yes, then reform is required.

IV. What Would Be the Key Elements of Reform?

A. General Considerations when Issuing a Compulsory Licence of Trade Secrets

With compulsory licensing of patents, the IP owner can regain the full right to utilise their exclusionary patent rights after the emergency has passed and the licence has been terminated. Whereas once confidential information ceases to be secret, its legal protectability, and its value, can be lost. Hence, compulsory licensing of trade secrets raises a complication which does not arise with patents. To ensure secrecy is not damaged to such an

[116] Thambisetty et al., "Addressing Vaccine Inequity", 377–88.

[117] Z. Becker, "'Betrayal of Public Trust': Pfizer under Fire for Resisting Paxlovid Compulsory License", *Fierce Pharma*, available at https://www.fiercepharma.com/pharma/stark-betrayal-public-trust-pfizer-rebuked-advocacy-groups-intellectual-property-human-right (last accessed 27 August 2025).

[118] Pharmaceutical Researchers and Manufacturers of America (PhRMA), "Special 301 Submission 2022", 17, available at https://www.phrma.org/resources/phrma-special-301-submission-2022 (last accessed 27 August 2025).

extent that the protection no longer exists after the licence ends, a new mechanism would need to differ from the scheme already developed for patents. In line with the constraints outlined above, this would require the balancing of public and private interests, ensuring proportionality and preventing unfair competition. Thus, the new compulsory mechanism must aim to facilitate full access to the relevant trade secrets (e.g. manufacturing information and a sample), while guaranteeing that the licensee will protect the transferred trade secrets to avoid their inadvertent widespread disclosure, which would deprive the originator/licensor of their value. As far as possible, the below terms follow the model of a voluntary licensing/technology transfer agreement, while also reflecting the compulsory nature of the licence, with the major difference being that, in the compulsory licensing scenario, the trade secret owner would not have a choice as to which third party they were transferring the information.

Under our proposed legislative mechanism, compulsory licensing of trade secrets would be made possible via governmental order. This order could supplement the authorisation under the Patents Act 1977 for a compulsory patent licence (by the UK IPO) or Crown use (by the Ministry of Health). Nonetheless, we suggest the option of compulsory licensing of trade secrets should be standalone, so that it be available if an alternative producer requires only a compulsory licence for the trade secrets, such as for a product where no patents were granted, or where the relevant patents have expired but the key manufacturing processes are still held confidentially. While the paradigm case for the use of such a licence would be a health emergency, this mechanism should not be limited to such emergencies (as we note above, compulsory licensing of patents is not limited to crises). Similarly, we do not suggest limiting the mechanism to large-molecule medicines, though these would be the main products for which a licence would be useful.

There would be three parties to the compulsory technology transfer order: the Government, the originator (compulsory licensor) and the alternative producer (compulsory licensee). The key function of the Government order would be that it would oblige the originator company (as licensor) to transfer, to a specific third-party manufacturer (as compulsory licensee), all necessary information, including trade secrets and needed samples, required to manufacture the relevant medical product. The duties imposed on the licensor and licensee would arise from the statute and would be specified in the compulsory licence. For instance, the originator company would be given time to comply, with the exact period to be specified by the Government considering the particular circumstances of the emergency. We provide further detail on enforceability below.

In terms of applicability, a potential compulsory licensee of trade secrets would need to meet certain standards, namely (1) "suitability to produce"; and (2) "good faith". These provisions would ensure that the alternative manufacturer must demonstrate not just good faith willingness but also suitable capability to manufacture the product, by evidencing appropriate facilities, experience and knowledge.[119] The UK Government should have the power to refuse an application for, or to revoke, a compulsory trade secret licence if, in the circumstances, the Government has reason to believe the potential licensee may be making a bad faith attempt to use the process as a "fishing exercise". Attempts to misuse the procedure would also be limited via the key terms detailed below.

B. Key Terms of the Licence

The key terms of a compulsory licence of trade secrets would address: (1) the scope of the transfer; (2) maintenance of confidentiality; (3) restrictions on future use; (4) provision of compensation; and (5) enforcement and remedies. In line with the above constraints, these terms aim to balance the public and private interests, ensure proportionality and prevent unfair competition.

On (1), the licence must identify – and thus limit – the scope of the technology transfer so that it includes only the range of information necessary to enable production of the specific product. Inevitably, this would go beyond the disclosure already contained within the patent information; it would require the precise technical know-how on manufacturing processes that would enable the licensee to make effective use of the technology. Li-Dar Wang recommends that it should include "technical documents that contain the know-how or other technologies that the licensee identifies as necessary".[120] Notably, in the case of a large-molecule product, a sample would need to be provided.[121] Hence, disclosure could be more in depth than that required during, for example, the discovery process of litigation.[122] Given the diversity of large-molecule products, defining this know-how precisely would need to be done on a case-by-case basis in conjunction with the above requirements of suitability to produce and good faith.

[119] When pharmaceutical patents were subject to licences of right, there were arguments over suitability, as in *Smith, Kline & French Laboratories' Patent* [1967] R.P.C. 123 (C.A.), at [25]–[30] (Lord Denning M.R.).

[120] Li-Dar Wang, "Ancillary Orders", 96–97.

[121] If a micro-organism is deposited as part of the patent application, under the Budapest Treaty a deposit of the sample(s) will be made accessible if a compulsory patent licence is granted; see Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (adopted 28 April 1977, as amended 26 September 1980). Also see the EPO rules of disclosure under Budapest Article 4(ii)(a), available at https://www.wipo.int/documents/d/budapest-system/docs-en-guide-section-e-epo.pdf (last accessed 27 August 2025).

[122] *IPCom GmbH v HTC Europe* [2013] EWHC 2880 (Ch), at [44]–[51] (Roth J.).

On scope, we take guidance from both voluntary and compulsory models. Voluntary technology transfer agreements often include a combination of patent and trade secret licensing.[123] The bulk of this information is transferred via documentation, though in some circumstances there may be "show-how" demonstrations by personnel to aid transfer.[124] A prominent recent voluntary example occurred when Oxford University transferred documentation on vaccine know-how and a vaccine sample to the Serum Institute of India during 2020.[125] Moreover, an example of open-source COVID-19 technology transfer occurred with the Corbevax vaccine developed at Baylor College and the Texas Children's Center in 2020–21. Corbevax's creators, Peter Hotez and Maria Bottazzi, did not seek patents and published all available information as academic papers rather than relying on trade secrets.[126] This open documentation, coupled with the transfer of samples, enabled production at open-licensed recipient firms in India and Botswana.[127] Another relevant example, mentioned above, is that of Afrigen. Although Moderna refused to share its trade secrets with Afrigen, Moderna's partner, the (public) NIH, agreed to provide extensive scientific assistance to Afrigen. This included sharing detailed know-how on mRNA manufacturing. The precise detail of what the NIH shared with Afrigen is not known, but it is likely that previously undisclosed knowledge was shared, because Afrigen was able to use the information to create an equivalent vaccine to the NIH-Moderna one.[128]

Furthermore, with respect to compulsory transfer of trade secrets, guidance could be taken from the actions of the US Federal Trade Commission ("FTC") under competition law. Competition law has long been utilised to justify compulsory mandates for transfer of technical know-how and materials to competitors in the pharmaceutical industry. A recent report by Knowledge Ecology International documents 37 such cases in the US, of which 10 involved medical technology.[129] One pertinent example occurred in 2007 when the FTC acted after the two main providers of five injectable pharmaceuticals, Hospira, Inc. and

[123] M. Polanyi, *The Tacit Dimension* (Chicago 2009); and P. Lee, "Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer" (2012) 100 California Law Review 1503.

[124] Levine and Sarnoff, "Compelling", 993.

[125] M.Z. Medeiros et al., "Vaccine Innovation Model: A Technology Transfer Perspective in Pandemic Contexts" (2022) 40 Vaccine 4748.

[126] Maria Bottazzi confirmed via email correspondence that the inventors did not seek patents, published all available information as academic papers rather than relying on trade secrets and provided samples.

[127] O. Gurgula and L. McDonagh, "Access Denied: The Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools", available at https://stopaids.org.uk/wp-content/uploads/2023/03/Trade-Secrets-Report-FINAL.pdf (last accessed 27 August 2025).

[128] This was not an exact copy of the Moderna vaccine, but it shows how much can be achieved even in imperfect information circumstances.

[129] A. Schouten, "Examples of US Competition Cases that Mandate Transfer of Technology and Know-How", available at https://www.keionline.org/wp-content/uploads/KEI-BN-2024-2.pdf (last accessed 27 August 2025).

Mayne Pharma Limited, planned to merge, thus eliminating competition for those medicines. The FTC intervened by entering a Consent Agreement between the agency and the merging parties, containing the following mandatory order to transfer know-how and materials to a new approved competitor, Barr Pharmaceuticals, Inc.: "The Order requires Hospira and Mayne to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Hospira and Mayne."[130]

The FTC appointed an independent expert to oversee the transfer and to ensure Hospira and Mayne's compliance. The FTC further required Hospira and Mayne to file periodic reports until the completion of the transfer. Another example of a compulsory licence imposed by the FTC is the case of *Mallinckrodt Ard Inc. (Questcor Pharmaceuticals)*.[131] The firm was compelled to share its technology related to a biologic drug, adrenocorticotropic hormone ("ACTH"), including patents and trade secrets, with a designated third-party licensee. While taken under the rationale of competition law, the above examples prove that involuntary technology transfer of complicated pharmaceutical information and materials is viable and not unprecedented.

On (2) – maintaining confidentiality – a key point to recall is that the compulsory transfer of trade secrets to an alternative manufacturer would not, of itself, cause undue harm to the inherent confidentiality of the information, since this would not be "widespread circulation".[132] To ensure this, the compulsory licence should impose strict confidentiality obligations on the party to whom the trade secrets are being transferred, namely: (a) a responsibility to observe security over the information transferred under the licence to ensure it does not "leak" and (b) restrictions on future use.[133] A compulsory licence of trade secrets would follow the pattern of the typical voluntary technology transfer agreement mentioned above, whereby the recipient of the technology is bound under a non-disclosure agreement from disclosing the confidential information received. In any dispute a court could evaluate the extent to which the recipient of the trade secrets is acting in good faith given its obligation to keep the information secret.

Regarding (3) – restrictions on future use – the licence should follow similar terms as in voluntary technology transfer agreements: once the

[130] Federal Trade Commission, "Hospira, Inc., and Mayne Pharma Limited; Analysis of Proposed Consent Order To Aid Public Comment (File no. 071 0002)", 72 Federal Register 4009.
[131] See "Stipulated Order for Permanent Injunction and Equitable Monetary Relief" handed down in *FTC v Mallinckrodt Ard Inc.* No. 1:17-cv-00120 (District Court for the District of Columbia, 18 January 2017).
[132] Aplin, "Reverse Engineering", 355.
[133] Aplin, "Data Act", 95–97, noting that transferred data be treated as confidential by the licensee/recipient.

Government gives notice that the public need has come to an end, the licence would be terminated and the party would no longer have the right to utilise the information.

On (4) – compensation – we envisage that the compulsory licence would primarily be used when the usual procurement model has been insufficient to deal with public need and attempts to achieve voluntary transfer have failed. Nonetheless, there is a second possibility, namely, when the price is too high. Since this would be a compulsory licence granted by order, the royalties paid to the licensor should be set by the UK Government. Royalties should be set at a level that would adequately compensate the owner, but which would not impede the rationale of the compulsory licence. We favour a flexible approach whereby the Government could use a variable scale depending on product type and market. We take account of the WHO approach to calculating royalties with respect to compulsory licensing of patents, whereby a royalty of not more than 2–4 per cent of product price is suggested.[134] We also note recent research that indicates a royalty of 6 per cent is the norm in technology transfer agreements.[135] We recommend that the UK Government should consider these factors in calculating compensation.

On (5) – enforcement – if a licensor originator company refuses to abide by the compulsory licence for the trade secrets within the specified period, we suggest that the company be subject to enforcement proceedings. Here again, we take guidance from the FTC process described above, which required periodic reporting of the ongoing transfer and independent oversight. Moreover, following the approach taken by the European Commission in its draft compulsory licensing proposal, the statutory provisions should include a fine or a penalty imposed on the originator if it refuses to comply.[136] On remedies, such as injunctions, we suggest that these will need to be dealt with in a flexible manner by the courts.[137] For breach of the licence by the licensee, compensation to the originator should be the primary remedy, not an injunction, which might block the needed production.[138]

[134] J. Love, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies", available at https://iris.who.int/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf?sequence=1&isAllowed=y (last accessed 27 August 2025).

[135] A. Kapacinskaite, R. Vrajesh and C. Cunningham, "Markets for Trade Secrets" (2025) Draft Working Paper (on file with authors) 1.

[136] DG for Internal Market, Industry, Entrepreneurship and SMEs, "Proposal", arts. 15, 16.

[137] The English courts have developed a flexible approach to remedies in the context of patent law, as explored in L. Bently and R. Arnold, "United Kingdom" in J. Contreras and M. Husovec (eds.), *Injunctions in Patent Law: Trans-Atlantic Dialogues on Flexibility and Tailoring* (Cambridge 2022), 262.

[138] Basheer, "Protection".

C. Jurisdiction

Given that the UK is a hub for life sciences, both for domestic and multinational companies, our primary focus is on UK-based compulsorily licensed activities. However, if the originator firm possessing the necessary trade secrets were based entirely overseas, we acknowledge this could complicate, and potentially frustrate, any transfer. In such a case, no recommendation we make could offer a complete solution, though we note such concerns will remain a relevant matter for interpreting and analysing the WHO Pandemic Agreement and any other future pandemic-related treaties.[139] A solution could include a form of reciprocal enforcement of an order by a foreign Government or foreign court to oblige the originator to disclose the required information.[140] Yet, in the absence of mutual treaty obligations to recognise and enforce each other's court orders, this option may not be workable. Nonetheless, in a world where multi-national firms are often based in several states it may be possible for the UK to impose enforcement measures (such as a fine) on certain parts of the originator firm's business, or its subsidiaries, with the aim of compelling compliance with the licence.

V. What Additional Reforms May Be Required?

The focus of this article is on the compulsory licensing of trade secrets. Consequently, it is beyond our scope to conduct in depth analysis of additional issues relevant to the process of administering a compulsorily produced health product. Here we provide a brief commentary on these issues, suggesting directions for future scholarly research.

One such direction relates to the need to undertake minor reforms to the compulsory licensing system for patents to streamline the process. We concur with Liddicoat and Parish that the grounds for awarding compulsory licences during health emergencies should be broadened and that licences should cover not only product patents but also process patents.[141] To this we add two further points. First, in an emergency the timing of a compulsory licence issuance may be crucial. Under section 48(1) Patents Act 1977, there is a time restriction – that is, a compulsory licence can be issued only three years after patent grant. Yet, the Crown use provision does not contain such a limitation. To ensure the widest range of options we recommend removal of the three-year restriction, bringing the rules on timing of a compulsory licence in line with Crown use. Our second suggestion is that compulsory licences and Crown use

[139] Gurgula and McDonagh, "Proposal".
[140] Ibid.
[141] Liddicoat and Parish, "Ironing Out", 245–47. They note another provision that may need revising – Patent Act 1977, s. 57A – which allows for compensation to include lost profits, thereby making compulsory licensing less cost-effective that it otherwise would be.

should be applicable to pending (not yet granted) patent applications and to Supplementary Protection Certificates ("SPCs"), which can extend the exclusivity of a patent for up to five years where regulatory approval has taken a long time.[142]

This brings us to the issue of regulatory exclusivities. All medicines, including those produced under a compulsory licence, must be authorised by the MHRA before they can be administered.[143] Via this MHRA authorisation process the originator firm obtains regulatory exclusivities relevant to its product: (1) an 8-year period of data exclusivity over efficacy/safety data produced via preclinical tests and clinical trials; and (2) a 10-year period of marketing exclusivity to sell the medicine, with the two periods running concurrently $(8 + 2)$.[144] This means that, under the current law, even if a compulsory licensee were able to produce a needed health product, such regulatory exclusivities, if still in force, would block the licensee from obtaining authorisation for the compulsorily licensed product.[145] At present, UK law does not offer a way to resolve this. Thus, a direction of future research could be to explore whether these data and marketing exclusivities should be suspended for the duration of a compulsory licence, namely to order that such protection will have no effect in relation to the licensee of the compulsory licence while that licence is in effect.[146] This suspension could be for the period of the compulsory licence and would enable the compulsory licensee to obtain their own marketing authorisation and bring their product to market.

A related direction for future research would be to examine how best to facilitate the alternative producer's MHRA authorisation application for the compulsorily licensed product (which could be for conditional authorisation in emergency circumstances).[147] One issue to explore would be whether the MHRA should disclose the originator's clinical data to the alternative producer, as considered above, but in this case, not to enable production, but to assist the alternative producer to demonstrate to the MHRA that their large-molecule product is identical to the one produced by the

[142] The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020, SI 2020/1471. See also Council Regulation (EC) No 469/2009 (OJ 2009 L 152 p.1) and UK Patents Act 1977, s. 128B and schd. 4A.

[143] Human Medicines Regulations 2012, SI 2012/1916. See also Commission Directive (EU) 2010/84/EU (OJ 2010 L 348 p.74).

[144] For a new therapeutic indication, an additional 1 year can be claimed $(8 + 2 + 1)$; see Council Regulation (EC) No 726/2004 (OJ 2004 L 136 p.1), art. 14(11), as transposed in the Human Medicines Regulations 2012, SI 2012/1916.

[145] R.C. Feldman, "Regulatory Property: The New IP" (2016) 40 Columbia Journal of Law & the Arts 53.

[146] A similar approach is outlined in the DG for Internal Market, Industry, Entrepreneurship and SMEs, "Proposal".

[147] MHRA, "Guidance on Conditional Marketing Authorisations, Exceptional Circumstances Marketing Authorisations and National Scientific Advice", available at https://www.gov.uk/guidance/conditional-marketing-authorisations-exceptional-circumstances-marketing-authorisations-and-national-scientific-advice (last accessed 27 August 2025).

originator. This could enable the producer to conduct a speedier set of clinical trials than otherwise would be possible.[148]

VI. Conclusion

The increasing reliance on trade secrets to protect essential medicines, particularly large-molecule products, necessitates a re-evaluation of the UK's compulsory licensing framework. Despite certain differences between patent and trade secret protection, our analysis demonstrates that the doctrinal, political and practical constraints do not prevent compulsory licensing of trade secrets. We propose a new mechanism that would provide balance between the private interests of technology owners and the public interest in accessing required health technologies.

To conclude, we note that as the international community continues to grapple with how best to prepare for future pandemics, UK legislative reform may become a model for other jurisdictions to follow. Furthermore, while this article focuses on safeguarding public health, future research may explore how reform of compulsory licensing can be relevant to other industries, such as climate change, where technologies are often protected via undisclosed information and compulsory transfer of trade secrets may be required to enable global action.

[148] Another factor to examine, beyond the scope of this article, would be whether a compulsory licence of trade secrets should be accompanied by immunity from suit, with the UK Government taking on product liability.