LEX | SCIENTIA
SCOTT FARNSWORTH

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DHSC plan for clinical research delivery

June saw the Department of Health and Social Care (DHSC) publish its policy paper headed 'The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan' (the Plan). The Plan is the first step toward making the government's vision for 'Saving and Improving Lives: The Future of UK Clinical Research Delivery' become a reality.

The Plan sets out how the DHSC will work with the clinical research community and the UK Clinical Research Recovery Resilience and Growth (RRG) programme's delivery partners, to establish existing commitments that make UK clinical research delivery easier, more efficient, and effective, as well as to produce new research initiatives.

The Plan sets out 7 action areas taking place over the coming months of 2021, which are:

- improving the speed and efficiency of study set up;
- building upon digital platforms to deliver clinical research;
- increasing the use of innovative research designs;
- aligning research programmes and processes with the needs of the UK's health and care systems;
- improving visibility and making research matter to the NHS;
- making research more diverse and of greater relevance to the whole of the UK; and
- strengthening public, patient, and service user involvement in research.

To support the delivery of the Plan, over £64 million in funding has been secured. According to the government, the funding demonstrates the UK's ongoing commitment to saving and improving lives through clinical research and will ensure the government can take the first steps toward delivering upon its overarching vision.

The specifics of the Plan will be kept under review through the RRG delivery programme, while the RRG will also have responsibility for the monitoring and evaluation of delivery, to ensure progress against the government's commitments is measured and assessed.

The Plan is intended to make the UK one of the most attractive places in the world to conduct efficient and cutting-edge clinical research into new treatments and technologies that will revolutionise patient care.

Business insurance and the life sciences

Background

In transactional work, business insurance is a party matter and, generally, not a legal consideration. On occasion, it becomes necessary to consider terms of insurance, the need borne out of the usual trite squabbling over liabilities, limitations, indemnities, and caps including super caps. During a negotiation and with plenty at stake and without instructions, I decided to satisfy myself that certain insurances were in place, with the sense it was likely I would be the only person to have gone to such lengths.

Limitations work to limit a party's liability and may be capped, often by reference to the fee level: x1, x3, and x5 are commonplace, in each case limiting a claim arising from a specific event and confined to the fee level for the work in question from which the event had arisen. Alternatively, limitations may extend to the insurance level: the level of cover held by a party is commonplace, although this carries risk as to cap at such a level assumes the insurer will pay out, when what a party intends is a cap at a level recovered under the insurance: note recovered and not recoverable, the latter capable of causing confusion. Frequently, limitations are set as combinations of the greater or lesser value of the two levels. No party should accept unlimited liability or a limitation that goes beyond any sum actually recovered under its insurance, especially if the limitation is linked with an indemnity: a means of security given by a party for losses suffered by the other party.

The phrase 'indemnify, defend, and hold harmless' is quite often misunderstood and stretches the concept of an indemnity. The term 'defend' means to oppose allegations and claims made by third parties against the defended party. Defended claims entitle the defending party to procure a settlement, which may be to the detriment of the defended party, as a settlement may include undesirable outcomes beyond pure financial remedy. There is no limit to the lengths the defending party must go, even if that means to the financial detriment of that party. The term 'hold harmless' means to absolve a party from responsibility for liability, usually arising from a transaction, which can operate to exclude liability altogether and may be to the detriment of the holding party. In each case, the financial burden for the party assuming the responsibility is increased significantly and, where appropriate, should be avoided.

During the negotiation, an unlimited indemnity was presented solely with regard to certain liabilities: breach of confidence and infringement of third party intellectual property (IP): standard practise in the life sciences. It was clear a super cap would be introduced at some point, as an alternative: a super cap is the little brother of an unlimited indemnity, the next step down so to speak. A red line, the unlimited indemnity was dismissed, and the predicted super cap was introduced, albeit at the insurance level and on an indemnity basis. The super cap was rejected in favour of a (not so super and rather standard) cap at the fee level, albeit still on an indemnity basis. What happened next?

Terms of insurance

At the super cap stage, it was time to consider the insurance position, concerned to know the nature of cover held and avoid any wiggle room (by the insurers), and the lid to a Pandora's box was opened. There was in place a standard package of insurance tailored, in the loosest sense, to a start-up within the life sciences sector: apart from standout cover in respect of lab equipment and clinical trials (my client being a pre-clin CRO), the policy could just as easily have applied to any business in any sector. The range of insurances within the package included, among other usual covers, professional indemnity, the cover most relevant to a party providing services. With GBP 1,000,000.00 worth of cover worldwide, the package was nice on the outside but quite useless for two reasons.

The first hurdle was well signposted within the main body of the policy, a contractual bombshell: a general exclusion of cover for claims regarding, among others, any actual or alleged liability under any oral or written contract or agreement, including but not limited to express warranties or guarantees, which by necessary implication included indemnities. The second hurdle lay hidden at the back of the policy within a schedule headed professional indemnity, namely cover in respect of any claim in relation to any act, error, or omission committed by the client in the rendering of professional services, which means negligence, but excluding protection against alleged or actual infringement of any IP rights, save for any unintentional breach of confidentiality.

Business insurance

Business insurance is a predictive, cost effective means of

transferring risk from a business to an insurer. Insurance is often borne of a requirement, rather than a desire, to insure, whether that requirement is legal, regulatory, contractual, or third party. The extent of the requirement depends upon the business: the greater the risk to the business the more there is a requirement for insurance and vice versa. Enhancement of the business, in whatever form, will often act as a trigger for more insurance, so that premiums become a direct consequence of the various underlying exposures faced. In terms of insurance, the balance for any business is to keep the insurance and premiums commensurate with the exposures and not way out in front or playing catch up.

Packaged insurance is like a packaged holiday: not quite as nice as the brochure makes out, with covers for most matters but not all nature of incidents and, as always, the devil is in the detail. In the negotiation, insurance had been taken some 9 years earlier, renewed automatically, and remained useful but it was time to consider additional, bolt-on, cover and plug some hitherto unknown gaps. Several proposals of insurance later, it became apparent that bolt-on cover for third party IP and contractual claims is almost impossible to come by, at least for a premium that is commensurate and reasonably affordable.

Despite IP often being heralded as the top prize within the life sciences, certainly at the start-up stage, there is no reasonable solution to IP insurance. The lack of affordable IP insurance is fundamentally due to an unquantifiable risk associated with IP valuation and, therefore, the level of consequential damage caused by IP loss or infringement. The lack of a solution is due also, in part, to certain business tactics, common down Silicon Valley way, of using IP insurance (it is available to well off multi-organisations) as a litigation tool to threaten competition and stymie growth. Thus, there exists a vicious circle: for insurers to be profitable and not over expose themselves to unquantifiable risk, the premiums are set deliberately high, high enough to be off-putting, which means almost no (if any) packaged insurances include cover for third party IP and very few start-ups can afford to purchase bolt-on third party IP insurance.

The reasoning behind a lack of insurance regarding contractual claims is beautifully subtle. The theory goes, the availability of insurance in respect of contractual claims would represent a moral hazard to insurers and their customers in that, should the urge take a contracting party, it would pose a temptation to purposely breach an obligation, in the full knowledge that an insurer would always pick up the tab. I like the idea that insurers look out for the moral well-being of their customers and that insurance is founded on the premise of there being an unanticipated event and not some contractual sabotage at hand. It is a fact, however, that contractual claims often go hand in hand with claims in negligence, and the losses under each cause of action are calculated differently. The obvious catch is that insurance may cover claims under certain heads of damage but not others.

Conclusion

In my years of practise, it never occurred to me to assess the insurance risks taken by parties but only the legal risks. Now, I question the parties' insurance position and, where necessary, seek a warranty regarding the same, so that it may be legitimately married to potential liability in a given transaction.

Limit the risk by:

- making an assessment of your insurance position, especially with regard to the general exclusions;
- a consideration of the adequacy of insurances held, especially upon any enhancement of the business;
- a consideration of what constitutes a claim against the business, according to the policy, especially concerning the causes of action included, such as negligent acts, errors or omissions, or loss or physical destruction, as well as those excluded.
- a determination of the extent you may go on liabilities and limitations based upon a consideration of what constitutes a claim;
- a consideration of the insurance position with regard to indemnities;
- asserting caps on liabilities that are set at a fee level or at any sum actually recovered under insurance;
- rejecting indemnities on liabilities that are not covered by insurance (such as third party IP, contractual claims and other causes of action); and
- removing any provision declaring valid insurance for claims arising under an agreement, in the event that no such insurance is in place.

No exclusive patent licence[1]

Exclusivity in respect of a patent licence means the grant of rights to the licensee and is to the exclusion of all others, including the licensor.[2] Nonetheless, it is possible to have a plurality of exclusive licensees in respect of any one patent[3] such that a licensee has the exclusive right to manufacture, another to sell in respect of indication X, and another to sell in respect of indication Y.

Background

In Neurim, the licence dispute turned on the construction of two different agreements between Neurim (as the licensor) and Flynn (as the licensee) being a November 2011 agreement (the November agreement) and a January 2020 agreement (the January agreement). The November agreement did not claim to grant an exclusive licence. By clause 3.6 of the January agreement, clause 3.1 of the November agreement was deleted and replaced to read:

"Neurim grants Flynn which accepts… an exclusive licence to Distribute the Product in the Territory for use in the Field during the Term."

Clause 17.3 of the November agreement concerned litigation and provided:

"Neurim shall have the sole right to bring an infringement action… To the extent that the infringement or misuse takes place in the Territory and Neurim elects not to take action… Flynn may do…"

Neurim and Flynn commenced patent infringement proceedings against Mylan, and Mylan counterclaimed for revocation of the patent. In its defence, Mylan argued, among other things, that Flynn was not Neurim's exclusive licensee under the patent and that Flynn could have no standing in the proceedings.

Judgment

The High Court (Mr Justice Marcus Smith) decided:

- reading clause 3.1 on its own, without considering clause 17.3, gave an entirely misleading view of Flynn's rights under the licence;
- merely referring to the grant of rights being 'exclusive' is not on its own sufficient;
- the key question is whether the licensee has the right to vindicate the rights granted, that is to have the same rights as the proprietor to bring infringement proceedings;[4]
- where the licensor seeks to use other licence terms to retain control over infringement proceedings, the licensee does not have the same rights as the proprietor and cannot be considered an exclusive licensee;
- the effect of the other licence terms was to render the licence non-exclusive; and
- construing the agreement as a whole, Flynn was not Neurim's exclusive licensee and had no standing in the proceedings.

Conclusion

Although focused upon provisions for the control of litigation, the decision highlights other implications when drafting patent licences. Licences are frequently drafted across different intellectual property rights (patent and know-how licences are common), company structures (it is not uncommon to see a licence granted to a licensee and its affiliates), territories, and jurisdictions and what works in one context may not work in another.

Whether the licence granted by a licensor to a licensee is exclusive or non-exclusive is one of construction. The essential element of an exclusive licence is that it is a licence to the exclusion of all other persons, including the patentee or applicant.[5] Each exclusive licence may only be granted to one entity, and a licence will not be exclusive if granted to a number of entities, even if they are under the same control.[6]

Parties involved in the licensing of patented technology should consider the licence terms relating to the grant of rights and the control of proceedings to avoid an inadvertent grant that could be construed as non-exclusive. Each exclusive licence may only be granted to one person. In the event parties desire that affiliates benefit from an exclusive licence, this should be done instead through appropriate sub-licensing terms.[7]

[1] Neurim Pharmaceuticals (1991) Ltd and another v Generics UK Ltd (t\a MYLAN) [2020] EWHC 3270 (Pat).
[2] Patents Act 1977, s. 130(1).
[3] Courtauld, [1956] RPC 208 at 210; Illumina Inc v. Premaitha Health plc [2017] EWHC 2930 (Pat).
[4] Patents Act 1977, s. 67(1).
[5] Dendron v. University of California [2004] EWHC 1163 (Pat).
[6] Illumina at 254.
[7] An exclusive licensee may grant sub-licences to persons authorised by him: Dendron at 11; Illumina at 254.

Confidentiality matters

Introduction

Recently, I advised in arbitration proceedings in which the issues surrounded the subject of confidentiality, an often overlooked subject and something of a poor relation to traditional forms of intellectual property. Confidentiality is often taken for granted, with little understanding of its many nuanced applications. Below are some pretty basic but largely unknown matters of its application.

- A non-proprietary consideration. The law does not regard information as property. There is no proprietary right to information as ideas or concepts by or in of themselves, just as traditional forms of intellectual property are concerned only with physical expression.

- Context is key. Circumstances define whether information is to be treated as confidential. Determine the circumstances in which information is generated and the purpose for dissemination, and the law will determine whether such information is protected.

- Rendering confidential the non-confidential. A contractual term restricting the disclosure of information acts as a negative covenant or agreement, even though the information in question may be common knowledge or easily ascertainable.[1]

- Contractual and equitable considerations. A recipient's agreement that information is confidential will give rise to an express or implied contractual obligation of confidence.[2] In the absence of an agreement, equity will determine it sufficient that a recipient has notice of information being confidential.

- Delayed notice. Delayed notice that information is subject to a duty of confidence will not prevent such a duty affecting a recipient when the true position becomes known.[3] In the event of anticipated notice, a 30 days period of notice is commonplace, information is held on trust and treated as confidential regardless.[4]

- Passage of time. There is a limit in time after which the confidential character of information may lapse. In each case, the original purpose of the duty of confidence is relevant and duration will vary according to the nature of the information and the nature of the relationship.

- Concurrent obligations. Where a confidential relationship arises from a contract, which contract is absent an express confidentiality term, a contractual duty of confidentiality is implied, and the scope of that duty will be the same, whether viewed as an implied term or an equitable duty.

- An express contractual obligation of confidentiality will not preclude the existence of a concurrent equitable duty of confidentiality, and the extent of the equitable duty will be determined by reference to the underlying contractual relationship and not equity.

- Necessity of identity. Information must be specific in that it is clear and identifiable, although a party's obligation of particularisation is not absolute. In a contractual context, the entirety of a collection of information may fall within a contractual obligation of confidence, subject to exceptions.[5]

- Trivial or useless information. Confidentiality does not attach to trivial or useless information. Relief is available only if the information is significant, not in the sense of being commercially valuable but in the sense that the preservation of its confidentiality is of substantial concern to the claimant.[6]

- Public domain. Apart from contract, for information to be confidential it must have the necessary quality of confidence, namely it must not be something that is public property and public knowledge. Once information enters into the public domain, the principle of confidentiality is lost.[7]

- A third party may receive information in circumstances where the supplier is in breach of confidence to another (the confider). Where the third party knows, ought reasonably to know, or has notice that it has been disclosed by their informant in breach of confidence, they will themselves owe a duty of confidence to the confider.

[1] Att Gen v Barker [1990] 3 All ER 257 at 259.
[2] Compared with the position in equity, where information must have the necessary quality of confidence.
[3] In Toulson & Phipps on Confidentiality, the scenarios under consideration concerned the position of a third party, who receives information innocently and subsequently learns that it was supplied to him in breach of confidence.
[4] Most common to oral disclosures, especially US NDAs, with written confirmation within a given period of time.
[5] Force India Formula One Team Ltd v Aerolab SRL [2013] EWCA Civ 780.
[6] Moorgate Tobacco Co Ltd v Philip Morris Ltd (No.2) [1984] 156 C.L.R. 414.
[7] Attorney General v Guardian Newspapers Ltd (No. 2) [1990] 1 A.C. 109 at 282.

EC v. AZ - best reasonable efforts

Introduction

The European Commission (EC) has lost its interim action against Anglo-Swedish drug maker AstraZeneca AB (AZ)[1] to force AZ to supply 120 million doses (md) of its ChAdOx1 nCov-19 vaccine (Vaccine) by the end of June or face a €10 euros daily fine for each dose[2] that is not delivered. The objective of the action before the Court of First Instance in Brussels was to expedite delivery of the necessary Initial Europe Doses.

The Court ordered that AZ should deliver a total of 80.2md by 27 September, comprising 15md by 26 July, 20md by 23 August, and 15md by 27 September.[3] Should AZ miss the deadlines, it would face a penalty of €10 euros per dose not delivered, less than the daily fine sought by the EC. In response, AZ said it had already supplied more than 70md to the EU and would substantially exceed 80.2md doses by the end of June.

Background

At the end of January 2021, AZ announced it would cut back the supply of its Initial Europe Doses[4] to the European Union (EU) in the first quarter to 31md. AZ referred to a disruption at a production plant in Belgium[5] and stated it could not compensate for the delay with doses produced at its United Kingdom production sites, which it would use to meet its obligations toward the United Kingdom.

There are two stages to the Vaccine production process: (1) production of the drug substance (the Vaccine itself);[6] and (2) production of the drug product (the Initial Europe Doses).[7] The problem occurred with production of the Vaccine, causing a knock-on effect with the Initial Europe Doses. Cell cultures infected with the virus seed produce a Vaccine molecule, and whereas some of the batches produced a high yield, other batches produced a low yield.

The EC-AZ Advance Purchase Agreement (APA) dated the 27 August 2020 imposes a "Best Reasonable Efforts" obligation upon AZ to manufacture its Initial Europe Doses within the EU[8] for distribution and to deliver to distribution hubs, following EU marketing authorisation, approximately (i) 30md to 40md by the end of 2020, (ii) 80md to 100md in Q1 2021, and (iii) the remainder of the Initial Europe Doses by the end of Q2 2021.[9]

The concept of best reasonable efforts originates from common law and is familiar within civil law systems, such as that under Belgian law, being the law of the APA. Efforts (or endeavours), whether best or reasonable, are less than absolute obligations, relevant for determining the nature of an obligation and may cause a cumbersome evidential burden. In any event, AZ has no absolute obligation to supply the Initial Europe Doses.

Generally, the concept is to do all that can reasonably be done in the circumstances but will not require actions detrimental to the financial interests of a party or that would undermine its commercial goodwill or standing. In practice, a party must take all commercially practicable action and incur reasonable expense, diverting resources from elsewhere within the business, where necessary.

Specifically for AZ, the concept is objective, its activities and degree of effort to be comparable to those that would be exerted by a company of similar size, with a similarly-sized infrastructure and similar resources as AZ would undertake or use in the development and manufacture of a Vaccine at the relevant stage of development or commercialization having regard to the urgent need for a Vaccine to end a global pandemic.[10]

The APA's definition of best reasonable efforts takes into consideration the relevant stage of development or commercialisation, efficacy, and safety factors that sway in the favour of AZ. The Vaccine is a new biological product, and a certain inherent level of production uncertainty may be expected. AZ is not the only company that has encountered production delays, as Pfizer will temporarily decrease deliveries of its vaccine to countries outside of the United States, as it renovates a factory also in Belgium.

Only in the event the EC is able to show that AZ did not undertake or use all activities and degree of effort that a company of similar size, infrastructure, and resources would undertake or use, to scale up its manufacturing of the Vaccine, whether at the Belgian production plant or elsewhere within the EU, could the EC claim, on a balance of probabilities, that AZ had failed to fulfil its obligation under the APA.

The EC's claim is not simply that AZ failed to deliver the Initial Europe Doses according to the APA but that AZ failed to manufacture the Vaccine according to the APA. There is also the claim that doses were manufactured and the EC is entitled to claim them. The doses referred to by the EC were manufactured for and on behalf of AstraZeneca UK Limited (AZ UK),[11] with the drug substance produced at facilities in the United Kingdom and finished in the Netherlands.

The APA obliges AZ to use its best reasonable efforts to manufacture the Vaccine[12] at manufacturing sites located within the EU, which for the purpose of the section only includes the United Kingdom and may manufacture the Vaccine in non-EU facilities.[13] Accordingly, the obligation of best reasonable efforts to manufacture the Vaccine applies to all of AZ's manufacturing sites within the EU and the United Kingdom.

A difficult claim

- On the face of it, the claim may seem about a failure to use best reasonable efforts to deliver the Initial Europe Doses (which according to the APA must be manufactured within the EU) but instead it is about a failure to use best reasonable efforts to manufacture the Vaccine.
- It is not a breach of the APA by AZ to fail to use manufacturing sites within the United Kingdom to deliver the Initial Europe Doses, as the APA only requires AZ to manufacture the Vaccine from sites located within the EU (which for the purpose of the section only shall include the United Kingdom). AZ UK has licensed production of the Vaccine to 15 different countries, to supply dedicated regional supply chains. There are no significant exports of finished Vaccine doses from the United Kingdom because of the regional supply chains.
- The EC is entitled only to the Initial Europe Doses AZ succeeds in producing under the APA, using its best reasonable efforts. The EC is not entitled to doses that exist because of earlier contractual arrangements involving third parties,[14] even if such doses are produced within the EU. In other words, the EC has no exclusivity or right of priority over other parties.
- In the case of AZ, best reasonable efforts, as defined, means the development and manufacture of the Vaccine and not the diversion of doses developed and made under third party arrangements, whether within or outside of the EU.
- According to the APA, there is no stipulation to manufacture the Vaccine within the United Kingdom, only that the United Kingdom is an optional manufacturing site.[15]
- It is highly unlikely a company of similar size, infrastructure, and resources as AZ would divert doses developed and made under third party arrangements, which arrangements contain identical obligations (upon AZ UK) of best reasonable efforts.[16] As such, a failure by AZ to so act should not be seen as a breach of the APA.[17]
- The EC and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against AZ arising out of or relating to… delays in delivery of the Vaccine under the APA.[18] Delays in delivery of Initial Europe Doses arise out of or relate to delays in delivery of the Vaccine.
- In any event, the aggregate liability of AZ… shall not exceed the amounts actually paid by the EC and Participating Member States under the APA.[19]

Conclusion

A further court hearing will take place on 24 and 27 September to determine whether AZ made its best reasonable efforts to fulfil its obligations toward the EC under the APA. It is a decision that could go either way, with both sides claiming victory, as they did following the interim decision.

[1] A company incorporated in Sweden having a business address of Kvarnbergag 16, 151 85 Södertälje.
[2] A dose is approximately 5.0 x 1010 virus particles/dose in no more than 0.5m1.
[3] The doses will be in addition to 30 million that had been supplied to the EU by the commencement of the proceedings.
[4] 300 million doses of the Vaccine for distribution within the EU by the first half of 2021.
[5] AZ's Belgian partner, Novasep, struggled with low yields of the Vaccine.
[6] Produced in Belgium (Novasep), the Netherlands (Halix Biologics), and the United Kingdom (Oxford Biomedica and Cobra Biologics).
[7] Produced in Italy (Catalent) and Germany (ADT Biologika).
[8] Section 5.4 of the APA imposes upon AZ an obligation to use its best reasonable efforts to manufacture the Vaccine within the EU, which for the purpose of that section only includes the United Kingdom.
[9] Schedule 1 of the APA corroborates section 5.1 of the APA for the Initial Europe Doses with an "Estimated Delivery Schedule" indicating monthly and cumulative doses between December 2020 and June 2021 to 300md.
[10] Section 1.9 of the APA.
[11] A company incorporated in England and Wales having a registered address is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom CB2 0AA.
[12] For the purposes of the APA, Doses, Vaccine, and Initial Europe Doses are defined differently.
[13] Section 5.4 of the APA.
[14] Licence Agreement dated the 17th May 2020 between AZ UK and Oxford University Innovation Limited.
[15] A spokesperson for the EC appears to have misinterpreted the decision of the Court in this regard: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_3107.
[16] Clause 1.1 of the Supply Agreement between AZ UK and Secretary of State for Business, Energy, and Industrial Strategy (Supply Agreement).
[17] Pacta sunt servanda (agreements must be kept): a principle applicable across the EU.
[18] Section 15.1(e) of the APA.
[19] Section 15.2 of the APA.

Advanced Research and Invention Agency

Introduction

June saw the House of Commons debate the Bill to establish the Advanced Research and Invention Agency (ARIA), a research funding body, whose role will be to conduct, commission, and support ambitious scientific research with a tolerance to failure.

ARIA's functions

It is anticipated ARIA will:

- commission or support others to conduct scientific research, develop, and exploit scientific knowledge and collect, share, publish, and advance scientific knowledge;
- identify areas that would benefit from further scientific research or carry out laboratory work itself: the Bill allows ARIA to contract or partner with academic or industry teams in connection ARIA's research programmes;
- develop and exploit scientific knowledge that will enable ARIA to use scientific research for the purposes of creating prototypes or introducing products to market: ARIA may commission or support others to do the same and may take an equity stake in a company with which it had partnered to conduct basic research with the intent of bringing a product to market;
- disseminate scientific knowledge by convening conferences or seminars, publishing academic or other papers for closed or public consumption: ARIA may commission or support others to do the same, with such activities bringing people and organisations together to advance scientific knowledge; and
- convene meetings and conferences to discuss how research can be progressed.

ARIA may provide financial support including making grants, loans, investments in companies or other entities, or any other payments including prizes. In providing financial support or making property available, ARIA may do so on conditions that:

- financial support be repaid or made good, for example, where conditions have been breached. ARIA may also require interest to be payable;
- property is restored or returned; and
- information is provided to ARIA.

Conclusion

The Bill stands out for its lack of detail. Most noticeably, there is no clear purpose for ARIA, and there is much that remains unclear about what ARIA is meant to be. Efforts by the SNP to amend the Bill and give ARIA a primary mission of support for scientific research into:

- human health and the development of new medicines and health technologies; and
- the development of technologies and research that support the UK's transition to net-zero carbon emissions or reduce the harmful effects of climate change,

met with resistance. According to government support, it is not so much that ARIA had not got a mission: its mission to discover areas of research that could potentially be high risk but deliver high rewards, but that tying ARIA to specifics such as health research or climate change, although they are very important, would potentially hamper ARIA's ability to find that cutting-edge science and make the most of it.

Further, concern was expressed over a lack of potential scrutiny and transparency, namely a blanket exemption for ARIA from the Freedom of Information Act 2000 and the Public Contracts Regulations 2015. Amid concerns over possible cronyism, further efforts by the SNP to amend the Bill and make ARIA:

- a public authority within the meaning of section 3 of the Freedom of Information Act 2000; and
- a central government authority within the meaning of regulation 2(1) of the Public Contracts Regulations 2015,

again met with resistance. It was argued that ARIA should not be weighed down by bureaucracy and the burden of administration. With its unique freedoms and independence to enable transformational research, ARIA would inevitably receive a disproportionate number of FOI requests relative to its size. Such requests could call into question whether ARIA was able to deliver the game-changing R&D sought by the Bill.

Pinged by the NHS Covid-19 app

Introduction

In the week to 10 July, the NHS Covid-19 App (the App) sent a record 520,194 alerts. There is plenty of concern over the number of persons expected to self-isolate in the coming months either following a positive test outcome for coronavirus or upon receipt of a notification alerting a person they have come into close contact with someone who has tested positive for coronavirus. I received such a notification through the App. Subsequently, I tested negative twice and received no follow up call or text.

The test and trace scheme

The test & trace scheme was launched in England on 28 May 2020 with similar manual tracing schemes operating within each of the devolved jurisdictions. Initially, compliance with the test & trace scheme was voluntary, with no sanctions for individuals who refused to self-isolate. On 28 September 2020, however, the Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 SI: 2020/1045 (the Regulations) made it a legal requirement to self-isolate.

Persons who had tested positive for coronavirus or had been notified as close contacts through the test & trace scheme would have a legal duty to self-isolate, with fines for non-compliance of between £1,000 and £10,000. For the purposes of the Regulations, close contact means a face to face contact within 1 metre; more than 15 minutes within a 2 metres distance; or travelling in a car or other small vehicle with an individual or in close proximity to an individual on an aeroplane.

The NHS Covid-19 app

The App was released on 24 September 2020 for use within England and Wales following trials of the technology on the Isle of Wight and in the London Borough of Newham. The release of the App followed the earlier launch of similar apps by the Northern Ireland Executive and Scottish government. With the use of Bluetooth technology, the App automates the human process by alerting people when they have been near someone who has tested positive for coronavirus. There is no requirement in law to download the App due in part to the fact that a proportion of the population does not have access to a smartphone or to sufficiently up-to-date operating software.

The App also allows people to check symptoms, book a test, and 'check-in' to places they visit using a QR code system. The App complements the test & trace scheme rather than replaces it and should help to capture possible transmission that manual contact tracing cannot, such as someone in the same queue or bus, who is not known to the person who has tested positive and whose details could not, therefore, be provided to the contact tracer.

The App has not been without its issues. There was some confusion about notifications from the App, which informs the user that there has been a possible Covid-19 exposure (as opposed to a strict self-isolation notification). This message means that a potential exposure has been detected but that it is being verified. As the exposure has yet to be confirmed, users who receive these messages are not asked to self-isolate and are only told to do so if they subsequently receive a self-isolation notification, which will provide a countdown feature. This was my own experience.

Conclusion

The NHS makes almost no mention of the differences between the test and trace scheme and the App:

- the main difference lies in non-compliance. According to the Regulations, self-isolation is obligatory only where an adult is notified by a relevant person, other than by means of the App;
- an instruction to self-isolate through the App carries no force of law and is advisory only, whereas the same instruction through the test & trace scheme may give rise to a financial penalty for non-compliance;
- the App is completely anonymous. Use of the App cannot be monitored, and any data collected about an individual cannot be used to identify that individual (hence there can be no force of law), unlike the test and trace scheme;
- the App does not track users (for example, at home or in a public space), unlike the test and trace scheme; and
- enforced self-isolation through notification from the App may only be possible upon a reasonable instruction from an employer to an employee.

WTO debates EU's IP waiver proposal

June saw a World Trade Organization (WTO) committee meet to discuss an EU proposal to boost the global distribution of COVID-19 vaccines through the waiving of certain regulatory hurdles rather than suspending intellectual property (IP) protections for the vaccines.

The Biden administration's about-face in early May 2021 supporting the waiver put pressure on other nations that remained opposed. Supported by more than 100 other WTO members, the waiver would suspend four provisions of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that require members to enact laws protecting IP. The waiver would last for three years, targeting health products and technologies.

The EU's proposal was suggested as an alternative to the Biden administration's support for a temporary waiver on IP protections for the life-saving doses. Instead, the proposal called for expanding the production of doses (a surprising aspect given current issues over production), phasing out export restrictions, and using existing flexibilities within the WTO's IP rules.

According to a Geneva-based EU trade official, ensuring vaccine access could be achieved while maintaining IP protections. The official pointed out the benefit of its proposal would be that it could be implemented quickly as it would not change the WTO's IP rules and that governments would not need to negotiate with patent holders, often the longest process of the compulsory licensing procedure.

Those in support of waiving IP, including South Africa and India, argued the EU's proposal was simply a reiteration of existing rights that members have under TRIPS and asked the EU to explain how it would actually ensure more vaccines, given the EU is a geopolitical body and not a drug manufacturer. The proposal also suggested expanding production by increasing manufacturing capacity in Africa and by encouraging vaccine producers to make pledges to increase supplies to vulnerable developing countries.

The EU proposal voiced support for compulsory licensing, in which a government grants a limited licence to create vaccines without the patent holder's consent, when companies will not agree to voluntarily licence the technology. Compulsory licences for patents are already authorised under TRIPS and have been used during previous public health emergencies, including to boost the production of AIDS and HIV drugs.

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