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SCOTT FARNSWORTH

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Valneva deal brought to an end

On 13 September 2021, French biotech company Valneva SE (Valneva) announced it had received a termination notice from the government in relation to a Supply Agreement (Agreement) for its COVID-19 vaccine candidate, VLA2001 (Vaccine), despite the government having invested £100 million in the expansion of Valneva's factory in Livingston, Scotland. The announcement took many by surprise.

The French company is still testing the Vaccine in human trials, with phase 3 results and MHRA approval expected by Valneva in Q4 and late this year, respectively. Valneva submitted a rolling review to the MHRA in August 2021. The deal was worth up to €1.4 billion, with manufacturing to take place in Livingston and deliveries due to begin in 2022.

According to the announcement, the government terminated the Agreement saying Valneva was in 'breach of its obligations' under the deal. Valneva strenuously denied the claim. At the time of the announcement, the precise nature of the breach was unclear, and curiously, Valneva had not specified the breach relied upon or whether it intended to challenge the government's decision, notwithstanding the money at stake.

On 14 September 2021, however, Health Secretary Sajid Javid told the House of Commons there were 'commercial reasons' for terminating the Agreement, adding it was also clear the Vaccine would not get approval from the MHRA. The Health Secretary has since been accused of lying: watch this space.

It is likely the Agreement requires notice from Valneva to the government in the event Valneva knows or believes there to be any delay to, rejection of, or other issue jeopardising its grant or renewal of regulatory approval. Such a provision is commonplace and appears within the government's supply agreements with other vaccine manufacturers. It is purely a notification provision and does not entitle termination per se.

A right to terminate will exist (usually) if regulatory approval is rejected, withdrawn, or suspended by the MHRA. There has been no public indication of any such decision, although it is likely an issue has been identified in the rolling review. The Financial Times reported a preliminary look at the results suggested the Vaccine was less effective than other vaccines. A failure to gain regulatory approval does not constitute a breach of the Agreement but merely a termination event.

Intellectual property and R&D

Introduction

Frequently with transactional R&D, consideration of the intellectual property (IP) position, as well as dealings with intellectual property rights (IPR), are not given sufficient attention.[1] Rightly, there is sufficient consideration given to other subject matters, particularly compensation (payment in layman's terms) and indemnities. The position is reversed with collaborative R&D, where the IP position is given centre stage, arguably more bespoke, and its treatment determined largely according to a term sheet agreed between the parties in advance of a main agreement. Often it seems, the lack of sufficient attention with transactional R&D is down to a lack of understanding.

The objectives of parties involved with transactional R&D can differ quite significantly from those of parties involved with collaborative R&D. Transactional R&D may be a straightforward service in return for compensation, most commonly subject to multiple work orders and an overlying framework agreement, such as an MSA. Objectives with collaborative R&D may involve more: supplementing internal research efforts and resources; accelerating research programmes; achieving a commercial advantage; obtaining financial support to carry out research; publishing the findings of research; attracting better staff (and students); and increasing profile within academia or industry (or both).

IP and IPR

With transactional R&D and collaborative R&D, IP and IPR are used interchangeably and can be whatever the parties define them to mean. Legally, however, there is a significant difference between IP and IPR. For instance, any patent or application for a patent is personal property (without being a thing in action),[2] and rights in or under a patent or patent application may be transferred, created, or granted.[3] The right (the IPR) is the lawful means to have dealings with a patent or patent application[4] and not the patent or patent application (the IP) itself. It is common for definitions within transactional R&D to overlook the difference, possibly to the detriment of a party, when IP and IPR should be inclusively defined.

Subsistence

IP is intangible property and subsists within or is granted for something that is tangible. IP cannot exist without something that is tangible. Frustratingly and too often, IP is not identified with any tangible object in mind but instead treated in isolation, as if it floated in the air. Subject to qualifications:

- copyright subsists within literary, dramatic, musical, and artistic works;
- patents are granted for product and process inventions;
- design (unregistered) right subsists within the shape or configuration (whether internal or external) of the whole or part of an article;
- registered designs are granted for the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture or materials of the product or its ornamentation; and
- trade marks are granted for goods and services.

Capturing IP

With any transaction, it is best practise to understand the research undertaken and the expectations of the parties. Each aspect determines when and what may be some outcome of the research undertaken. Wrongly, it is said the results of research (Results) cannot be guaranteed. In fact, there can be no guarantee that research will lead to any particular Results. Results are the purpose and product of research, whether as raw primary information or as analysed secondary information (or both), like them or not. Accordingly, Results should be an item specified as deliverable. Parties should ensure that as well as the ownership of Results transferring between them, the ownership of foreground IP (IP arising from the research), expressly identified as subsisting within Results, is assigned.[5]

With any research agreement the starting point for capturing IP is the accurate interpretation of its terms, such as IP and foreground IP.[6] Items such as confidential information, know-how,[7] and trade secrets are not IP. Although frequently included within the definition of IP, they are not property in law. They are specified types of information protected by rights arising out of a set of circumstances, most commonly contractual or in equity (or both). Accurate interpretation of terms creates certainty of contract. Unknowingly, parties and their advisors show a tendency to seek to capture IP, which the research will not nor be intended to produce, as deliverables in which such IP would subsist cannot be expected from the research undertaken.

Often terms are not defined at all, which by necessary implication creates uncertainty. It is surprising how few parties and their advisors understand the accurate interpretation of certain terms, such as know-how and trade secrets.[8]

Licence of IP

Quite often with transactional R&D, no express licence (Customer to Provider)[9] is granted for the use of background IP in the course of research. By necessary implication, the law assumes a permission to use the background IP of the Customer by the Provider, but unlike a licence, a permission to use is an informal, bare (unconditional) consent, with little actual control. A background licence should grant the Provider a revocable, terminable, non-exclusive, royalty free licence to use the background IP of the Customer, for the sole purpose of carrying out the research and for no other purpose. Upon completion of the research, such a licence should be expressed to terminate automatically.

Importantly, the Customer should obtain from the Provider a non-exclusive, revocable, terminable and royalty-free licence, with no right to grant sub-licences, to use the background IP of the Provider but only for such purposes as are necessary, in the reasonable opinion of the Provider, to allow the use and exploitation of Results or any deliverables (or both) by the Customer and for no other purpose. There is often disagreement over such a licence, namely with sub-licensing and control over the grant being with the Provider.

The parties should agree the Provider must carry out the research in compliance with all applicable laws and having obtained all necessary licences and consents. This is particularly significant in research requiring a cell line transfer and the Customer and the Provider must ensure that such transfers do not require a licence back of Results and provide end users, usually Customers but note the clients of Customers, with unconditional use of Results, achieved through the licensed cell line. Furthermore, it is common that cell line transfers permit only non-commercial exploitation of Results achieved through use of cell lines in research, which is problematic for the Customer.

Process inventions

In the course of transactional R&D, it is likely the parties will each introduce their background IP as part of the research. The Customer will seek ownership or a licence of foreground IP, and the Provider must ensure any foreground IP is expressly non-inclusive of process inventions. Process inventions are any alteration, enhancement, improvement, input, or modification to the know-how of the Provider, arising from and as a result of the research but should not include or be dependent upon the background IP of the Customer.

IP warranties

Transactional R&D features few IP warranties, as opposed to warranties in general. The most common is a warranty from the Customer that receipt, storage, and/or use of Customer materials by the Provider, in accordance with the research agreement, of any information, documents, materials, data or other items provided by the Customer, including the background IP of the Customer, will not infringe third-party rights, which warranty is often coupled with a conditional indemnity[10] from the Customer in favour of the Provider.

The Customer may seek a warranty from the Provider that use of Results will not infringe third-party rights. Such a warranty is unreasonable. Unlike the use warranty given by the Customer, use of Results will not be within the scope of the research agreement and will be outside the control of the Provider. Such a warranty, if demanded, may be negated by wording that conditions the warranty upon the knowledge, information, and belief of the Provider. A more appropriate, warranty from the Provider would be that Results do not contain or depend upon any background IP of the Provider for their use or exploitation.[11]

[1] For the purposes of this article, IP will mean IP and IPR.
[2] A chose in action or thing in action is a right to sue. It is an intangible property right recognised and protected by law that has no existence apart from the recognition given by the law and that confers no present possession of a tangible object.
[3] Section 30(1) of the Patents Act 1977 with rights transferred created, or granted in accordance with subsections (2) to (7) of section 30.
[4] Thaler v The Comptroller-General of Patents, Designs and Trade Marks [2020] EWHC 2412 (Pat). Judgment of the Court of Appeal (hearing 27th July 2021) pending but will not affect the proposition as between IP and IPR.
[5] Transfer of ownership of foreground IP between parties is by way of assignment of all present and future rights, title, and interest.
[6] Background IP is IP that exists (a) at the commencement of the research or (b) after the commencement of the research but not as a result of the research or in connection with the relevant research agreement.
[7] Often poorly defined, if at all, know-how is any scientific, technical, or other practical knowledge including algorithms, concepts, data, drawings, formulae, methods, models, plans, practices, processes, recipes, specifications, statistics, systems, techniques, tests, or tools, in all cases not known to or readily ascertainable by the general public.
[8] Almost never defined, trade secrets are any know-how, which having regard to the reasonable written evidence of a party is (1) proprietary to or in the control of that party and (2) within the general standards applied to trade secrets according to article 39 of the agreement of the member nations of the WTO upon Trade Related Aspects of Intellectual Property Rights. Note the distinction from know-how.
[9] Customer being the party seeking the research and Provider being the party providing the research.
[10] Conditional upon notice of claims, no admissions by the Provider, and control given to the Customer.
[11] A licence of the background IP of the Provider may negate the need for such a warranty.

Pingdemic within a pandemic

No doubt, many of you will have heard of the term 'pingdemic'. For those of you who have not, it is a play on words for being 'pinged' to self-isolate by the NHS COVID-19 app (the App) during the COVID-19 pandemic.

The Impact

Needless to say, prior to 16 August 2021, being pinged proved disruptive to both people's social and working lives. In particular, employers have struggled to cope in supply chains where a number of employees have been asked by the App to self-isolate. The Chief Executive of Marks and Spencer commented on this;[1] you may also have seen the effects of the pingdemic upon KFC (in terms of certain missing menu items) and Nando's closing some branches temporarily.[2] Further, you could see the impact of staff shortages when people could not work from home, e.g. supermarkets and the transport industry, in particular rail and the London Underground.

At its peak, the App was pinging in excess of 600,000 people per week.[3] This was bringing industry and commerce to its knees. The government then sought to fine tune the App which brought the weekly figure down.

Also, from and including 16 August 2021, changes to the law meant that those who are fully-vaccinated (for at least 14 days prior to notification) plus under 18s would not have to self-isolate after coming into contact with someone with COVID-19. Instead, they should take a PCR test – if positive, they would still need to self-isolate, but if not, they could carry on as normal. This is welcome news, as over 79% of the UK population (16 years old and above) are fully-vaccinated (at the time of writing).[4]

What should and shouldn't employers do?

This is not an easy question to answer. In an ideal world, employers would have other staff who could step in for absentees at short notice. This is not always possible and could involve having to engage agency staff at further cost when such funds are not readily available. It is important to have a contingency plan for staff shortages.

Obviously, if an employee can work from home, they should do so. If this is not possible, you should consider if it might be possible to furlough an employee who is required to self-isolate – the Treasury Directions govern the Coronavirus Job Retention Scheme's (CJRS) eligibility rules and suggest it could be possible to do this, "as a measure taken to prevent or limit [the] further transmission [of COVID-19]".

Before placing an employee on furlough, you should take specific legal and accountancy advice, as the landscape is rapidly changing and you would not want any ramifications from HMRC for using the CJRS incorrectly.[5]

I was asked whether an employer could legitimately ask an employee to delete the App and/or ignore any pings. Unsurprisingly, the answer is no. Interestingly, whilst a ping from the App does not legally require you to self-isolate,[6] there is still a moral obligation to do so and, as an employer, any instructions to the contrary could leave you facing claims, such as:

- personal injury, e.g. where other employees catch the virus from an employee who did not self-isolate upon your instruction;
- constructive unfair dismissal (if an employee has two years' continuous service or more): there is an implied obligation on the employer to provide a safe working environment; and/or
- detriment claim: if the employee complains your instruction breaches health and safety obligations, but you still force them to comply. Such a claim could be very costly in terms of compensation and an employee does not need any requisite period of service to bring this claim.

The above list is not exhaustive. Employers should consider the moral stance and reputational damage if they give such instructions. The damage could be irreparable.

The author is Roscoe Fernandes, principal solicitor at and director of Centurion Legal Limited, specialising solely in employment law. Contact Roscoe on +44 (0) 115 822 4847 or at roscoe@centurionlegal.co.uk.

[1] https://www.theguardian.com/business/2021/jul/19/cbi-and-marks-spencer-join-calls-for-government-to-tackle-pingdemic.
[2] https://www.reuters.com/world/uk/fast-food-chain-nandos-temporarily-shuts-over-40-uk-outlets-2021-08-17/.
[3] https://news.sky.com/story/covid-19-pingdemic-record-numbers-as-689-313-alerts-sent-from-nhs-app-in-a-week-in-england-and-wales-12367080.
[4] https://www.bbc.co.uk/news/health-55274833.
[5] https://www.gov.uk/government/publications/treasury-direction-made-under-sections-71-and-76-of-the-coronavirus-act-2020/cjrs-direction (paragraphs 2.2 and 2.3 under the Schedule).
[6] The Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 SI: 2020/1045, regulations 2A(1), 5(1) and 5(3).

Artificial intelligence and inventions

Introduction

On 27 July, the Court of Appeal[1] heard an appeal against the Order of Mr Justice Marcus Smith[2] in which he refused to accept Dr Stephen Thaler's appeal against the decision of the Comptroller-General of Patents, Designs and Trade Marks (the Comptroller) of 4 December 2019, number BL O/741/19, in connection with two British patent application numbers.

Background

The case concerned inventions created by an artificial intelligence (AI) system under circumstances in which the AI system was the sole and actual deviser of the inventions. Issues for determination by the Court included whether the AI system could and should be designated as the inventor, pursuant to section 13(2)(a) of the Patents Act 1977 and Dr Thaler, as the owner of the AI system, was entitled to the grant of the patents pursuant to section 7(2)(b). The Court was required to assume certain matters, which were not in issue namely that the inventions were actually devised by the AI system, Dr Thaler was the owner of the AI system, and the inventions were deemed to meet the substantive requirements for patentability, so there was no objection to the granting of the patents in principle.[3]

Summary of Dr Thaler's case

Entitlement and the right to apply for and obtain a patent is a property right, conferred by section 7(2). There are three classes of person with entitlement, which classes of person represent a closed list. A patent for an invention may be granted:

- primarily to the inventor or joint inventors - section 7(2)(a);
- in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law... or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was at the time of making the invention entitled to the whole of the property in it (other than equitable interests) - section 7(2)(b);
- in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned - section 7(2)(c);

and to no other person.

Dr Thaler relied upon being the first owner of the inventions pursuant to section 7(2)(b) and claimed a rule of law to name himself as applicant.[4] According to Dr Thaler, the rule of law entitling him to ownership was based upon statute, as creating a property right[5] and the doctrine[6] of accession, which provides the owner of a thing is owner of the fruits of that thing. Thus, the owner of a fruit tree will generally own the fruit produced by that tree, and the owner of a cow will generally own the milk of that cow. By analogy, Dr Thaler argued that as he was the owner of the AI system, he was entitled to ownership of the inventions produced by that system.

Quoting from Sir William Blackstone's commentaries on the Laws of England, Dr Thaler submitted:

"*The doctrine of property arising from accession is also grounded on the right of occupancy. By the Roman law, if any given corporeal substance received afterwards an accession by natural or by artificial means, as by the growth of vegetables, the pregnancy of animals, the embroidering of cloth, or the conversion of wood or metal into vessels and utensils, the original owner of the thing was entitled by his right of possession to the property of it under such its state of improvement.*"

Summary of the Comptroller's case

First and to give some context, the Comptroller explained the distinction between inventions that related to or were AI technology, of which there had been many applications to the UKIPO and were proceeding and inventions said to be by AI technology, of which Dr Thaler's applications had been the only two seen by the UKIPO, so far. Accordingly, when it came to talk of stifling creativity and the work going on within the AI industry, the Comptroller submitted those inventions that related to or were AI technology were not stifled.[7]

The starting point for consideration was section 7(3), which defines the inventor as the actual deviser of the invention. The word 'actual' denotes a contrast with a deemed or pretended deviser of the invention and means the natural person who

came up with the inventive concept.[8] Dr Thaler accepted and had nominated his AI system as the inventor in each of his applications. As such, the Comptroller objected that an AI system could not lawfully be the inventor.[9]

Furthermore, section 7(2) confers a property right upon a person or persons with entitlement. A machine is not a person and is without personality, whether natural or legal. Put simply, machines do not have rights.[10] As such, Dr Thaler's AI system could not be granted the property right conferred by section 7(2)(a), and references to a person or persons within sections 7(2)(b) and 7(2)(c)[11] and in the tail piece to no other person suggested the framers of the Patents Act 1977 understood an inventor and joint inventors would be a person or persons.

To be granted a patent, the Comptroller submitted, one must be a person and fall into one of the three classes of person set out within section 7(2). Someone who was not within one of those classes could not be granted a patent for that invention no matter how easily that invention had met the substantive requirements for patentability and no matter who the inventor was.

The Comptroller considered procedural compliance. Section 13 sets out information that must be given to the UKIPO by a non-inventor applicant.[12] The provision is intended to confer some moral right, affirming the position that an inventor must be a natural person and not a machine. Section 13(2) provides: an applicant for a patent shall file with the Patent Office a statement:

- identifying the person or persons whom he believes to be the inventor or inventors; and
- where the applicant is not the sole inventor or the applicants are not the joint inventors, indicating the derivation of his or their right to be granted the patent;

and, if he fails to do so, the application shall be taken to be withdrawn. Such was the position taken by the UKIPO and Mr Justice Marcus Smith.

Conclusion

Often, it can be difficult to read the body language of the bench. Plenty of writing suggests listening and interesting things to note, whereas little writing suggests listening and waiting for interesting things to note. Such were the reactions of the bench toward the Comptroller and Dr Thaler respectively. The analogous reliance upon accession seemed overplayed. The doctrine had only ever been applied to tangible objects and was unsupported by a single example of its application to an intangible object. The doctrine of property arising from accession is based upon tangibles (corporeal substance according to Blackstone). There is a fundamental difference between tangibles and intangibles. Most aspects of property law are routed in possession. Tangibles are rivalrous goods, so possession by A excludes possession by B. Intangibles are non-rivalrous goods and intellectual property is a paradigm example, so possession by A does not exclude possession by B. There is, therefore, a rational basis for the doctrine of accession not to apply to intangible objects.

Dr Thaler has been granted patents in South Africa and Australia: he enjoyed success before the Federal Court of Australia, although The Commissioner of Patents in Australia has decided to appeal the Federal Court's decision. In the United States District Court for the Eastern District of Virginia, a judge has denied Dr Thaler's motion for summary judgment, which upholds an earlier denial of two patent applications for AI-generated inventions by the USPTO. Dr Thaler has decided to appeal.

There is a steady stream of decisions and appeals ongoing, each applying different bodies of law. The Court of Appeal is not due to deliver its judgment until September 2021. In the meantime, Dr Thaler has pointed out the United Kingdom is required to accept a PCT designation in an ex-PCT application. In the United Kingdom, Dr Thaler has filed an ex-PCT application, and it remains to be seen what approach the UKIPO will take, regardless of the decision of the Court of Appeal.

[1] Lord Justice Arnold, Lady Justice Laing, and Lord Justice Birss.
[2] [2020] EWHC 2412 (Pat).
[3] The hearing follows grants of patents, including the world's first such grant, in South Africa and Australia, for an AI-generated invention without a traditional human inventor.
[4] Sections 7(2)(a) and 7(2)(c) of the Act were not relied upon by Dr Thaler.
[5] Section 30(1) of the Act.
[6] Legal doctrine is the currency of the law. In many respects, doctrine or precedent is the law as it comes from the courts, comprising judicial opinion to create rules or standards.
[7] A distinction emphasised by the Comptroller during the Court of Appeal hearing.
[8] University of Southampton's Applications [2005] RPC 220 at 234, affirmed in Yeda Research and Development Company Limited v Rhone-Poulenc Rourer International Holdings Inc and others [2007] UKHL 43.
[9] Paragraph 3.05 of the UKIPO's Formalities Manual provides: An 'AI Inventor' is not acceptable as this does not identify 'a person' which is required by law. The consequence of failing to supply this is that the application is taken to be withdrawn under section 13(2) of the Act.
[10] It was not in issue that Dr Thaler's AI system was the actual deviser of the inventions claimed.
[11] Particularly, section 7(2)(c) of the Act refers back to person or persons mentioned in section 7(2)(a), which by necessary implication suggests an inventor or joint inventors are persons.
[12] Section 13(2) of the Act applied to Dr Thaler as a non-inventor applicant.

Out of control - Innova lateral flow test

Introduction

Project Moonshot was the government's polymerase chain reaction (PCR) mass testing programme for SARS-CoV-2, intended to administer 10 million tests per day by the early part of 2021 and with a whopping budget of £100 billion. Unknown to many, Project Moonshot per se was shelved less than 4 weeks of its announcement[1] following the threat of legal action by the Good Law Project claiming the programme was unlawful as it ignored scientific evidence and committed a vast sum of public money with no transparency over decision making.[2] Quietly, Project Moonshot became part of the NHS Test and Trace scheme: gone and forgotten.[3]

Innova Medical Group Inc

Bent upon the idea of mass testing, the government turned its attention to a different testing strategy and went on to spend and commit to spend eye-watering sums of public money in order to purchase huge numbers of SARS-CoV-2 antigen rapid qualitative test kits, commonly known as lateral flow tests (LFTs). These LFTs were purchased and continue to be purchased from a newly formed start-up, founded on 20 March 2020, called Innova Medical Group Inc (Innova), a US corporation wholly owned by Los Angeles based private equity house Pasaca Capital.[4] Pasaca Capital was founded in 2017 by Chinese-born billionaire Dr Charles Huang (PhD in marketing), who was born and studied in Wuhan: small world.

Introducing LFTs

In charge of the new unprecedented mass screening programme was the head of NHS Test and Trace, Baroness (Dido) Harding. It was under the backing of Baroness Harding that the assessment of LFTs was carried out by Public Health England's Porton Down laboratory and Oxford University, for the purpose of evaluating LFT specificity and sensitivity. Specificity (true negative rate) is the ability of a test to correctly identify people without the disease: the person does not have the disease and the test is negative, whereas sensitivity (true positive rate) is the ability of a test to correctly identify people with the disease: the person has the disease and the test is positive. The preliminary report (the Report) was published on 8 November 2020.

The Innova LFT

Over 130 suppliers of LFTs were identified by the DHSC for desktop review, 40 of which were sufficiently promising and referred to Porton Down for evaluation. According to the Report, the Innova LFT, the test that had been used in a Liverpool pilot scheme, was the most advanced in stages of validation and nearing completion. The Report summarised its performance characteristics: a test specificity recorded as 99.68%; an overall false positive rate of 0.32%, and an overall sensitivity of 76.8% for all PCR-positive individuals – over 95% of individuals with high viral loads – and showing a minimal difference between the ability of the test to pick up viral antigens in symptomatic and asymptomatic individuals.

The Innova LFT was the only test to have been part of the pilot scheme and was different to other LFTs in the rapidity of its results. Working in a similar way to a pregnancy-style test, a result could be delivered between 15 and 30 minutes. The Innova LFT was also portable, much cheaper than the PCR test, did not need to be processed in a laboratory, and could detect the virus directly without the amplification steps of the RT-PCR test.

Red flags

In fact, sensitivity of the Innova LFT was optimal only when used by laboratory scientists at Porton Down (156/197 positive [79.2%, 95% CI: 72.8-84.6%])]. Sensitivity fell when used by fully trained research healthcare workers (92/126 positive [73.0%, 95% CI: 64.3-80.5%]) and fell dramatically still when used by self-trained members of the public given a protocol (214/372 positive [57.5%, 95% CI:52.3-62.6%]; $p<0.0001$ $chi2(2)=30.1$. The far lower rate was not flagged as a problem, notwithstanding the Report's concession that delivery of appropriate training appeared important to test performance.[5]

Necessarily, it was the government's intention that Innova LFTs would be used for self-administration by members of the public. It is a reasonable assumption that training in the use of LFTs (if any) would be minimal and random and test performance lower than the 57.5% stated in the Report. In fact, such lower performance was evidenced in real world data taken from the

pilot scheme and produced by scientists from Liverpool University. In the pilot scheme, Innova LFTs detected only 48.89% of SARS-CoV-2 infections in asymptomatic people, when compared with a PCR test and failed to detect 3 in 10 cases with the highest viral loads.[6]

Within days of the Report, experts warned that Innova LFTs may miss as many as half of COVID-19 cases.[7] Jon Deeks, professor of biostatistics at the University of Birmingham, highlighted concerns over figures for self-administration by members of the public. The Report stated the test's sensitivity was 58% [sic. 57.5%], when used by the public and that the false positive rate was 0.38% (0.16% to 0.88%). While 0.4% (400 in 100,000) was a very low rate, with a sensitivity of 58% [sic. 57.5%] and specificity of 99.6%, this would mean that 100,000 people being tested would find 630 positives, of which only 230 would actually have COVID-19, while 400 would be false positives.

The poor detection rate of Innova LFTs made it entirely unsuitable for the government's proclamation at the time that it would allow the safe test and release of people from lockdown and students from university in the lead up to Christmas 2020, as the tests may miss up to half of COVID-19 cases, and although a negative test result indicated a reduced risk of infection, it did not exclude COVID-19. Independent evaluations for the WHO had shown other LFTs likely to outperform Innova and even those did not have high enough sensitivity to rule out the SARS-CoV-2 virus.

Other research[8] claimed Innova LFTs were highly inaccurate, when early results from students testing at the University of Birmingham and universities in Scotland showed tests had a sensitivity of just 3% and that 58% of positive test results were false.

Birmingham spent six days testing 7,500 students with Innova LFTs in a process overseen by Alan McNally, director of the university's Institute of Microbiology and Infection, who in March 2021 was seconded to set up the first flagship COVID-19 testing facility in Milton Keynes. The team found 2 positives in 7,189 students, which scaled up to 30 per 100 000 and was shocking in itself, as the city of Birmingham, in fact, had a rate of 250 cases per 100,000. The team retested 10% of samples that had been negative with Innova LFTs and found 6 false negative cases, raising the rate to 60 per 100,000.

Scottish universities conducted a total of 43,925 LFTs. Of those, 79 (0.2%) were positive, although a preliminary analysis of 31 of the positive samples showed that only 13 were, in fact, positive on PCR testing, giving a false positive rate of 58%.

Warning signs

On 10 June 2021, the US Food & Drug Administration (FDA) warned the public to stop using Innova LFTs. The FDA stated its significant concerns that the performance of Innova LFTs had not been adequately established, presenting a risk to health. In addition, labelling distributed with certain configurations of the test included performance claims that did not accurately reflect the performance estimates observed during clinical studies of the tests. Recommendations of the FDA warned the public to either destroy the tests by placing them in the trash or return them to Innova.

In fact, limitations of Innova LFTs had been acknowledged in the manufacturer's original instructions for use (the Instructions). The Instructions made it clear the test was for:

- the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs or throat swabs from individuals, who were suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms, meaning it was not designed to screen the asymptomatic; and
- use by clinical laboratory personnel and individuals similarly trained in point of care settings, meaning it was not designed for self-administration by members of the public.

Alarmingly and notwithstanding the Instructions, Innova LFTs were repackaged for the NHS with a different version of the Instructions as of 24 November 2020, which stated 'You can use this self-test kit if you have symptoms or if you are asymptomatic (you do not have symptoms).' The NHS version of the Instructions were hastily updated on 16 January 2021 with the removal of the referenced sentence.

Costing the earth

Confidence in the efficacy of Innova LFTs pre-dated and post-dated their clinical evaluation and by some months. Examination of the government's purchase contracts for Innova LFTs has shown Innova's first contract was agreed as early as September 2020 and before PHE and Oxford University had published results of their evaluation. On 11 November 2020, in response to the Report, Sir John Bell, Regius Professor of Medicine at Oxford University, described the Innova LFTs as

inexpensive. To date, government contracts for Innova LFTs total in excess of £3.3 billion:[9]

- on 17 September 2020, details of a first contract were published with a contract price of £103 million (Σ £103 million);
- on 6 November 2020 details of a second contract were published with a contract price of £496 million (Σ £599 million);
- on 18 December 2020, a modification notice was published indicating an increase of the first contract price to £226 million (Σ £722 million);
- on 9 February 2021, a modification notice was published indicating an increase of the second contract price to £722 million (Σ £948 million);
- on 19 March 2021, details of a third contract were published with a contract price of £912 million[10] (Σ £1,860 million);
- on 23 March 2021, a modification notice was published indicating a second increase of the second contract price to £875 million (Σ £2,013 million);
- on 20 May 2021, details of a fourth contract were published with a contract price of £1,200 million (Σ £3,213 million); and
- on 15 July 2021, details of a fifth contract were published with a contract price of £144 million (Σ £3,357 million).

Made in China

Disregarding the FDA's safety concerns, on 17 June 2021, the MHRA announced that it was extending the UK's emergency use authorisation (EUA) for Innova LFTs through to 28 August 2021. Graeme Tunbridge, the MHRA Director of Devices, stated in the announcement that a full risk assessment had been undertaken by the DHSC as legal manufacturer of [Innova LFTs] in the UK. According to law, one device may have multiple legal manufacturers and each may have regulatory responsibility for that device. Innova LFTs are 'Manufactured for the NHS' and their labelling makes this clear. As the DHSC buys finished LFTs from Innova and relabels them with NHS branding, the DHSC is considered the legal manufacturer. In fact, Innova LFTs are made by Innova's primary contract manufacturer, Xiamen Biotime Biotechnology Co Ltd, based in Fujian, China, and by 31 August 2021, the government had spent in excess of £100 million transporting Innova LFTs from China.

Innova claims to be investing in a facility in Rhymney, South Wales, as part of a collaboration with Sharp Packaging, a division of Healthcare PLC, to make Innova LFTs within the UK. Production was expected to begin in early July 2021. A request from this author to Sharp Packaging for an update upon the production schedule was declined for reasons of confidentiality. The DHSC will continue responsibility for Innova LFTs as the legal manufacturer, as Innova and Sharp Packaging go to lengths to talk of their collaboration to manufacture Innova LFTs over the next 3 to 4 years. Meanwhile, Innova's EUA has expired, suggesting more government contracts for Innova LFTs lay on the horizon, or why begin the collaboration at all?

Conclusion

There is an overwhelming sense of government undermining superior domestic diagnostic tests, while propping up discredited Chinese imports. Of the total £4.5 billion spent by the government purchasing LFTs so far, 74% (£3,357 million) has gone to Innova alone. Such spending has led to widespread concern the UK is too reliant upon Chinese-manufactured imports, rather than investing in its domestic manufacturing capacity and raised the risk of shortages: so much for a greater economic autonomy post-Brexit.

To exacerbate the undermining in domestic manufacturing capacity, it was reported in June 2021 that Lord Bethell (DHSC minister) had contacted members of the UK Rapid Antigen Test Consortium, a coalition of industry scientists and manufacturers, who had come together to secure LFTs and manufacturing capability for the UK, telling the members the government would draw the consortium's efforts to a close.[11]

[1] The project was announced at a Downing Street briefing led by Boris Johnson on the 9 September 2020 and abandoned by the 6 October 2020.
[2] Government lawyers responded to the claim that Project Moonshot was designed to provoke discussion: it did not reflect an adopted policy, and there had been no decision to approve and commit £100 billion of public money to Project Moonshot. Indeed, no financial commitment had been entered into approaching anything like that sum.
[3] PCR testing was reintroduced in January 2021, under the NHS Test and Trace programme, as confirmatory tests for positive results taken from LFTs. The NHS Test and Trace programme had its own approved 'core' budget of approximately £12.1 billion.
[4] Innova and Pasaca Capital act, in effect, as one. The head office address for Innova is the same as that for Pasaca Capital. The board of Innova is the same as that of Pasaca Capital.
[5] The Phase 3b evaluation (with laboratory scientists and fully trained research healthcare workers) involved throat swabs placed directly into the kit buffer solution rather than using a viral transport medium.
[6] BMJ 2020;371:m4848.
[7] BMJ 2020;371:m4469.
[8] BMJ 2020;371:m4941.
[9] Source: https://bidstats.uk/tenders/?q=innova#757268479-737214508-70
[10] The contract was a 5 supplier agreement including Innova, Una Health, Siemens Healthcare Diagnostics, Tanner Pharma, and Abbott Rapid Diagnostics.
[11] Source: https://bylinetimes.com/2021/08/20/uk-covid-testing-dependent-on-imports-despite-british-companies-being-available-to-do-the-same-work/.

EC v. AZ - settlement with benefits

Introduction

In the last edition of Lex Scientia, I wrote of the legal proceedings initiated by the European Commission (EC) against AstraZeneca AB (AZ) on 21 April 2021 regarding the execution of the EC-AZ Advance Purchase Agreement (APA) for the delivery of the ChAdOx1nCov-19 vaccine (Vaccine) and the Court hearings listed for 24 and 27 September 2021. Following an interim decision of the Court of First Instance in Brussels on 18 June 2021, AZ delivered, as requested, 50 million doses (md) of Vaccine and complied with the Court's decision avoiding any penalty being applied.

Settlement

On 3 September 2021, AZ announced it had reached a settlement with the EC that brings to an end the legal proceedings. Under the settlement, AZ commits to deliver 60md of Vaccine by the end of Q3 2021, 75md by the end of Q4 2021, and 65md by the end of Q1 2022. Tiered and capped rebates on the cost of any delayed dose will apply, subject to the delay in delivery being within is beyond the reasonable control of AZ (Rebates). According to the settlement, AZ will deliver the remaining 200md within a new time frame and whereas the APA was based upon the notion of best reasonable efforts, the settlement foresees delivery upon an absolute basis.

Conclusion

The legal proceedings had no prospect of a final judgment before completion of the original delivery schedule, as a difficult case meandered its way through the Belgian judicial system. It seems to me, however, we have a clear winner. Congratulations to AZ, which has:

- avoided penalties;
- discontinued the legal proceedings it faced;
- gained a 9 months' extension of time to deliver the remaining doses of Vaccine;
- ensured Rebates bite only where delay is within AZ's reasonable control. Force majeure applies separately;
- conditioned the settlement upon the EMA approving 2 additional sites for manufacture, such approval not to be unreasonably withheld and given before delivery commences;
- ensured Rebates as the remedy, instead of damages;
- subject to Rebates, which are unlikely to bite, protected its entire income stream from the EC; and
- seemingly made a better deal than the APA.

Lex Scientia is produced and published by Scott Farnsworth. Scott is an independent, self-employed barrister, regulated by the Bar Standards Board and a qualified solicitor. Specialising in intellectual property law for over 26 years, including legal practises within the life sciences sector for more than 23 years, Scott is highly regarded as a leading practitioner, well known for his understanding of scientific and technical subject matter, as well as his structuring of transactions and compensation models. Scott is authorised to undertake public access work.

Contact Scott on +44 (0) 7885 798 853 or at scott@scottfarnsworth.biz.