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SCOTT FARNSWORTH

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Moderna's vaccine patent dispute

And so it begins. Moderna Therapeutics Inc (Moderna) and government researchers at the US National Institutes of Health (NIH) are locked in a dispute over three NIH researchers whom, according to the NIH, should have been named as co-inventors on a key patent application for the Moderna mRNA vaccine (Vaccine).

The Vaccine contains mRNA that encodes a modified form of the SARS-CoV-2 spike protein. The NIH claims the modified mRNA-1273 sequence, the principal component of the Vaccine, was developed by researchers at its National Institute of Allergy and Infectious Diseases, and that it published analogous modifications for another coronavirus in 2017. On the contrary, Moderna argues that only its scientists independently developed the mRNA-1273 sequence for the Vaccine.

Moderna has filed several patent applications for the Vaccine that name NIH investigators as co-inventors but only in relation to dosing, while other patent applications do not, including at least one that claims the mRNA-1273 sequence. The patent application in question is critical as it covers the principal component. A valid claim on the active ingredient within a pharmaceutical product is significant, as it can prove to be impossible for competitors to design around it.

In September, Moderna offered the NIH co-ownership of the patent and made clear the NIH would be able to license the patent as the NIH saw fit. So far, the offer has not been accepted. The issue is one co-inventorship, however, and the terms of any co-ownership deal would be subject to negotiation and in all likelihood come with conditions. The NIH may also want its scientists named on the patent for scientific credit or political reasons.

The stakes are high. Moderna has projected it will make sales on the Vaccine, its first and only commercial product, of up to $18 billion this year alone. Inventor status could enable the NIH to collect royalties, recouping some of its investment of taxpayer money and allow the NIH to licence the patent, including to competing vaccine makers in low and middle income countries, where vaccines remain scarce. In the meantime, Dr Francis Collins, the head of the NIH, has indicated to Reuters the dispute is heading to court.

Pathway to patents - entitlement

In the recent Court of Appeal judgment of Thaler v. Comptroller General of Patents, Trade Marks and Designs,[1] aside from the glamorous consideration of artificial intelligence (AI) and whether AI-based machines can be inventors for the purposes of the Patents Act 1977 (the Act) – they cannot, there was a comparatively mundane consideration regarding the right to apply for and obtain a patent. Below are some fundamental yet often overlooked issues regarding entitlement.

The starting point is that an invention is purely information.[2] Previously,[3] I wrote there is no property in information even if the information is confidential.[4] The law does not regard information as property. As such, there can be no proprietary right to information as ideas or concepts per se.

It is possible to control the use of information by means of other rights, notably contractual rights and rights to enforce equitable obligations of confidence, but such rights should not be confused with property rights. The circumstances will determine whether certain information is confidential but they will not give rise to any form of proprietary claim.

Although section 30(1) of the Act provides that any patent or application for a patent is personal property, it makes no such provision with respect to an invention prior to the filing of a patent application in respect of the invention.

The right to apply for and obtain a patent[5] is a right as against persons who derive knowledge of the invention from the inventor. The inventor, and those who derive entitlement from the inventor, may use safeguards provided within the Act in the event a person with no entitlement wrongfully files an application.

In the event another inventor independently devises the same invention and both inventors file applications, neither inventor is entitled to the other's application, but the first to file will be entitled, if the invention is patentable, to a patent, whereas the second will not.

In the event someone who derives knowledge of the invention from the inventor publishes the invention, thereby destroying its novelty, or exploits the invention without publishing it, before any application is filed, the inventor will not have any remedy under the Act but only such remedy as the inventor may have under other laws, typically contract or equitable confidentiality.

Section 7(2)(b) of the Act provides a patent for an invention may be granted … to any person or persons who, by virtue of any enactment or rule of law… was or were at the time of the making of the invention entitled to the whole of the property in it. The exact nature of what the Act means by the property in the invention is unclear although it may not matter in practice.

In Thaler, Birss LJ ventured that whatever its precise nature, the property right must include the right to apply for and to be granted a patent for the invention.[6] Read literally, the wording used by Birss LJ cannot be right, as anyone may apply for a patent[7] but only those according to section 7(2) of the Act may be entitled to its grant. The heading in section 7 of the Act is misleading, inserted for convenience, and does not affect its construction.

The property referred to in section 7(2)(b) is best described as inchoate, incomplete, and anticipatory, which comes into existence the moment an invention is made and before an application is filed.[8] An invention must be given definition by the drafting of its specification and established in its full legal existence by the grant of a patent in terms of that specified in a claim of the final specification.[9]

Whatever its precise nature, it is suggested the property in section 7(2)(b) of the Act must include the right to apply for and to be granted a patent for the invention. As suggested by the heading to section 7 of the Act, a proprietary right exists in the right to apply for and obtain a patent for an invention but not in the invention itself.

There is no enforceable property right in an invention per se, a proposition consistent with an invention as information and the well-established precedent that the law does not recognise information as property.

[1] [2021] EWCA Civ 1374.
[2] Merrell Dow Pharmaceuticals Inc v HH Norton & Co Ltd [1996] RPC 76 at 86 (Lord Hoffmann).
[3] Lex Scientia – edition one: confidentiality matters.
[4] Celgard LLC v Shenzhen Senior Technology Material Co [2020] EWCA Civ 1293, [2021] FSR 1.
[5] Section 7(2) of the Act.
[6] [2021] EWCA Civ 1374; Birss LJ at 11.
[7] Section 7(1) of the Act.
[8] Yeda Research and Development Company Ltd v. Rhone-Poulenc Rorer International Holdings [2007] UKHL 43 at para. 53.
[9] Section 125(1) of the Act.

Valneva - what is going on?

Introduction

Previously, I wrote that French biotech company Valneva SE (Valneva) had announced it had received a termination notice from the government regarding a €1.4billion Supply Agreement (Agreement) for the clinical development of its inactivated whole virus, human vaccine candidate known as VAL2001 (Vaccine), despite the government having invested £100 million in the expansion of Valneva's factory in Livingston, Scotland. The Vaccine is the only inactivated whole virus, human vaccine candidate in clinical trials against SARS-CoV-2 in Europe. Unlike most other SARS-CoV-2 vaccines, the Vaccine does not just target the SARS-CoV-2 spike protein but rather the whole virus.

Following the termination notice, on 14 September 2021 Health Secretary Sajid Javid gave a statement that 'commercial reasons' had played into the decision and added "it was also clear to us that the [Vaccine] would not get approval by the [MHRA]." Javid's statement was later corrected to say the Vaccine had not gained approval and may not gain it. Javid's comments were surprising as Valneva was only part of the way through a rolling review of phase 3 clinical trials for the Vaccine. The phase 3 trials compare the Vaccine with the Oxford AstraZeneca ChAdOx1 nCov-19 vaccine, with the final assay validation to verify the integrity of the Vaccine ongoing and a prerequisite for the final submission of the clinical study report.

A spokesman for the MHRA made clear that due to commercial confidentiality the MHRA was unable to provide details of the review. I know from my knowledge of the supply agreement between AstraZeneca UK Limited and the government for the supply of the ChAdOx1 recombinant viral vector vaccine, it is likely there existed within the Agreement an obligation upon Valneva to inform the government in the event it knew or believed there to be any delay to, the rejection of, or other issue jeopardising the grant of any regulatory approval required for or applicable to the Vaccine. In the event of such occurrence, the government would, without prejudice to its other remedies, be entitled to terminate the Agreement.

Encouraging outcomes

On 18 October 2021, after Javid's comments, Valneva announced positive interim efficacy results from its phase 3 trial. The randomised, observer-blind, controlled, comparative immunogenicity trial recruited a total of 4,012 clinical subjects aged 18 years and older across 26 trial sites in the United Kingdom. The trial met its co-primary endpoints, namely the Vaccine's tolerability profile was significantly more favourable compared to the (only) active comparator vaccine of AstraZeneca, in terms of geometric mean titre for neutralisation antibodies (GMT ratio=1.39, $p<0.0001$), (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59)), (AZD1222(ChAdOx1-S) GMT 576.6 (95% CI 543.6, 611.7)), as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination in adults aged 30 years and older.

Commercial considerations

The official reason for the termination notice was that Valneva had breached the Agreement, though no detail was given and Valneva disputes the allegation. Some have speculated nonsense that it was a casualty of Brexit-related animosities. What seems clear, however, is that Valneva's product is not a must have vaccine. At the time of the termination notice, the Vaccine was still working its way through phase 3 trials, when other vaccines were already well established and being administered around the world. The long lead time for the Vaccine appears to have made it a less attractive prospect for purchasers compared with what is already available in the market. The government has plenty of supply coming from a range of other vaccines.

For Valneva, the Vaccine's route to market is hampered. There is comparative effectiveness data for the mRNA vaccine of Pfizer and BioNTech versus the adenoviral vaccine of AstraZeneca, showing the mRNA vaccine to be more effective when it comes to the prevention of symptomatic disease but not when it comes to hospitalisations or death. There is also data from the United Kingdom's Com-COV trial, showing that Pfizer and BioNTech's vaccine induced 2.33 to 3.55 times more neutralising antibodies than AstraZeneca's vaccine. The 1.39 Valneva result may not, therefore, show any increased protection unless it is studied in a large scale trial.

In order to prove an efficacy benefit or, at least, an efficacy

level comparable to the leading vaccines will require a large scale trial, involving tens of thousands of participants. It is unlikely Valneva will want to conduct such a trial as it will cost a huge amount and would need to look at all spectrum of disease severities. Furthermore, time has passed, and it is unlikely Valneva will manufacture the billions of doses that producers of the mRNA and adenoviral vaccines can and continue to produce, partly because of the need to grow relatively large quantities of live SARS-CoV-2 virus and making new vaccines based upon novel variants may take longer than current vaccines require.

Conclusion

Valneva hopes the Vaccine, combined with an adjuvant, will evoke a broader immune response than with other vaccines. Furthermore, the Valneva (whole inactivated) approach to manufacture of the Vaccine is more conventional and may be more acceptable to those who are hesitant with current vaccine products so far deployed in the United Kingdom, Europe, and North America. These are possible benefits, however, not evidenced in the rolling review and not likely to win MHRA approval by themselves. It seems the government, evidenced by Javid's comments, has predetermined the outcome of the rolling review.

There is no evidence of a breach of the Agreement nor is there any reasonable evidence of a lack of efficacy or benefit, notwithstanding the availability of other proven vaccines. Such absences, or rather silences surrounding such absences are surprising. On the contrary, there is evidence that optimum responses are sometimes obtained by priming with a DNA or RNA vaccine and boosting with a protein vaccine, such as an inactivated whole-virus vaccine, like that of Valneva.

The United Kingdom is in good shape but may have taken its eye off the ball and ignored a plan devised to protect the country against a variant that evades vaccines altogether. It is unlikely that current vaccines would not work at all against the Omicron variant. Valneva was one of three manufacturing pharmaceutical companies intended to produce vaccines within the United Kingdom. On 3 December 2021, the EMA announced it had started a rolling review of the Vaccine, meaning 60 million doses and an advanced manufacturing capability will now go to Europe.

Data protection considerations

The United Kingdom (UK) and European Union (EU) agreed a binding withdrawal agreement (the Agreement), which included an implementation period, determined as the period from 1 February 2020 (exit day) to 11 pm GMT on 31 December 2020 (inclusive). During the implementation period, EU laws were generally applicable to the UK. The Agreement included provisions regarding the processing of personal data (GDPR) to apply following the implementation period in certain circumstances.

The UK is subject to the UK GDPR rather than the EU GDPR. Persons within the UK processing personal data are bound by the UK GDPR. Persons within the EU processing personal data are bound by the EU GDPR. Cross border dealings between persons within the UK and the EU processing personal data may give rise to issues regarding the application of the different GDPR regimes.

In cross border dealings, the parties should determine the application of one or both regimes. Where both the UK GDPR and the EU GDPR apply to the processing of personal data under an agreement, there should be a single data protection clause or addendum that contains the relevant data processing obligations required under the UK GDPR and under the EU GDPR. For the time being, a single clause or addendum will be sufficient as the obligations required under the different GDPR regimes are substantially the same.

Drafting provisions for the processing of personal data between parties to an agreement should begin with the interpretation of terms. Terms should be defined by reference to the definition 'Data Protection Laws'. It is likely the definition of data protection laws will include the EU GDPR. In the event the definition is updated to include the UK GDPR (as well as the EU GDPR), terms defined by reference to data protection laws risk uncertainty, should the UK GDPR diverge from the EU GDPR. Where there is divergence, the parties should state within the agreement whether the UK GDPR or EU GDPR applies. It should be apparent, where the personal data relates to a particular controller's activities within the UK or EU.

Bayer and obviousness

Introduction

On 8 October 2021, the High Court delivered judgment[1] on the validity of Bayer HealthCare's patent[2] concerning the formulation of a drug called sorafenib. Although on familiar territory, in his judgment Mellor J considered the applicable legal principles relating to obviousness, which he took from the judgment[3] of Arnold J (as he then was) in which Arnold J described the overall tenor of the Supreme Court's judgment as confirming the approach which had previously been adopted by the courts to the question of obviousness.

Assessing obviousness

There are five points to be distilled from judgment:

- first, the place of inventive concept in relation to obviousness required a structured approach.[4] The first step is to identify the inventive concept embodied in the patent in suit. The court must then assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention. Finally, the court must ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention;

- secondly, while such a structured approach was not exhaustive, the question of obviousness must be considered on the facts of each case and the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them, and the expectation of success;[5]

- thirdly, it is relevant to consider whether something was obvious to try, as in many cases the consideration that there is a likelihood of success, which is sufficient to warrant an actual trial, is an important pointer to obviousness. Nevertheless, it should be noted that some experiments, which are undertaken without any particular expectation as to the result, are obvious;

- fourthly, the existence of alternative or multiple paths of research will often be an indicator that the invention … was not obvious, although if a particular route is an obvious one to take or try, it is not rendered any less obvious from a technical point of view merely because there are a number, and perhaps a large number, of other obvious routes as well. It is implicit and is the law that what matters is whether the claimed invention is obvious from a technical point of view, not whether it would be commercially obvious to implement it; and

- finally, the motive of the skilled person is a relevant consideration. The notional skilled person is not assumed to undertake technical trials for the sake of doing so but rather because he or she has some end in mind. It is not sufficient that a skilled person could undertake a particular trial. One must ask whether in the circumstances he or she would be motivated to do so. The absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult.

Conclusion

Mellor J had particular regard to the could/would distinction of the fifth point. The law of obviousness cannot be accurately summarised simply by stating that the question is whether the skilled person would have arrived at the claimed invention, not whether they could have. The issue is multifactorial and based closely upon the particular circumstances. If the skilled person, acting without invention and only on the basis of routine approaches, which are part of their common general knowledge, arrived at the precise subject matter claimed, the subject matter claimed is obvious.

[1] Teva Pharmaceutical Industries Limited v. Bayer Healthcare LLC [2021] EWHC 2690 (Pat).
[2] EP (UK) 2,305,255.
[3] Allergan Inc. and anor v. Aspire Pharma Ltd [2019] EWHC 1085 (Pat).
[4] Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd [1985] RPC 59, as reformulated in Pozzoli SPA v. BDMO SA [2007] EWCA Civ 588.
[5] Generics (UK) Ltd v. H Lundbeck A/S [2007] EWHC 1040 (Pat), [2007] RPC 32 at [72].

Confidentiality matters - employees

Introduction

Employee confidentiality is a subject frequently taken for granted. Previously, I wrote of confidentiality as an often misunderstood area of the law and considered some basic, yet largely unknown, general principles. One aspect not covered previously was employee confidentiality. Just as with confidentiality generally, circumstances define whether information obtained by the employee during the course of his employment is to be treated confidentially. The law does not assume such information is confidential without an inquiry into the background of any protection.

Contractual relationship

The relationship between the employer and the employee is contractual. The existence of a contract will not prevent the concurrent application of the equitable doctrine of confidence. The scope of the employee's duty of confidence, whether in contract or equity, will be governed by the employment contract, whether expressly or by necessary implication, for as long as the parties remain bound by it. Where the employment contract is absent an express confidentiality term, a contractual duty of confidentiality will be implied, and the scope of that duty will be the same, whether viewed as an implied term or an equitable duty.

The law draws a distinction between the duties of confidentiality owed by the employee during the period of the employment contract and any duties which may continue after the employment contract has ended. The distinction is intended to reflect the nature of the employment contract and a fundamental principle that the former employee holds a legitimate interest in being able to use his skills and knowledge for his own benefit or the benefit of another without the imposition of unduly onerous or impractical restraints in favour of his former employer.

Implied obligations during employment

The law will imply into any employment contract a general obligation on the part of the employee not to use or disclose confidential information or materials acquired in his capacity as an employee, except for the purposes of his employment. The obligation is subject to qualifications, known as protected disclosures. Protected disclosures include that:

- a criminal offence has been committed, is being committed, or is likely to be committed;
- a person has failed, is failing, or is likely to fail to comply with any legal obligation to which he is subject;
- a miscarriage of justice has occurred, is occurring, or is likely to occur;
- the health or safety of any individual has been, is being, or is likely to be endangered;
- the environment has been, is being, or is likely to be damaged; or
- information tending to show any matter falling within any one of the preceding paragraphs has been, is being, or is likely to be deliberately concealed.

Any provision in an agreement between the employer and the employee, which purports to prevent the employee from making a protected disclosure is to that extent void. The stockpiling or banking of confidential information by the employee in anticipation of litigation with his employer is not justified and will be treated as a breach of confidentiality.

Implied obligations after employment

Any confidentiality obligations that continue after the employment contract has ended are seen, in the absence of any express contractual provision, as a matter of implied contract. Protection, if any, is a matter of fact and information is categorised. A distinction is made between information that forms part of the employee's general stock of knowledge and information that is more personal to the employer.

The underlying reason for the distinction between different types of information is intended to reflect the fundamental principle. Insofar as the knowledge gained has become part of the employee's general skill and knowledge, he owes no duty of confidence to his former employer after the employment contract has ended. An exception to this general rule is that after the employment contract has ended, the former employee may be prevented from taking advantage of a breach of the implied duty that occurred during the term of his employment.

Otherwise, such information is distinguished from particular information including trade secrets or items of equivalent confidentiality.

Trade secrets

Trade secrets are exceptional and will be protected both during the employment contract and following its termination, even if there is no express provision within the employment contract. There will be no time limitation on the protection. There is no universal formula for determining what amounts to a trade secret or an item of equivalent confidentiality, whether in an employment or R&D context. As with implied obligations post-employment, whether information is a trade secret or an item of equivalent confidentiality is a matter of fact.

Trade secrets and confidential information may have a limited shelf-life following which they will cease to be confidential. The limitation can occur for two reasons, namely the information has come into the public domain, such as inventions that are published or the information has become out-of-date, such as market-sensitive information including pricing levels, margins, and costs. Each case will be fact-specific, and the court will consider evidence that shows:

- how the information was designated and kept confidential;
- market practice;
- how disclosure in the public domain came about. Disclosure by the employee is unlikely to deprive confidential information of protection because of the principle that the employee should not be able to benefit from their own wrongdoing; and
- inherent ephemerality of the information, such as where the information changes very frequently.

Customer lists

As a general rule, the employer will want to protect its customer list from becoming known to competitors or potential competitors, and the employee will be under a duty during the term of his employment to treat such information as confidential. The employee will be in breach of his duty of confidentiality if he solicits his employer's customers before his employment contract has ended. When the employment contract has ended, subject to the condition below and in the absence of a valid, meaning reasonable, non-solicitation covenant to the contrary, the former employee will be entitled to compete with his former employer.

The rule applies to knowledge of customers' names and addresses the employee acquires, bona fide, during the ordinary course of his employment and extends to making contact with customers of his former employer, whose names he can recall because they have been learned during the ordinary course of employment and extends to permit the employee researching their contact details through publicly available information such as telephone directories, electoral rolls, and utilising the resources of the internet.

The rule is conditional and it does not give licence to the employee who intends to leave his employment and work in competition with his employer, whether for his own benefit or the benefit of another, to copy or commit to memory his employer's customer list, with a view to using it for competitive purposes after he has left. Such action is unlawful and an injunction may be granted against the former employee requiring him to deliver up the list for destruction and restraining him from making use of the information obtained.

The prohibition against pursuing the former employer's customers is entirely dependent upon there being an abuse on the part of the employee during the course of his employment, such that the abuse constitutes a breach of confidentiality. In the absence of such abuse, the former employee may approach as many of his former employer's customers, including those customers of whom the employee has acquired no knowledge, without fear or consequence.

Termination for repudiatory breach

Where termination of employment occurs for a repudiatory breach by the employer, typically a wrongful dismissal, the employee is generally relieved from further performance of his own contractual obligations, including any post-employment restrictive covenants. Where all primary contractual obligations are ended by a termination for repudiatory breach, the parties may nonetheless be left in a relationship in which duties are owed by operation of other law rather than the employment contract. A repudiatory breach does not end the employee's equitable duty in respect of trade secrets or items of equivalent confidentiality.

Made in Britain - lateral flow tests

Introduction

Previously, I wrote regarding the Innova Medical Group Inc (Innova) and the government contracts awarded to Innova for its SARS-CoV-2 antigen rapid qualitative test kits, commonly referred to as lateral flow tests (LFTs), which contracts at the time of writing stood in excess of £3.3 billion. A lot of money for a start-up founded on 20 March 2020 and with LFTs of somewhat dubious sensitivity and specificity data. On 14 October 2021, however, UCL published a report and found recalibrating an apparent relative sensitivity of 50% (in other words, using a different formula), on average would approximate absolute sensitivity of over 80% in testing for individuals shedding SARS-CoV-2 antigens.

To say British companies have struggled bringing their own LFTs to market,[1] in the UK at least, is an understatement. Following my article on Innova, I made enquiries of British manufacturers of LFTs by direct, open contact through a series of identical questions. A number replied with useful information to present an overall state of British manufacturing and the regard or indifference given to them by the government. Bear in mind, the award of a contract by the UK government does not mean orders have been or must be placed by the government.

The Brit Awards

- SureScreen Diagnostics Limited (03235601). The most successful of the British to date. Although the government claims SureScreen's LFTs are British-made, key materials required to make them are sourced from the EU, US, and Far East depending on the material. That may be so with many of the British manufacturers. SureScreen's R&D team is based in the UK. The SureScreen LFT shows sensitivity at 95% and specificity at 99.9%. It is CE marked for professional use only and is not for sale to the general public. Contract award worth £503 million; delivery 15.01.21 to 15.01.23.

- Abingdon Health Limited (06475379). Contract award worth £75 million; delivery 02.06.20 to 14.02.21 to provide antibody tests rather than antigen tests.[2] A judicial review regarding the award by the Good Law Project has meant the DHSC refusing to release the £6.7 million it owes to Abingdon, pending a hearing of the matter in December 2021.

- Mologic Limited (04784437). Mologic received a £1 million grant from the government. Porton Down recorded a 60% failure rate in Mologic's LFTs, whereas other labs in the UK and in Germany gathered very different results and found they only had a 1-2% failure rate. The Mologic LFT is accredited for professional use only and cannot be used by the UK public. Mologic is suing the government over validation of its LFTs in the UK. Mologic LFTs are sold in the US and EU. Limited UK purchase orders to date.

- Avacta Group PLC (04748597). Developed and manufactured in the UK. The Avacta LFT has been shown by independent clinical evaluation to be 100% sensitive for patient samples with a PCR Ct value below 27 (high viral load), 98.0% sensitive across a much wider range of viral loads and with 99% specificity. Avacta carried out analytical tests with the spike proteins isolated from both the B117 and D614G variants and confirmed that its LFT detected both variants as well as the original strain. Avacta recently appointed Calibre Scientific, a global distributor of diagnostic and life science products, as the first distributor for Avacta LFTs in the UK and EU and is progressing multiple commercial opportunities with distributors and end users in the UK, EU, Asia, and elsewhere. No contract awarded. No UK purchase orders to date.

- Omega Diagnostics Limited (SC107178). Omega signed a material transfer agreement with Mologic, providing access to raw materials and know-how to manufacture their LFTs. The Omega LFT is MHRA approved for professional use only and is waiting on CE marking for self-test approval. The latest update on 6 September 2021 notified investors that all supporting data and documentation relating to the submission for CE marking for self-test use had been filed with the European Notified Body. Omega expects MHRA approval for sale in the UK to follow soon after CE marking for self-test use is confirmed. The Omega LFT provides for

the detection of the nucleocapsid protein of the SARS-CoV-2 virus in respiratory swabs and has sensitivity of 98.4% on samples with a cycle threshold (Ct) of < 20 (85% overall sensitivity on samples with Ct values ranging from 9.8 to 43) and specificity of 97.8%. Contract award worth between £50 million and £374 million; delivery 12.02.21 to 11.02.23. No UK purchase orders to date.

- Global Access Diagnostics Limited (12558218). GAD is a high volume manufacturing social enterprise spun out from Mologic in April 2020 with funding from the Bill & Melinda Gates Foundation, FIND DX, the Soros Economic Development Fund, and UK government. GAD's principal focus is upon the development and manufacture of reliable, relevant, and affordable diagnostic tests for the public health systems of around 30 countries across Africa, Asia, and Latin America. GAD is Mologic's manufacturing partner across its full LFT R&D pipeline. The GAD LFT has been found, in the largest independent study run by FIND DX, to have an overall sensitivity of 91% and specificity of 100%, with a limit of detection of 2.5 x 10_2. At CT scores <20, sensitivity rises to 100%. GAD is one of 3 UK companies working with the government to scale up manufacturing capacity in UK for LFTs. Contract award worth between £50 million and £1.15 billion; delivery 15.02.21 to 15.02.23. No UK purchase orders to date.

- Excalibur Healthcare Services Limited (12414592). The first UK company to receive MHRA certification for its LFT. Excalibur exports its LFTs to other countries. The new Excalibur Rapid SARS-CoV-2 antigen test kit is one of the most accurate and reliable tests of its kind. The test has 100% sensitivity for high viral loads (equivalent to positive PCR values below Ct=28) and 100% specificity for SARS-CoV-2 with very few false positives observed in tens of thousands of samples tested. The Excalibur LFT is CE marked and MHRA registered for professional use only and is in use in Germany, Italy, Austria, Belgium, and the UK by customers including governments, hospitals, care homes, businesses and educational establishments. No contract awarded.

Conclusion

It is true to say the preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: rapid evaluation of LFTs for mass community testing dated the 8 November 2020 (Report) identified the Innova LFT as that in the most advanced stages of validation and nearing completion of the four-phase evaluation. The Innova LFT showed performance characteristics of having a low failure rate, a high specificity of 99.6%, and a high viral antigen detection. The Report acknowledged that many of the other LFTs tested had not performed to levels established by the test and validation cell and confirmed by the LFT Oversight Group to proceed to community field service evaluations.

The summaries in the Report clearly had the Innova LFT out in front and undoubtedly corroborated the DHSC's subsequent justification, in the early days of the procurement at least, for using Innova as its sole supplier without a call for competition according to regulation 32(2)(c) of The Public Contract Regulations 2015 (the Regulations)[3] (the extreme urgency test) and later according to regulation 32(2)(b)(ii)[4] of the Regulations (the absence of competition test). As the months have gone bye, however, and British manufacturers have received approval for the supply of their own LFTs, such justifications can no longer be relied upon.

It is quite obvious the SARS-CoV-2 virus is going to be around for some time yet. The LFT market is volatile and demand already outstrips supply with global manufacturing capacity limited to c. 120 million LFTs per day. Delivery dates for British made LFTs will run a few more years based upon current contract awards, ignoring any extensions. Time will tell if the government chooses LFTs made in Britain.

[1] Medco Solutions Limited (12535625) is a British company awarded a government contract (delivery: 02 Sep 2021 to 31 Jul 2022) worth up to £325,220.00 to import foreign LFTs.
[2] An antigen test detects the current presence of an infective agent (in this case the SARS-CoV-2 virus). An antibody test detects antibodies in the blood, produced in response to a previous infection and indicates immunity to the virus.
[3] The negotiated procedure without prior publication may be used for public works contracts, public supply contracts and public service contracts, where for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with.
[4] The negotiated procedure without prior publication may be used for public works contracts, public supply contract and public service contracts where the works, supplies or services can be supplied only by a particular economic operator and competition is absent for technical reasons, but only where no reasonable alternative or substitute exists.

Licence of right endorsements

From the 8 December 2021, the Intellectual Property Office (IPO) has updated its 'Licensing intellectual property' guidance to state that when making an application for a licence of right endorsement. The IPO holds a database of patents that are endorsed 'licence of right'. A patent holder, as licensor, may ask the IPO to endorse their patent with a licence of right in the register of patents. The effect is the patent holder agrees to licence their patent to anyone who requests a licence of the patent in question. This means the patent holder must grant a licence to anyone who wants one. Any licence granted, however, will be an ordinary, commercial licence and the terms and fees will be a private matter as between the licensor and the licensee. The IPO will not investigate the validity of a licence unless the terms under a licence of right cannot be agreed.

The main advantages of having a patent endorsed with a licence of right is that it allows others to know the patent holder is happy to licence their patent. In such cases, the IPO will reduce its annual renewal fees to half the usual cost if a patent is endorsed licence of right. To apply for a licence of right endorsement, an application should reach the IPO at least 28 working days ahead of the next renewal due date. Previously, the deadline was 10 days ahead of the next renewal date. In the event a person wishes to licence a patent on the database, they must approach the patent holder directly.

A patent holder may cancel a licence of right endorsement at any time, following which cancellation, the patent holder will have to pay the standard renewal fees, backdated to the renewal date. The IPO will advertise any such cancellation request in the Patents Journal for 4 weeks to allow anyone to oppose the cancellation request. A licence of right entry will be cancelled if there are no existing licences, the patent holder has paid the balance of renewal fees, and any opposition to the cancellation has been dealt with.

A patent holder is not obliged to notify the IPO in the event a licence is granted under the scheme, but it is advised they should do so. A patent holder should give the IPO such notification within 6 months of the grant of any licence. A licensee may lose some rights in the event the patent holder fails to do so. The patent holder usually notifies the IPO of the type of licence. In the event the licensee notifies the IPO, additional information such as the date of the licence agreement, the names and addresses of the parties involved, and the patent number will be required.

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