Intellectual Property Office

BL O/1082/22

08 December 2022

PATENTS ACT 1977

APPLICANT	Peter J Mollick
ISSUE	Whether patent application GB2113325.1 complies with the requirements of sections 14(3) and 14(5)(c) of the Act
HEARING OFFICER	Dr L Cullen

DECISION

1 This decision concerns patent application GB2113325.1 which concerns a medical use of the herb thyme to treat COVID-19 and whether this application discloses enough information to meet the requirements for sufficiency under section 14(3) and for support under section 14(5)(c) set down by the Patents Act 1977 ("the Act").

Introduction

2 Patent application GB2113325.1 was originally filed as an international application under the Patent Cooperation Treaty (PCT) on 1 April 2021 and entered the GB national phase on 17 September 2021. The application was first published by the World Intellectual Property Organisation (WIPO) as WO2021/202823 A1 on 7 October 2021 and, after entry into the national phase, was subsequently republished as GB2595427 A. The earliest priority declared for 2 April 2020 was based on an application filed before the United States Patent and Trademark Office (USPTO).

3 The first substantive examination report under section 18(3) was issued on 12 October 2021 and, among other matters, objections to insufficiency of disclosure and lack of support were raised to the medical use claims. The examiner also updated and broadened the search completed by the International Search Authority such that two

documents published after the earliest priority date were initially cited in relation to inventive step[1,2].

4 After two rounds of examination and response, the application was forwarded for an oral hearing via video conference. The inventor-applicant (who is also the patient referred to in the application-in-suit) Mr Peter Mollick was represented in his written submissions by his patent attorney; however, Mr Mollick chose to present his own submissions at the oral hearing before myself on 12 September 2022. I was assisted by senior patent examiner Dr Graham Feeney.

5 In the pre-hearing report dated 13 July 2022, the examiner indicated that if I find that the application meets the requirements of section 14(3) and section 14(5)(c), then the application will need to be remitted to them so that they can complete examination of this application.

6 I note that the compliance date under section 20 of the Act and rule 30 of the Patents Rules 2007, as amended, is 1 October 2025.

The Invention

7 The present application seeks protection for a new pharmaceutical use of the well-known herb thyme to treat COVID-19 in humans[3]. The application describes coronaviruses using information referenced from Wikipedia and contrasts the various diseases caused by them (see pages 1-17 of the application as filed). The application then describes the anti-viral effects of thyme[4] citing a number of scientific articles describing these effects. Four journal articles are cited that report that thyme has anti-viral activity against herpes simplex viruses. The patent application then cites an internet post from the *Journal of Plant Disease*[5] stating that thyme has activity against herpes simplex viruses and against Newcastle Disease virus; this post then goes on to describe how thyme has long been used as a traditional herbal treatment "*for colds, flu, headaches, fatigue and digestive issues.*" The application then briefly asserts that[6]:

> *"The five above disclosed studies mention the antiviral activity and effectiveness of the herb thyme and of certain components of the herb*

---

[1] *Journal of Advances in Medical and Biomedical Research, vol. 29, No. 133, 2021, Sardari et al. "*Therapeutic effect of thyme (Thymus vulgaris) essential oil on patients with COVID-19: A randomized clinical trial*", pages 83-91.*

[2] *Current Science, vol. 118, No. 7, 2020, Sampangi-Ramaiah et al. "*Molecular docking analysis of selected natural products from plants for inhibition of SARS-CoV-2 main protease*", pages 1087-1092.*

[3] *COVID-19 or Coronavirus disease 2019 is a contagious disease caused by a virus, the severe acute respiratory syndrome coronavirus 2 also known as SARS-CoV-2.*

[4] *See paragraphs [0033]-[0038] of the application as filed.*

[5] *See https://plantmedicines.org/thyme-provides-antiviral-protection-against-herpes-and-other-viruses/*

[6] *See paragraph [0038] of the application as filed*

thyme such as thymol in treating certain viral diseases, suggesting the herb thyme and its known antiviral components as being a second use treatment of disease for use in treating the disease Covid-19. Some of the many antiviral substances in the herb thyme may be thymol, camphor, bomeol, carvacrol, terpinenes, pinenes, cymene, terpinenols, citral and cineoles, and any one of or combination thereof these constituents may be beneficial for use in the treatment of the disease Covid-19"

8 By way of experimental evidence, the applicant then describes how at the beginning of the COVID-19 pandemic during February 2020, he took the precaution of buying large quantities of the herb thyme on the basis that he considered that the herb has anti-viral activities[7]. There follows an anecdote about the patient, then located at or near Phoenix and Camp Verde, both in the state of Arizona in the United States of America (USA).

9 As disclosed in the patent application, the patient ingested a large helping of ice cream on 1 March 2020 and became unwell around 30-60 minutes later. He reported his symptoms as slight headache, slight fever, chills and '*aching in his bones'*. During the following night, the patient suffered aching joints and reports that he was unable to perform some physical exercise - some push-ups - because of soreness in his shoulders. During breakfast at a café in Camp Verde the next morning (2 March 2020), the patient noted sharp stabbing pains to his lower back which he describes as kidney pains. In the morning, the patient consumed a substantial breakfast, then worked at least during the morning and rested during the afternoon. At 3:00 PM[8] on 2 March 2020, the patient began to assume that he was suffering from COVID-19 and took a first dose (one heaped teaspoon, 0.2 oz, 5.7 g) of thyme in a glass of water. A second dose was taken at 8:00 PM. The headaches and fever persisted throughout the night of 2 March 2020 and a third dose of thyme was taken at 5:30 AM the following morning. The symptoms subsided by around 8:30 AM, with the patient meeting his friend at a café to assist with applying lubrication to his truck. The patient considered himself fully recovered around four days later on 6 March 2020.

10 A second episode of illness with headache and fever commenced on 12 March 2020 around 3-4 hours after the ingestion of '*very sweet milk tea'*. The illness was treated the same day using thyme at 8:00 PM and then by two further doses of thyme on the following day, 13 March 2020. The applicant reported that he had recovered by 15 March 2020.

11 Following these disclosures, the patent application then describes the patient consuming various high sugar foods. I understood these to be attempts to induce illness once more, an assumption which was confirmed by Mr Mollick at the hearing. No further instances of illness were reported by the patient to be attributable to this consumption of further sugary and high fat foods.

---

[7] *See paragraphs [0051]-[0052] of the application as filed*

[8] *All times referred to are local time in Arizona, USA.*

The Claims

12 There are nineteen claims on file, independent claim 1 concerns the use of thyme to treat COVID-19 and reads as follows:

> *"A composition for oral ingestion comprising ground or powdered leaf of a herb thyme for use in a method of treating the disease Covid-19 in humans."*

13 Dependent claim 2 further defines a mechanism of action. Dependent claims 3-15 concern further details as to the thyme composition and dosage schedule.

14 Accordingly, I can confirm that claims 1-15 clearly define the second medical use of thyme as set out under the provisions of section 4A(4) of the Act.

15 Claim 16 is directed to a thyme composition for use in the prevention of COVID-19:

> *"The composition of any preceding claim, for use in prevention of the disease Covid-19."*

16 Claim 16 defines the second medical use of thyme as set out under section 4A(4) to prevent COVID-19.

17 As set out in the pre-hearing report, the claims have not yet been examined for clarity. This is important to note because claims 17-19 can be construed as defining well-known thyme compositions *per se* rather than the medical use of thyme to treat or prevent COVID-19. In view of the disclosure as a whole, I have assumed that it is intended that, following amendment for clarity, claims 17-19 would have been restricted to their second medical use.

The Law

18 Section 14 of the Act, entitled 'Making of Application', refers to certain requirements that the specification and its associated claims must meet to be allowable. In this instance, we are concerned with Sections 14(3) and 14(5).

Section 14(3)

19 Section 14(3) relates to the specification and reads as follows:

> ***.....***
>
> *(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.*
>
> ***.....***

20 This requirement is usually referred to as that for sufficiency of disclosure. In this case, we are concerned with whether the application in suit meets this requirement and

discloses sufficient detail about the new medical use to allow the invention to be carried out by a person skilled in the art.

Section 14(5)

21 Section 14(5) relates to the claims and reads as follows (my emphasis added):

> *(5)* ***The claim or claims shall –***
> *(a) define the matter for which the applicant seeks protection;*
> *(b) be clear and concise;*
> ***(c) be supported by the description;***
> *(d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept. ….*

In the present case we are concerned specifically with Section 14(5)(c) (as highlighted above).

22 This is the support requirement. In this case, we are concerned whether the description in the application in suit provides enough information to justify the claim to the new medical use.

Overlapping Requirements

23 As they are set out separately in statute, the requirements for sufficiency of disclosure under section 14(3) of the Act and the requirement for support for the claims under section 14(5)(c) of the Act are distinct. Also, it is only the requirement for sufficiency of disclosure that serves as a basis to seek revocation of a granted patent under section 72(1)(c) of the Act. Nevertheless, the judgement from the House of Lords in *Biogen v Medeva*[9] held that that the requirements for sufficiency under section 14(3) and for support under section 14(5)(c) both relate to the requirement for an enabling disclosure. Both of these sections of the Act deal with the difference between a speculation and a contribution to the art, and so there is considerable overlap between the two requirements. As a result, the case law in relation to sufficiency is persuasive (where relevant) on questions of support and *vice versa*.

24 However, whilst being fully aware of this overlap, I will consider each requirement separately to determine if each requirement has been met.

The Relevant Case Law

Sufficiency of Disclosure as applied to Second Medical Use Claims

25 The judgement of the UK Supreme Court (UKSC) in *Warner-Lambert*[10] is the leading authority in relation to the sufficiency requirement for a claim to a second medical use of a substance or composition. In this judgement, the plausibility of a new medical use and the relationship between plausibility and sufficiency of disclosure was considered

---

[9] *Biogen Inc v Medeva Plc [1996] UKHL 18; [1997] RPC 1.*

[10] *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan and anr [2018] UKSC 56.*

in detail[11]. At paragraph 37 of the judgement, Lord Sumption set out seven principles to describe how the threshold of plausibility for a second medical use claim may be reached. He stated as follows:

> "*Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made.*
>
> *i) First, the proposition that a product is efficacious for the treatment of a given condition must be plausible.*
>
> *ii) Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion. As Lord Hoffmann observed in Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] RPC 28[12], para 28, "it is hard to see how the notion that something is worth trying or might have some effect can be described as an invention in respect of which anyone would be entitled to a monopoly".*
>
> *iii) Third, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, i.e. not just because there was an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work. The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of article 56, when addressing the sufficiency of disclosure made in support of claims extending beyond the teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in section 14 of the Patents Act. In both contexts, the test has the same purpose.*
>
> *iv) Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true.*
>
> *v) Fifth, that reasonable prospect must be based on what the TBA[13] in SALK[14] (para 9) called "a direct effect on a metabolic mechanism*

---

[11] Although the claim discussed was a medical use claim in the Swiss form and the present claim is in the form for a second medical use under the revised European Patent Convention 2000, nothing turns on this and the same reasoning applies.

[12] Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] RPC 28

[13] Technical Board of Appeal at the European Patent Office (EPO), for more details see EPO - About the Boards of Appeal

[14] T-0609/02 (AP-I complex/SALK INSTITUTE), see https://www.epo.org/law-practice/case-law-appeals/pdf/t020609eu1.pdf

specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se."

vi) *Sixth, in SALK, this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by a priori reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person.*

vii) *Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person. But* ***it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent.***

Support for the Claims as applied to Second Medical Use Claims

26 There is a long-recognised requirement that a second medical use claim must derive support from the application as originally filed and that it cannot be supported by mere assertion alone. Thus was confirmed by Neuberger J, as he then was, in the *Prendergast's Applications* decision from the UK Patents Court, on appeal from the decision of the Comptroller[15]. The judge's conclusion can be summarised as follows:

(1) The absence of any practical evidence of the idea (i.e., the use of a known pharmaceutical for a new use) working involved the absence of a description.

(2) Whether or not there was an adequate description for the purposes of section 14(5)(c) of the Act had to be judged by reference to the nature of the application. Where there was a claim for the use of a known pharmaceutical in the preparation of a medicament for the treatment of a particular condition, the specification had to provide, by way of description, enough material to enable the relevantly skilled man to say that this medicament did treat the condition alleged. Mere assertion was insufficient.

(3) It was not practical to lay down what the tests should be in each case but it was clear that, in general, relatively rudimentary tests would suffice. It was not necessary for an applicant to have carried out full rigorous detailed and conclusive tests.

27 In the proceedings on the present case, Mr Mollick also referred us to several Comptroller's decisions, in particular *Consultant Suppliers Ltd's Application*[16], and to three decisions from the Technical Boards of Appeal of the European Patent Office

---

[15] *Prendergast's Applications [2000] RPC 446-450.*

[16] *Consultant Suppliers Ltd's Application [1996] RPC 348-360.*

(TBA-EPO)[13]: T-0433/05[17]; T-0950/13[18] and T-1616/09[19]. Consistent with *Prendergast's Applications,* the decision of the Comptroller in *Consultant Suppliers Ltd's Application* concerned an application where no evidence of efficacy whatsoever was disclosed in support of claims to a second medical use in the applications as filed. In his written submissions and at the hearing, Mr Mollick used the precedent of *Prendergast's Applications,* backed up with the persuasive Comptroller's decisions in *Consultant Suppliers Ltd's Application*, *Hoerrman's Application*[20] and *McManus' Application*[21]*,* to assert that because the application in suit discloses some experimental evidence, there is more than a mere assertion in the application in suit and that therefore there is adequate material to satisfy the requirements for support. However, I cannot agree that all that is required by *Prendergast's Applications* is that 'some' evidence is provided. This is because, as stated in *Prendergast's Applications* judgement[22] (my emphasis added in bold): *"the specification must provide, by way of description,* ***enough material to enable the relevantly skilled man to say that this medicament does treat the condition*** *alleged".* In other words, the threshold set in this decision requires more than the mere provision of some evidence because it asks that this evidence be viewed and interpreted through the eyes of the skilled person.

28 Mr Mollick has referred me to TBA-EPO decision T-0433/05 concerning the sufficiency of a second medical use claim. While not binding upon me, such decisions can be persuasive. Mr Mollick cites this decision to argue that post-published evidence should be taken into account to "*back up evidence in the specification"*. I have carefully thought about what Mr Mollick meant by this statement. I think that there is a semantic point to be made here in contrasting Mr Mollick's phrase (i.e., 'back up evidence in the specification'), which could be taken to mean that later-filed evidence may be used instead of information in the application as filed, in order to meet the requirements for sufficiency and support, with the stricter rationale of T-0433/05 where (for second medical use claims) the principle is that the application as filed is required to provide some information to show that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease and **only then** can post-published evidence be taken to confirm the evidence provided in the application in

---

[17] *T-0433/05 (Fusion Peptide Inhibitors/CONJUCHEM), see https://www.epo.org/law-practice/case-law-appeals/pdf/t050433eu1.pdf*

[18] *T-0950/13 (Dasatinib in the treatment of chronic myelogenous leukemia/BRISTOL), see https://www.epo.org/law-practice/case-law-appeals/pdf/t130950eu1.pdf*

[19] *T-1616/09 (Combination therapy with anti-neoplastic agent and DNA methylation inhibitor/ SUPERGEN), see https://www.epo.org/law-practice/case-law-appeals/pdf/t091616eu1.pdf*

[20] *Hoerrman's Application BL/O 095/93 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/433699/o09593.pdf, reported as [1996] RPC 341-347*

[21] *McManus's Application BL/O/129/93 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/436863/O-129-93.pdf*

[22] *See lines 15-23 on page 448 in Prendergast's Applications (footnote 15 above)*

suit[23]. In any case, I remain bound by, and must follow, the judgement of the UKSC in *Warner-Lambert* which requires that the material conferring sufficiency (and it follows, support) is to be contained within the application in suit.

29 Mr Mollick referred to TBA-EPO decisions T-0950/13 and T-1616/09 to support his argument that the standard of evidence required to meet the requirements for sufficiency and support are lower than those of clinical trials. Again, these decisions can only be persuasive to me, whilst I am bound by the precedent set in *Warner-Lambert*. However, I do not believe that *Warner-Lambert* sets a different bar. It has been widely accepted over a long period that the standard of evidence of efficacy in medial use patents is, as put in *Prendergast's Applications*, 'relatively rudimentary'[24]. Thus I accept that evidence of efficacy in this case does not require results of a clinical trial!

The Issues to be decided

30 With reference to the seven principles set down in *Warner-Lambert*, as far as sufficiency under section 14(3) is concerned, I must address whether, on the balance of probabilities, the application-in-suit renders plausible to the skilled reader the proposition that thyme is efficacious for the treatment of COVID-19.

31 As far as support under section 14(5)(c) is concerned, I must address whether the specification provides, by way of description, enough material to enable the relevantly skilled person to say that, on the balance of probabilities, thyme does treat COVID-19.

32 **If** I can be satisfied that the application in suit satisfies the requirements of the Act, later supplied additional evidence can then be used to confirm this.

---

[23] T-0433/05 (see footnote 17) at paragraph 28 on page 21 reads:

> "Where a therapeutic application is claimed in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, under Article 83 EPC the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application (cf decision T 609/02 of 27 October 2004, point (9) of the reasons for the decision). Taking into account the intrinsic difficulties for a compound to be officially certified as a drug, it is the practice of the Boards of Appeal that for acceptance of a sufficient disclosure of a therapeutic application in a patent/patent application, it is not always necessary that results of clinical trials are provided at the relevant date, but that it is required that the patent/patent application provides some information to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. Once this evidence is available from the patent/patent application, then post-published evidence may be taken into account to support the disclosure in the patent application"

.

[24] See lines 2-14 on page 450 in Prendergast's Applications (footnote 15 above)

33 It is important to note that these questions must be answered with regard to the understanding of the skilled person **at the priority date**. Their view at the priority date may well differ significantly from their view at a later date[25].

Analysis

The Person Skilled In the Art

34 In order to make a sound assessment as to whether the requirements for sufficiency and support have been met, it is first necessary to understand who the person (or team) skilled in the art is and what was their common general knowledge (CGK) at the priority date. This skilled person is a legal construction and should not be confused with another legal construction, the person on the Clapham Omnibus, i.e., the person in the street, a layperson. This distinction seems especially important when it comes to assessing how the COVID-19 pandemic was viewed during early April 2020, when the news media was full of various speculations, simplified scientific explanations and lay opinions. Accordingly, I believe that the person in the street would have had a different understanding to that of the person skilled in the art having relevant scientific training.

35 The person skilled in the art is an uninventive, but technically competent person (or team) having average skill and intelligence[26]. Within the art of anti-viral therapeutics, I believe that the skilled person is educated at least to degree level and has competencies in several technologies which allow for the formulation and testing of a new pharmaceutical preparation.

36 It is worthwhile remembering that, for the purposes of section 14(3), the "*person skilled in the art*" is considered to be seeking to make the patent work and does so with the CGK at the time the patent was filed. The skilled worker has the patent in front of them, and thus is "*trying to carry out the invention and achieve success, … not searching for a solution in ignorance of it*"[27].

37 As far as the working of the invention is concerned, the skilled person might consult someone else on a certain point when trying to implement the teaching of the patent[28]. Moreover, in *Regeneron v Kymab*[29], it was held that "*the skilled person is not bound to carry out the invention precisely as described and can use the common general*

---

*[25] At the hearing, when discussing how Mr Mollick concluded that his illness was COVID-19, documents D1 and D2 (see footnotes 1 and 2 above) were referred to briefly. Although these documents were initially cited by the examiner before being confirmed as having been published <u>after</u> the priority date of the invention, they are <u>not</u> relevant to this discussion. The basis for sufficiency and support **must** come from the application as filed and, as such, these documents do not help Mr Mollick's position.*

[26] Mentor Corporation v Hollister Inc., [1991] FSR 557

[27] Zipher Ltd v Markem Systems Ltd., [2009] FSR 1, see page 50.

[28] Kirin-Amgen Inc v Hoechst Marion Roussel Ltd., [2005] RPC 9

[29] Regeneron Pharmaceuticals Inc. v Kymab Ltd., [2018] EWCA Civ 271, see paragraph 262

knowledge to perform the invention and make any obvious changes that may be necessary, provided of course that any work involved is not undue". However, as far as a disclosure of the efficacy of a medicinal compound is concerned, I am not sure that much turns on these points which are more closely associated with making the invention work as described rather than assessing whether the invention will work.

38 I will comment here that while the examiner has asserted that the person skilled in the art is a clinician, the applicant, Mr Mollick, has not presented argument as to the identity of the skilled person or their CGK.

39 Taking account of the above-mentioned legal considerations and reflecting on the materials provided by Mr Mollick and the examiner in support of their arguments, I have taken the time to reflect in some detail on who is the skilled person and what is their CGK.

40 I consider that the present application should be read and interpreted through the eyes of a person skilled in the art of anti-viral therapies as applied to acute respiratory syndromes. This skilled person would have some common general knowledge concerning virology and the structure, function and life cycles of different viruses, the diagnosis of viral diseases, the identification of potential therapeutic substances, their formulation as pharmaceutical agents, and their testing in clinical trials. I consider that this skilled person would seek the assistance of both chest physicians and pharmacologists to aid medical understanding and of patent law professionals when seeking to understand the scope of the claims and the significance of the disclosure made.

The Common General Knowledge (CGK) at the Priority Date

41 The earliest priority date for the present application is 2 April 2020. In preparing this decision, I am reminded that this was an exceptional time in global history. On this date the COVID-19 pandemic, which is thought to have begun during December 2019, was beginning to spread across the world.

42 Whilst I am reminded that under UK law, the skilled person views the world with CGK from the UK[30], the application in suit describes an illness and subsequent treatment taking place in Arizona, USA. The skilled person in the UK, thus views the disclosure from a distance. Assessing the disclosure at this geographical distance would mean that the skilled person would find it necessary to find out some of the epidemiological details of the COVID-19 pandemic in Arizona, USA. The first COVID-19 case was reported in Arizona on 26 January 2020; the second case on 3 March 2020; and the third on 6 March 2020 (this was the first confirmed instance of community spread in Arizona)[31]. A public health emergency in Arizona was declared on 12 March 2020, but no restrictions on large gatherings were put in place. As of 12 March 2020, there were nine confirmed cases of coronavirus in Arizona, including five from the same household in Pinal County (reportedly the household of the healthcare worker announced as being positive for COVID-19 on 6 March 2020). The first significant

[30] *Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548*

[31] *See https://en.wikipedia.org/wiki/COVID-19_pandemic_in_Arizona#March_2020*

social restrictions were put in place on 19 March 2020 and a state-wide stay-at-home 'lockdown' commenced on 30 March 2020.

43 By April 2020, there were more than 100 confirmed cases of COVID-19 per day in Arizona. In the UK, the skilled person would be aware of media reports of the epidemic, with rising death rates, unprecedented lockdowns, and an urgent need to establish reliable COVID-19 testing and a potential prevention and/or cure for COVID-19. To that end various governments around the world were urgently redirecting their healthcare resources to addressing the pandemic. I consider that it is under these exceptional circumstances that the understanding and reaction of the skilled person to the application in suit must be interpreted/tested.

44 Helpfully, a great deal of information about COVID-19, which may be taken to be a part of the common general knowledge, is set out in pages 1-14 of the application which was filed approximately one year later during April 2021. In the table shown on page 13 of the application as filed, some of the symptoms of COVID-19 are listed (with frequencies among infected individuals) as:

- fever (87.9% cases),
- dry cough (67.7%),
- dyspnoea, i.e. laboured breathing (8.6%),
- diarrhoea (13.9%),
- necessity for mechanical ventilation (4.1%),

However the date and source of this information is unclear.

45 Helpfully, in the UK during March-April 2020, the reported symptoms of COVID-19 were only just becoming clear. According to a report by Oxford COVID-19 Evidence Service Team[32], cough occurred in 66% of mild to moderate COVID-19 cases whilst fever was the most frequent symptom, with anosmia (loss of sense of smell) potentially being a stronger predictor of COVID-19 than self-reported fever amongst people in the community. Other reported symptoms included dyspnoea, headache, diarrhoea, sore throat, fatigue, and rhinorrhoea ('runny nose'). It's worthwhile noting that as of 26 October 2022 the latest update to COVID-19 symptoms published by the US Centers for Disease Control (CDC) in the USA, remains remarkably similar.[33]

46 The genomic sequence for SARS Coronavirus 2, the virus that causes COVID-19, was published in January 2020[34]. This allowed for the design of the first diagnostic tests involving the extraction of DNA from sputum samples, followed by a quantitative polymerase chain reaction (qPCR). Early attempts at this test were less refined and may, in some instances, have given a higher number of false positive results than are

---

[32] See https://www.cebm.net/covid-19/in-patients-of-covid-19-what-are-the-symptoms-and-clinical-features-of-mild-and-moderate-case/

[33] See https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html updated 26 October 2022

[34] See https://www.ncbi.nlm.nih.gov/nuccore/MN908947.1

now considered acceptable[35], however at the priority date these were the cutting edge definitive diagnostic tests for COVID-19: they were the best that was available.

What is disclosed?

47 The applicant provided in excess of 200 pages of subsequently filed evidence in support of their application. With reference to the seventh principle set out by Lord Sumption in *Warner-Lambert*, it must be remembered that *"sufficiency is a characteristic of the disclosure, and these matters must appear from the patent"*, whilst "*the disclosure may be supplemented or explained by the common general knowledge of the skilled person.*" Whilst it is undoubtedly tempting to view the application for a patent in view of the later evidence provided; "*it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent."* I must therefore carefully consider the application as filed through the eyes of the skilled reader with their common general knowledge and without the hindsight of the later filed evidence. To put it another way *"The question is not whether it works but whether the contribution to the art consisting in the discovery that it can be expected to work has been sufficiently disclosed in the patent."* [36] So, it is to the application as originally filed (as supported by its earlier priority applications) that I must therefore turn.

48 As described above, the application may be split into several elements, with the opening pages of the description forming what might be taken to be *a priori* reasoning for the invention claimed. This may be most readily assessed against principles (iii)-(vi) of *Warner-Lambert* where *a priori* reasoning based on the prior art is accepted as being one way in which the invention can be rendered plausible because *"reasonable scientific grounds are disclosed for [the skilled person to] expect….that [the invention] might well work"*. However, principle (v) sets out that this must be *"based on a direct effect on a mechanism specifically involved in the disease"*, a concept that is also consistent with the EPO's jurisprudence in SALK[14]. None of the material provided in the application as filed including the citations referred to suggest or show that thyme has efficacy specifically against coronaviruses and no evidence was provided that thyme has efficacy against any molecular mechanisms known to be relevant to coronaviruses. Thus, with the *a priori* knowledge that thyme has antiviral activity against Newcastle disease virus and against herpes simplex viruses, it seems to me that the skilled person would seek to know the answer to two questions as they read the application: (i) what is the illness being treated? (ii) did thyme have efficacy against that illness?

According to the skilled person, what illness is being treated?

49 This question could have been most readily answered had the patient undergone a clinical test for COVID-19 or had had a clinical diagnosis been made on the basis of his symptoms. At the hearing and in his written submissions, Mr Mollick explained why he was unable to access testing for COVID-19 at the time of his illness. In

---

[35] See exhibit FP-2.

[36] See Warner Lambert UKSC decision (see footnote 10) at paragraph 40

particular, the document marked TS-6 "*Lack of Testing for COVID-19 in Arizona…*"[37], describes how on 15 March 2020, in order to be tested in Arizona, a patient must have recently travelled abroad or had direct contact with someone who tested positive for COVID-19. The document further tells of examples of patients being refused access to COVID-19 tests by local physicians in Arizona. Moreover, Mr Mollick submitted evidence that the tests may have been prone to giving false positive results[37,38], although I'm not sure how this fact helps his case. At the hearing, Mr Mollick further argued that even obtaining a medical consultation was impossible without the person affected exhibiting critical symptoms. As far as I recall, in March 2020 a similar situation was developing in the UK. I accept Mr Mollick's submissions about the difficulties in obtaining a satisfactory clinical test and even having an appropriate consultation with a medical professional. At the hearing, Mr Mollick argued that he was unable to obtain a clinical diagnosis of COVID-19 during his illness to meet the requirements for sufficiency and support. Accordingly, I understood that Mr Mollick considered that the lack of test availability could form the basis for a view that the benefit of the doubt be exercised in favour of allowing the patent to be granted even without further evidence of the identity of his illness. I have carefully considered whether this approach would be appropriate and find myself returning to ask how the application would be viewed through the eyes of the skilled reader during those exceptional times. Whilst I accept that Mr Mollick and, indeed most other moderately ill people, would not have been able to access a COVID-19 test at the priority date, I do not consider that a qPCR test result was the only way in which the skilled reader could be satisfied that Mr Mollick had suffered from COVID-19. For instance, a clinical history consistent with the commonly recognised course and symptoms of COVID-19 and, possibly, a history of having had contact with persons subsequently found to have been infectious with COVID-19 are both pieces of evidence that I could envision might readily convince the skilled reader of the identity of Mr Mollick's illness. On that basis I cannot see grounds for any exercise of the benefit of the doubt in the way that Mr Mollick is suggesting.

50 It thus seems entirely reasonable that in seeking to understand whether the patient was suffering from COVID-19, the skilled person would compare the patient's symptoms to those commonly reported to be associated with COVID-19. An additional element of confidence would be added to a positive diagnosis should the patient have had contact with confirmed COVID-19 cases determined, for example, through epidemiological contact-tracing.

51 In contrast to the symptoms commonly associated with COVID-19 infection (at least during April 2020), the applicant reported his symptoms as being a slight headache, slight fever, chills, aching in his bones and joints and sharp stabbing pains to his lower back. No cough, no cold-like symptoms and no respiratory symptoms were reported and the commonplace loss of a sense of smell was not noted. Later, there was a relapse of symptoms, which the applicant asserts alongside some evidence[39] is a phenomenon seen in COVID-19 infections and which indicates that he was suffering

---

[37] See exhibit TS-6 entitled "Lack of Testing for COVID-19 in Arizona…", here's what we know 15 March 2020, Arizona Department of Health Services, USA.

[38] See exhibits FP-2, TS-7

[39] See exhibit CvF-2

from COVID-19. The second bout of illness featured a headache and fever. I particularly note that, again, the patient did not suffer from a cough or respiratory symptoms and did not experience a characteristic loss of their sense of smell.

52 As set out above, the skilled person would also consider whether the patient had community contact with subjects infectious with COVID-19. However, the patient became ill for the first time **before** the second case in Arizona was reported on 3 March 2020 and **before** the first confirmed instance in Arizona of community spread. Therefore, no such evidence exists. It is worthwhile noting that at the hearing Mr Mollick confirmed that he had had no contact with known cases of COVID-19 during early March 2020.

53 In the application reference is made to the foods that the patient consumed. Moreover, an attempt was seemingly made to trigger the illness once more by consuming particular foodstuffs. I do not believe that the skilled person would have been aware of any reports that COVID-19 onset might be associated with the ingestion of large amounts of fat or sugar such that the relevance of these observations in the application in suit is, at best, highly uncertain.

54 Reading the specification from the point of view of trying to understand why the applicant considered that he was suffering from COVID-19, it is worthwhile noting that during his first illness he acknowledges that he did not know "*what the problem is*"[40] and later "*still did not know why or have any inclination he had contracted the coronavirus Covid-19*"[41,42]. It is only on Monday 2 March 2020 at 3:00 PM that *"Still feeling bad with the persistent slight headache and persistent slight fever, the disclosed patient is now assuming he has Covid-19 disease…"*[43]. Beyond his opinion that thyme was aiding his recovery, I cannot see the reason why the applicant thought that he had contracted COVID-19 perhaps other than that the slight headache and slight fever were persistent.

55 At the hearing, whilst it was very clear that Mr Mollick believes that he, the patient, was suffering from COVID-19 during the episodes of illness described in the application as filed, it was far from clear why he holds this opinion. I therefore offered Mr Mollick the opportunity to explain why he considered that he was suffering from COVID-19. His response was that he was unfamiliar with the illness and that it was unlike previous episodes of influenza that he had suffered from. Mr Mollick also referred to the decline in influenza cases in Arizona during the spring of 2020[44]. Unfortunately, I do not believe that in drawing a contrast with previous bouts of influenza Mr Mollick assists the skilled person in concluding that his episodes of illness during early March 2020 were indeed COVID-19.

---

[40] *See paragraph [0058] in application as filed*

[41] *See paragraph [0061] in application as filed*

[42] *See paragraph [0062] in application as filed*

[43] *See paragraph [0063] in application as filed*

[44] *See exhibits AZ-1 and AZ-2.*

56 Overall, from the information disclosed in the application as filed, I do not believe, on the balance of probabilities, that the skilled person would accept that the illness from which the applicant was suffering during March 2020 was COVID-19. There is no evidence of contact with subjects infectious with COVID-19 and the reported symptoms, although overlapping with some COVID-19 symptoms were not consistent with the most common symptoms of COVID-19. Indeed, it appears to me that the symptoms described are likely to be consistent with many different viral illnesses.

57 As far as my analysis as to whether the application meets the requirements of section 14(3) and section 14(5)(c), here the analysis must end simply because I have reached the conclusion that the skilled person cannot be sure from the application that, on the balance of probabilities, the illness was COVID-19. However, for completeness, I will briefly comment on some of the points raised by Mr Mollick at the hearing.

Consideration of the further evidence

58 As set out above, the information disclosed by the application may be supplemented by later filed evidence. I can confirm that I have reviewed all of the evidence submitted by Mr Mollick. Reviewing it, has assisted me in confirming my analysis as to the skilled reader's understanding of the original disclosure. For completeness, I will briefly comment on some items of evidence highlighted to me.

59 The applicant has provided a medical history of several severe prior illnesses that he wishes to distinguish from the illness described in his specification. I can confirm that I accept that it is unlikely that the applicant was suffering from one of these illnesses during March 2020.

60 Exhibit AR-1 provides age-stratified evidence of COVID-19 death rates by age, but I cannot see how this teaches the skilled person the nature of the applicant's illness.

61 Exhibit CvF-1 compares the symptoms of influenza with those of COVID-19. Whilst this may, to some extent, provide evidence to counter an argument that Mr Mollick's illness was some form of influenza such that it constitutes evidence as to what the illness was **not**, this evidence does not assist the skilled person in confirming that the patient **was** suffering from COVID-19.

62 Exhibit CvF-2 concerns the phenomenon of COVID-19 rebound (or relapse) shortly after resolution of illness in patients treated with the recognised COVID-19 antiviral drug Paxlovid. At the hearing, we discussed in some detail how COVID-19 symptoms may recur shortly after their resolution and Mr Mollick was keen to assert that the recurrence of his illness was indicative of the illness having been COVID-19. When viewed through the eyes of the skilled person, I do not believe that a relapse or recurrence of illness within a short timeframe would be taken by the skilled person to be a positive indication that the illness suffered was COVID-19.

63 I do not see that the later-filed evidence provides much assistance for Mr Mollick's position. The application in suit doesn't meet the requirements for sufficiency and support for the medical use claims and the later evidence does not and cannot cause me to reach a different conclusion.

Does the skilled person consider that thyme had efficacy against the illness?

64 Having concluded that the skilled person simply does not know whether the patient/applicant was suffering from COVID-19 or some other illness at the time they self-administered thyme, I do not consider that it is necessary to make any further determination as to whether there is adequate evidence that the skilled person can say it is plausible that the consumption of the thyme resulted in the recovery from illness described in this application.

Conclusion on sufficiency under Section 14(3)

65 Taking all of the above into account and bearing in mind the principles set down in *Warner-Lambert*, I consider that the application in suit provides no evidence or *a priori* reasoning (or indeed a combination of both) that thyme can interfere in a metabolic mechanism specific to coronaviruses. I consider that the application provides no evidence or *a priori* reasoning that thyme has any activity whatsoever against coronaviruses.

66 From the application as filed the skilled person is simply unable to say whether the applicant was suffering from COVID-19 during March 2020. It therefore follows that the application provides no evidence that COVID-19 was treated using thyme. It is my view that because the identity of the illness and infectious agent involved (if there was one) remains unknown, the application does not provide enough to render it plausible to the skilled person that thyme can treat COVID-19. The subsequently filed evidence does not change my view. At best this application appears to provide an anecdotal account of the treatment of an illness whose identify is not known in one patient using the herb thyme. Thus, the application does not meet the requirement for sufficiency under section 14(3)

Conclusion on support under Section 14(5)(c)

67 The specification does not provide enough material in the description to enable the skilled person to come to the view that thyme treats COVID-19. The description provides an account of the treatment of an illness using thyme. The skilled person is unable to identify the illness experienced by the patient sufficiently to say that, on the balance of probabilities, this was COVID-19 and that it was treated successfully using thyme. Thus, I consider that the application does not meet the requirement for support under section 14(3)

Other matters

Claims 17-19

68 As I mentioned above, the scope of claims 17-19 is not clear and these claims may be construed as defining well-known compositions of thyme *per se*. However, in view of the scientific evidence cited in the application in suit and referred to above, it is clear that these claims relate to subject matter that is not novel.

69 Moreover, as the invention being sought relates to the therapeutic use of the thyme composition and not the composition *per se* which (as I have already noted) are well-known, it is my view that it is unlikely that a saving amendment can be made.

Conclusion

70 Taking all of the above into account , I find that the present application GB2113325.1, in the name of Peter J Mollick, as claimed in claims 1-16 which relate to therapeutic use, does not meet the requirements of section 14(3) or section 14(5)(c) of the Act.

71 Having reviewed the application it would appear to me that the only subject matter that appears to be disclosed sufficiently and supported properly concerns preparations of the well-known and commonplace herb thyme as referred to in claims 17-19. I am satisfied that this is not novel subject-matter.

72 As this application fails to meet the requirements of the Act under Section 14, I refuse this application under section 18(3) of the Act.

Appeal

73 Any appeal must be lodged within 28 days after the date of this decision.

Dr L Cullen

Deputy Director, acting for the Comptroller