



Wadhwa and Rahul Bagga of Dentons Link Legal. Siddharth Pattnaik, one of the inventors, briefly joined the hearing to contribute.

- 5 No amendments or observations were filed in response to the pre-hearing report, and no skeleton arguments were provided in advance of the hearing. On the morning of the hearing, an email was received from Ms Wadhwa (and therefore not from the registered UK address for service), proposing amendments to the claims. I will discuss these briefly below.

### **Compliance period and late-filed amendments**

- 6 In their pre-hearing report of 26 January 2026, the examiner reminded the applicant that the compliance period ended on 8 December 2025, and that they could request a further extension of two months to the compliance period, under rule 108(3). However, no request to extend the compliance period beyond 8 December 2025 has been received, and so the time period allowed for extending under rule 108(3), and as set out by rule 108(7), has passed. This means that, as helpfully explained by section 20.04 of the Manual of Patent Practice<sup>2</sup> (“MoPP”), it is mandatory that the application is treated as refused if it fails to comply with any requirement of the Act and Rules at the end of the compliance period. This means that this hearing will be for the purpose of determining whether or not the application was in order at the end of the compliance period; there is no opportunity for the applicant to amend if I find that the application was not in order.
- 7 I have therefore based my decision on the description filed on 7 February 2025, and the claims filed on 8 December 2025.

### **The application**

- 8 The application relates to fertility and reproductive health monitoring in female subjects. It is well known to assess fertility status by observing variations in reproductive hormones during the menstrual cycle; existing approaches typically track individual hormones or require multiple separate tests to infer ovulation, luteal phase progression or other aspects relating to reproductive hormones. The description notes that such approaches can be unreliable due to hormonal variability, and the use of several different tests can be onerous.
- 9 The invention provides a method and handheld computer-implemented system for determining fertility level in a female subject, by simultaneously measuring and analysing multiple hormonal analytes from a single biological sample. The hormone analytes tested are: (i) estradiol glucuronide (E3G), a water soluble metabolite of estradiol (the major estrogen in the human body); (ii) lutenising hormone (LH), the hormone known to trigger ovulation; (iii) pregnanediol glucuronide (PdG), the major metabolite of progesterone; and (iv) follicle stimulating hormone (FSH), the hormone known to trigger follicular growth.
- 10 The method employs a test strip comprising multiple detecting zones, each specific to a different analyte. In use, a biological sample is applied to the test strip, with each analyte interacting with a corresponding biochemical reagent to produce a

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<sup>2</sup> [Manual of Patent Practice - Section 20: Failure of application - Guidance - GOV.UK](#)

characteristic colour signal. These signals are detected by a coupled user device, which quantifies the analyte concentrations and compares them with predefined reference values. On the basis of this comparison, the system is said to determine fertility level and, in some embodiments, related health conditions.

11 There are two independent claims:

*1. A method for determining fertility level in a female subject based on a plurality of analytes present in a biological sample from the female subject, the method comprising:*

*receiving the biological sample from the female body, at a test strip, wherein the plurality of analytes comprises E3G, LH, PdG and FSH;*

*reacting the biological sample with one or more detector antibodies at corresponding detecting zone generating a characteristic colour on one or more control lines on the test strip for each of the plurality of analytes;*

*determining, by a user device coupled to the test strip, a concentration value for each of the plurality of analytes based on the characteristic colour;*

*storing, by the user device, a pre-determined concentration value corresponding to each of the plurality of analytes, and the concentration value determined for each of the plurality of analytes at different times*

*corresponding to different days or phases of at least part of a menstrual cycle;*

*analysing, by the user device, the concentration value by comparing the determined concentration value with pre-defined concentration value corresponding to each of the plurality of analytes;*

*monitoring, by the user device, changes in the concentration value of the plurality of analytes across the at least part of the menstrual cycle by comparing concentration values obtained at different times; and*

*determining the fertility level based on the monitored changes in the concentration values of the plurality of analytes and the comparison with pre-defined concentration values.*

*13. A handheld computer-implemented system for determining fertility level in a female body based on a plurality of analytes present in a biological sample from the female body, the system comprising:*

*a plurality of test strips comprising:*

*a sample receiving area for receiving the biological sample from the female body, wherein the plurality of analytes comprises E3G, LH, PdG and FSH,*

*one or more conjugate pads provided with a detector reagent comprising one or more detector antibodies, wherein the detector reagent is reacted with the biological sample,*

*a plurality of detecting zones each provided with a corresponding biochemical reagent to receive the plurality of analytes, wherein the plurality of analytes, of the reacted biological sample, is reacted with the corresponding biochemical reagent at the corresponding detecting zone producing a characteristic colour on one or more control lines, and the corresponding biochemical reagent is covalently attached to magnetic and electronically charged labels, and*

*the one or more control lines for representing the characteristic colour for the plurality of analytes; and*

*a user device coupled with the plurality of test strips, the user device comprising:*

*a sensing unit configured to scan the plurality of test strips for receiving information from the plurality of test strips,*

*a quantification unit configured to determine a concentration value of the plurality of analytes based on received information from the sensing unit,*

*a storage unit configured to store pre-determined concentration value corresponding to each of the plurality of analytes, and the concentration value determined for each of the plurality of analytes at different times*

*corresponding to different days or phases of at least part of a menstrual cycle,*

*an analytic unit configured to monitor changes in the stored concentration values of the stored analytes by comparing the determined concentration value with the pre-defined concentration value of the plurality of analytes across the at least part of the menstrual cycle, and*

*a diagnostic unit configured to determine the fertility level based on the monitored changes in the concentration value of the plurality of analytes.*

## **The Law**

- 12 The relevant law is defined in the Patents Act 1977 (as amended) (“the Act”) and can be viewed online at the IPO’s website:

### **[The Patents Act 1977 \(as amended\)](#)**

- 13 The Manual of Patent Practice explains the IPO’s practice under the Act and makes helpful references to relevant case law. The Manual can be viewed online at the IPO’s website:

### **[Manual of Patent Practice](#)**

- 14 I have indicated below the sections of the Act which apply to each of the examiner’s objections.

## **Issues for decision**

- 15 There are several issues of contention between the applicant and the examiner, each relating to substantive requirements of the Act that need to be satisfied before the patent may be granted. Specifically, in their pre-hearing report, the examiner sets out that the application fails to meet the requirements for inventive step<sup>3</sup>, clarity<sup>4</sup>, sufficiency and/or support<sup>5</sup>.

## **Claim construction**

- 16 My starting point for assessing the invention lies in construing the claims. The claims are construed in a purposive manner, through the eyes of the skilled person, in light of the disclosure of the description, as set out in section 125 of the Act and following

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<sup>3</sup> Section 1(1)(b)

<sup>4</sup> Section 14(5)(b)

<sup>5</sup> Section 14(3), section 14(5)(c)

the established principles of UK patent law. I therefore need to first ask who the skilled person might be.

- 17 The only indication of who the skilled person might be from both the examiner and the applicant is in the context of inventive step, but as claim construction is an integral part of inventive step assessment, I am content that the skilled person would be the same. The applicant, in their letter of 9<sup>th</sup> June 2026, asserted the skilled person would be someone operating in the field of female health and hormone tracking. The examiner's viewpoint is that the skilled person would be a biomedical researcher, endocrinologist or biotechnologist with expertise in hormonal interactions and menstrual cycle analysis. I think both positions are similar, and I agree that the skilled person would be a researcher operating in the field of female health, with an expertise in hormonal interactions and menstrual cycle analysis.
- 18 The examiner has maintained that the claims are unclear with regards to the terms "fertility level" in claims 1, 9 and 13, and also that it is unclear as to whether the method of claims 1 and 13 require all four analytes collectively. I will consider each of these in turn.

#### Fertility level

- 19 In their letter of 8 December 2025, the applicant considers that the specification teaches that the "fertility level" is determined by comparing measured concentrations/ rates of change of E3G, LH, PdG and FSH against predetermined levels. It goes on to provide examples of how different combinations of hormones can predict conditions such as poor ovarian reserve, ovulation, miscarriage risk and sever PMS. However, none of this defines what the term "fertility level" is intended to mean in the eyes of the skilled person. In their pre-hearing report of 26 January, the examiner considers that the term "fertility" is widely accepted in that art as an individual's ability to conceive, but goes on to point out that several of the dependent claims define conditions that are not necessarily understood to be related to an individual's ability to conceive.
- 20 Specifically, the examiner is referring to the following claims that are depending on claim 1:
  - (i) claim 3, defining the method as predicting conditions pertaining to follicle health, ovarian reserves and egg quality in the female subject;
  - (ii) claim 4, defining the method as determining conditions pertaining to corpus luteum integrity, viability of embryo and risk of miscarriage;
  - (iii) claim 5, defining the method as determining conditions pertaining to early diagnosis of pregnancy; and
  - (iv) claim 6, defining a method for determining PMS severity.

According to the examiner, not all of the conditions defined in these claims are considered to be related to "fertility levels", and therefore render the scope of the independent claims unclear.

21 At the hearing, Ms Wadhwa explained that, in the context of the description, fertility level relates to the conception window during a menstrual cycle, rather than any broader interpretation or any gradient of fertility levels in general. She explained there is no gradient of fertility level; either a person is in a fertile window or is not. This does appear to be consistent with page 7 lines 6-9 of the description, which states:

*“The user device is then configured to analyse the test results and information and accordingly determine the fertility level and check whether the female body is in the phase of fertility/ovulation.”*

22 However, this does not address the concerns raised by the examiner regarding the inconsistencies introduced by dependent claims 3-6, as summarised above. These claims point towards the term “fertility level” as having a broader meaning than an indication of an individual’s ability to conceive. When pressed on this at the hearing, Ms Wadhwa described the relationship of the conditions defined in claims 3-6 with the term “fertility level” by explaining how the different hormone levels could be used to predict these different conditions. This appeared to be an elaboration of the explanation in the applicant’s letter of 8 December 2025, which provided examples (ovarian reserve, ovulation, etc.) that are considered to provide “clear, objective criteria for assessing fertility level and **associated reproductive health states**” (my emphasis). Again, none of this assists me in determining what is considered to fall within the scope of the term “fertility level” in claim 1.

23 The description adds to this uncertainty, where page 8 discusses the use of the system of Figure 1 for “*monitoring the several health conditions level in accordance with an embodiment of the present invention*”. These conditions are said to include (my emphasis): “...**fertility level, follicle health, ovarian reserve, egg quality, follicular growth, corpus luteum integrity, miscarriage, viability of embryo, early diagnosis of pregnancy, miscarriage, menopause, PMS severity, period of intercourse, right time to stimulate during in-vitro fertilisation procedure**”. It would therefore appear that the invention can be used to determine a range of health conditions, with fertility level being one of them. Consequently, the description provides little assistance in determining what is encompassed by the term “fertility level” in claim 1, given that the dependent claims suggests that follicle health, ovarian reserve etc should all fall within the scope of claim 1 and, therefore what is meant by “fertility level”, whereas the description suggests that follicle health, ovarian reserve etc are all conditions to be monitored that are distinct from “fertility level”.

24 I will therefore return to the basic principles of claim construction and ask what would the skilled person, reading the claims in light of the description, understand by the term “fertility level”. I agree with the applicant that it would be understood to extend beyond measurement of hormones to determine where in the menstrual cycle conception could occur; other conditions as mentioned in the specification, the applicant’s letters and their submissions during the hearing would also be considered by the skilled person to have a direct impact on fertility level. These conditions include measurements of follicular health, ovarian reserves and egg quality. However, I do not think the skilled person would consider viability of embryo and risk of miscarriage to be within the scope of the term “fertility level”, as these are not indicators of fertility levels but rather are indicators of the viability of the pregnancy

once the individual has conceived. Similarly, I would not expect the skilled person to consider early diagnosis of pregnancy or PMS severity to relate to “fertility level”.

- 25 Taking the above into account, I conclude the term “fertility level” would be understood by the skilled person as relating to the ability of an individual to conceive at a certain point in their menstrual cycle. This includes determining the separate conditions of fertility window, follicular health, ovarian reserves, corpus luteum integrity, and egg quality, which are all conditions linked to “fertility level”. They would not consider that viability of embryo, risk of miscarriage, early diagnosis of pregnancy or PMS severity, as defined in dependent claims 4, 5 and 6 fall within the ordinary meaning of the term “fertility level”.

#### Four analytes

- 26 Claims 1 and 13 also relate to the measurement of a plurality of analytes present in a biological sample. According to these claims, “*the plurality of analytes comprises E3G, LH, PdG and FSH*”, and they react with corresponding detecting zones, designated 203A-203D to generate a characteristic colour. This would therefore appear to define a method/system where four analytes are simultaneously measured. However, some of the claims dependent on claim 1 contradict this, as they define methods where not all analytes appear to be required. For example, follicular health, ovarian reserves and egg quality (which the applicant has argued, and I have accepted, fall under the term “fertility level”), are predicted by comparing FSH with E3G only, suggesting that the measurement of PdG or LH are not required.
- 27 The description does not help clarify this, as it contains several passages that make clear all four hormones are analysed as part of the invention but also has some passages that indicate otherwise. Page 9 lines 4-11 for example, contain the phrase (my emphasis) “*The method includes determining concentrations of levels of analytes selected from Estradiol glucuronide (E3G), Luteinizing hormone (LH), Pregnanediol Glucuronide (PdG) **and/or** Follicle-stimulating hormone (FSH) and human Chorionic Gonadotrophin (Hcg); mapping concentration of at least one analyte with respect to another in a luteal or follicular phase; and predicting a health condition of the Female subject.*”, and on page 15 “*In an embodiment, several health conditions are determined by comparing concentrations or levels **of two or more of the analytes** selected from E3G, PdG, LH and FSH*”.
- 28 At the hearing, the applicant’s representatives initially stated that the invention requires at least two analytes, although when pressed specifically on the wording of claim 1, they confirmed that claim 1 requires that all four analytes are measured as part of the method. They did, however, point out that the method relates to a comparison of the levels of the analytes across various time periods, and these levels do change during the female reproductive cycle, with various combinations relating to different conditions relating to fertility levels. From this, I can conclude that whilst all four analytes are measured, their concentrations vary and they may not always be detectable

#### Construction of independent claims 1 & 13

- 29 Taking into account my understanding as outlined above of what is meant by “fertility level” and how many analytes are measured, I construe claim 1 as:

*A method for determining fertility level, including fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality of an individual, by:*

- (a) measuring, at least, each of the analytes E3G, LH, PdG and FSH using corresponding antibodies on a test strip, wherein a colour change at a control line for each of the analytes indicates a concentration value for each of the analytes, as determined by a user device couple to the test strip;*
- (b) storing a pre-determined concentration value corresponding to each of the analytes at different days or phases of at least part the menstrual cycle in a user device;*
- (c) analysing changes in the concentration of each of E3G, LH, PdG and FSH, at least, by comparing with the concentration of pre-defined values;*
- (d) monitoring the changes in concentration values of E3G, LH, PdG and FSH, at least, across at least part of the menstrual cycle, by comparing concentration values obtained at different times;*
- (e) determining the fertility window, follicular health, ovarian reserves, corpus luteum integrity and/or egg quality based on the changes in the concentration values of E3G, LH, PdG and FSH, at least, and comparing with the pre-defined concentration values*

The same construction applies, *mutatis mutandis*, to claim 13.

- 30 In light of this construction of claim 1, dependent claim 4, which defines the viability of an embryo and the risk of miscarriage, and dependent claims 5 and 6, which define early diagnosis of pregnancy and PMS severity respectively, do not fall within the scope of claim 1. It is therefore worth noting that due to these inconsistencies and the difficulties in construction, the claims are inherently unclear and therefore do not appear to meet the requirements of section 14(5)(b). The corresponding inconsistencies in the description also make it difficult to determine which embodiments therein fall within the scope of claim 1, and therefore the claims do not appear to be supported, as required by section 14(5)(c). As such, the application was not in order at the compliance date. However, in the event that I may be incorrect in my understanding of the scope of term “fertility level” I will continue to decide upon the remaining issues.

### **Sufficiency**

- 31 Section 14(3) of the Act requires that:

*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.*

MoPP describes in detail what might be termed “classical insufficiency”.

- 32 The examiner considers that the invention defined by claims 1 and 13 does not meet the requirements for sufficiency of disclosure under section 14(3) of the Act. In particular, they are of the view that the inventions of claims 1 and 13, in that they require the presence of all four analytes, are “classically insufficient” because the skilled person would be unable to work that invention without undue burden. Specifically, the examiner argues that none of the examples provided require the monitoring of changes in the concentration of all four analytes in order to determine fertility levels, and therefore there is no disclosure of how the skilled person should use all four markers together in order to determine the “fertility level”.
- 33 The examiner then goes on to argue that the dependent claims are also insufficient as it is not clear how the balance between the various combinations of hormones can determine the different conditions defined in the dependent claims. For example, the examiner considers that the specification does not disclose how the skilled person would use the balance of FSH and E3G to determine egg quality as required of claim 3, and that it is unclear how the variation of PdG and E3G levels can determine PMS severity. In the examiner’s opinion, determining what these variations should be would require an undue burden for the skilled person.
- 34 The applicant, on the other hand, considers that there is sufficient in the specification as filed that would enable the skilled person to determine the varying levels of hormones that correspond to each condition that falls under the term “fertility level”. At the hearing, Ms Wadha explained that the application teaches a time series analysis of the four hormones; a multi-day value of the measured hormone is compared against a predefined threshold. Mr Sachs further explained that whilst the specification did not contain an illustration of all four hormonal levels against the threshold values, the information in the application as a whole provided qualitative data that pointed towards how comparisons can be made and how the hormones interrelate throughout a cycle to provide a result relating to fertility.
- 35 Ms Wadhwa also referred to the data in the inventor’s published scientific papers<sup>6</sup> that explained how the invention could be carried out by the skilled person. The information in these papers was also summarised in the applicant’s letter of 9 June 2025. As these papers were published some time after the priority date of the invention I cannot take them into account here as they would not have formed part of the common general knowledge at that time, although I note that both papers only relate to the measurement of E3G, LH and PdG to determine the fertile window so in any case it is difficult to see their relevance to claim 1, which also requires the monitoring of FSH.
- 36 Following the judgment in *Zipher*<sup>7</sup>, classical insufficiency arises where the express teaching of the patent does not enable the skilled addressee to perform the invention; to determine this, an assessment of the steps necessary for the skilled reader to take to arrive at the claimed invention must be carried out. Therefore, in assessing whether the present invention is sufficiently disclosed, the key questions are whether the skilled person, using their common general knowledge and trying to work the invention, would be able to identify how the measurement of each of LH,

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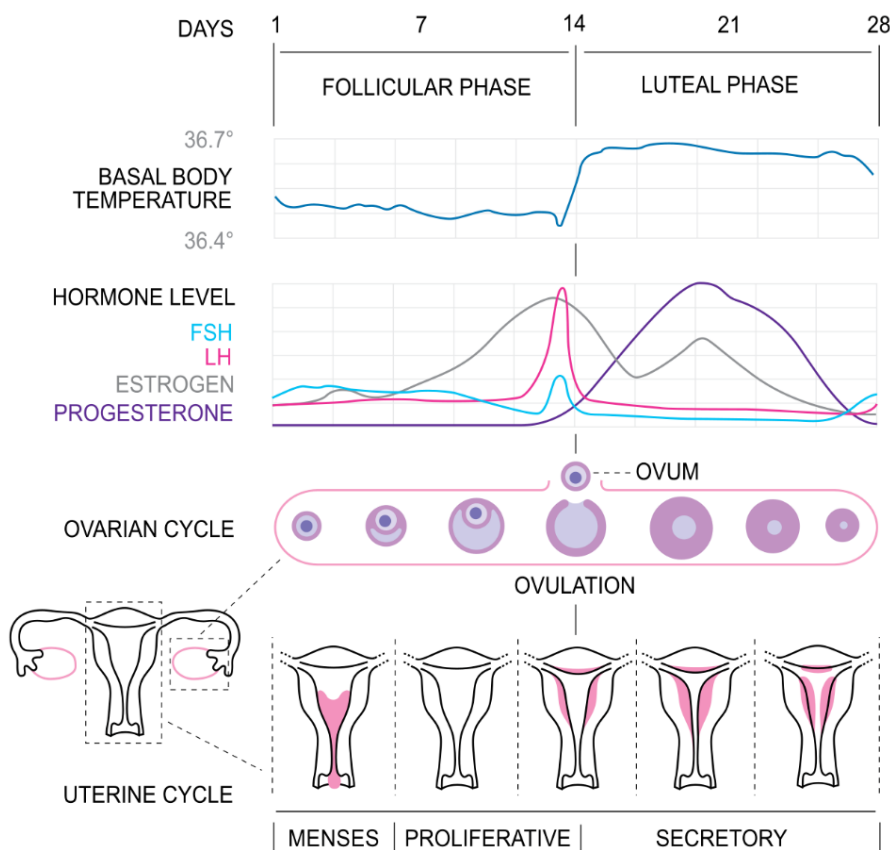
<sup>6</sup> Human Reproduction Open, Vol 2023, No. 1; Scientific Reports 2023 13:9227

<https://www.nature.com/articles/s41598-023-36539-w>

<sup>7</sup> *Zipher Ltd v Marken Systems Ltd* [2009] FSR 1

FSH, E3G and PdG would allow the fertility levels, including each of fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality, to be determined, and how to set the pre-defined concentration levels.

37 I have already set out who I think the skilled person would be, when construing the claims above. I will add the caveat that when considering the skilled person in relation to sufficiency, they are someone (or a team) who is trying to make the invention work, and would be capable of making routine workshop developments and that the skilled person is *“trying to carry out the invention and achieve success...not searching for a solution in ignorance of it”*. In this regard, I agree with the applicant’s position that the skilled person would be familiar with endocrinology and menstrual cycle analysis, and would readily understand that fertility can be calculated by comparing measured concentrations and/or rate of change of analytes against predefined hormonal profiles. They would be aware of the fluctuations of each of the hormones LH, FSH, estradiol and progesterone during the female menstrual cycle and that all four of these can be tracked to give insights into fertility. The variations in the levels of each of these is well known, as demonstrated below (Source: Wikipedia<sup>8</sup>):



38 I therefore accept that the skilled person would know when to expect increases or decreases in the levels of LH, FSH, E3G and PdG during the female menstrual cycle, and what this means for fertility in general. I also accept that, in light of the

<sup>8</sup> [Menstrual cycle - Wikipedia](#)

well-known role of hormonal changes during the menstrual cycle, the skilled person would know what “normal” levels of these hormones would look like, although they would also know that these “normal” levels themselves would be a range of concentrations, specific to the individual. Nevertheless, given the wealth of information in the prior art regarding hormonal changes during the menstrual cycle, I do not think it would be beyond the remit of the skilled person to generate a baseline pattern of hormonal changes, either based on well-document values, or indeed individualised to a specific female. It is therefore plausible that the skilled person would be able to determine a pre-defined, generic, change pattern for each analyte across various time points.

39 However, the invention itself requires the determination of the levels of each of these hormones in a sample from the user, taken at different days or phases of the menstrual cycle, comparing these to pre-defined concentrations taken at different times, and from that determining “fertility level” in the female subject, where the “fertility level” includes determining each of: fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality, at least. This would require an indication of the upper and/ or lower thresholds for each of these hormones, taken across various time points, calibrated for a specific individual, and capable of indicating (and, presumably distinguishing between) each of the fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality

40 I have carefully read the application originally filed and published by WIPO and can see no example in the description of how the skilled person would use the measurements of the levels of all four of E3G, LH, PdG and FSH taken at various time points during the user’s own menstrual cycle to determine “fertility level” in general. Moreover, given that the term “fertility level” encompasses a number of conditions, including fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality, there are no specific examples indicating how the skilled person would interpret the measurements obtained, compare them against the baseline levels, and, more importantly, distinguish between each individual condition.

41 As an example, page 15, line 15- page 16 line 2 of the specification as describes a method of determining follicle health, ovarian reserve, or egg quality (my emphasis):

*“In an aspect, a method of determining follicle health or ovarian reserve or egg quality in a female subject is provided by using methods and systems described above. The above systems and methods may be deployed to study relation between several hormones or all hormones and determine a health condition. In an embodiment, the method includes monitoring FSH and E3G on third day of the menstruation cycle, **such that a high FSH and a low E3G reading determines egg quality or follicle health in the female subject.** Further, a healthy follicular growth and normal behaviour in the female subject is determined by monitoring E3G pattern, which usually fluctuates every 36–38 hours with a constant E3G rise till LH attains peak. Further, **the egg quality as well as corpus luteum integrity is determined by analysing level of LH surge on the peak day of the menstrual cycle while monitoring the time taken by progesterone concentration to rise.** The corpus luteum is an endocrine structure that is involved in ovulation and early pregnancy. During ovulation, secondary follicles are formed from primary*

*follicles followed by formation of mature vesicular follicle. At ovulation, the follicle ruptures expelling the ovum into the fallopian tube. The corpus luteum produces oestrogen and progesterone to maintain conditions for implantation and if not implanted, the corpus luteum involutes and turns into a corpus albicans.”*

This passage describes the combination of “high FSH” and “low E3G” as a means to measure either egg quality or follicle health. There is no disclosure of the numerical threshold for “high FSH” and “low E3G”, nor is there any indication of how these values could be calibrated to an individual user, or how these measurements distinguish between “egg quality” and “follicle health”. The same passage also states that healthy follicular growth and normal behaviour are determined by the E3G pattern, which fluctuates every 36-38 hours, with a constant E3G rise until LH peaks. Again, there are no specifics of what the peaks might be, what level of E3G rise is required, or what constitutes a fluctuation. Also described is the determination of egg quality as well as corpus luteum integrity by analysing LH surge; there is no indication of what the LH surge would be or how this links back to the “high FSH” and “low E3G”, which are also disclosed to be indicators of egg quality.

- 42 I note that figures 4a and 4b illustrate graphs of hormone levels, and demonstrate to a degree what “high FSH” and “low E3G” looks like in comparison to normal levels. The reproduction of the figures themselves is unclear, but at the hearing the inventor helpfully described what was intended. According to the inventor, figure 4B (left) depicts comparisons of normal FSH levels with low FSH levels and normal E3G levels with high E3G levels; high E3G and low FSH are indicators that follicle growth has not happened, or follicle numbers are low, or there is low egg quality. However, there are no values on the Y axes that would indicate to a skilled person at what level the E3G levels would be considered “high”, and the FSH levels considered “low”. No explanation is given as to how the four measurements may be used over a period of time to give a precise reading of fertility for an individual user, and there is no experimental data provided demonstrating the use of the system across any menstrual cycle.
- 43 Nevertheless, the description is not without some indication of what “low” or “high” levels look like. Page 16 indicates that a period of “low fertility” can be indicated by PdG concentration falling by 6ng/ml in the luteal phase, although it does not indicate the upper or lower levels prior to this fall, or when in the luteal phase that this fall should be measured. There is also no indication of what the levels of the other three analytes should be when determining this period of “low fertility”, or what the user should expect to see when reading the device of the invention.
- 44 Consequently, I see no disclosure in the specification of the measurement of each of the four analytes E3G, LH, PdG and FSH, and how the combination of these can be used to determine “fertility level”, which includes fertility window, follicular health, ovarian reserves, corpus luteum integrity and egg quality of an individual. I acknowledge that the skilled person would be aware of how these hormones are known to vary across the female menstrual cycle, and what normal levels would look like in general. However, the claim requires that the device monitors changes in the concentration of the four analytes across at least part of the menstrual cycle, and compares this to concentration values obtained at different times, and that the “fertility level” is then determined based on these changes. However, there is no

disclosure of how the user can monitor changes in their own E3G, LH, PdG and FSH levels and determine whether the outcome of this monitoring is informing them of their fertility window, follicular health, ovarian reserves, corpus luteum integrity, or their egg quality, and how they would distinguish between each condition. Even if the user were to take into account the generic changes in hormonal levels documented in the prior art, there is nothing that would indicate how their own, personal changes in the concentration of E3G, LH, PdG and FSH should correlate with the known, generic changes in order to arrive at the method of determining “fertility level”, and distinguishing between the conditions associated with it, as required by the invention.

- 45 As such, the specification as filed does not contain enough information for the skilled person to work the invention without undue burden, and there is no indication that even if they could, they would know they had done so successfully. Claim 1 is classically insufficient. Claim 13 is also deemed to be classically insufficient for the same reasons as claim 1.

### **Inventive step**

- 46 The examiner has raised further objections to the claims under inventive step, and, as part of the objections, established the difference between claim 1 and the prior art being the use of four analytes to determine a fertility level rather than three. Given I have already found the independent claims to be insufficiently disclosed, I do not consider it reasonable or proportionate to make a detailed analysis of the inventive step of the independent claims.
- 47 However, if I am wrong in my determination of insufficiency, then the claims would necessarily lack an inventive step. In order to work the invention, the skilled person would need to rely heavily upon their common general knowledge in the field of fertility in order to monitor the different levels of E3G, LH, PdG and FSH at various time points in an individual’s menstrual cycle, and correlate those with the various conditions of “fertility level” claimed in the application. This determination of the levels of all four of E3G, LH, PdG and FSH across a period of time within the menstrual cycle is what the applicant has argued distinguishes the invention from the prior art cited by the examiner. In their letter of 8 December 2025, and at the hearing, the applicant acknowledged that it was known in the art to look at a combination of hormones across time points, but argued that none of the cited documents combines all four hormones. The inventor further commented that the measurement of FSH in combination with E3G, LH and PdG was able to improve confidence in the method.
- 48 However, as I note above in my discussion under sufficiency, there is nothing in the specification that demonstrates the measurement of FSH in combination with each of E3G, LH and PdG in the determination of “fertility level”, or any of the conditions associated with it. Where FSH is measured in combination with other hormones, the concentrations referenced are vague and described as no more than “high” or “low”, and these increases or decreases in FSH (and the corresponding increases or decreases in E3G, LH and PdG concentration) are well known in the art (as depicted in the figure above). There are no worked examples in the specification that indicates an improved confidence in existing methods by the addition of the measurement of FSH. There are also no examples demonstrating that the specific selection of FSH in combination with E3G, LH and PdG provides an improvement over the prior art by enabling the determination of “fertility level” by indicating the

fertility window, follicular health, ovarian reserves, corpus luteum integrity, or egg quality. This lack of a demonstration of the improvements to the known assays indicates that measurement of FSH is no more than an arbitrary addition to assays already measuring any of the remaining hormones.

- 49 Therefore, whilst I have not fully assessed the inventive step of the specification, it *prima facie* would appear to be obvious to the skilled person, as the lack of any worked examples demonstrating an improved assay over the prior art would indicate that the measurement of four hormones, whose fluctuations during the menstrual cycle and role in the fertility of an individual are well characterised, would appear to be no more than an arbitrary combination.

### **Conclusion**

- 50 I have concluded that the claims are not clear as required by section 14(5)(b) and are not supported, as required by section 14(5)(c). The invention is also insufficiently disclosed as required by section 14(3), and would also appear to lack inventive step, as required by section 1(1)(b). The application is therefore refused under section 18(3).

### **Appeal**

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

**Dr ROWENA DINHAM**

Patent Examination Group Head