

OPINION UNDER SECTION 74A

Patent	GB 2423721 B
Proprietor(s)	F T Tehrani
Exclusive Licensee	
Requester	F T Tehrani
Observer(s)	
Date Opinion issued	06 June 2018

The Request

1. The comptroller has been requested to issue an opinion as to whether the Intellivent-ASV¹ system (the product) identified in the request would infringe GB 2423721 (the patent). The patent was originally published as WO 2005/051280.
2. No observations have been filed in relation to this request.
3. The Patent was granted on 14 October 2008 and remains in force.

The Patent

4. The patent relates to a system for controlling a ventilator, i.e. an artificial respirator for a patient. It seeks to provide an improvement on prior art open-loop control ventilators which required considerable skill and monitoring to provide effective treatment, especially of less medically stable patients. The invention provides a closed-loop feedback control system whereby the ventilator is controlled based on the measured levels of oxygen of the patient. In particular, the concentration of oxygen in the air provided to the patient and the pressure at the end of the expiration phase are controlled with the aim of achieving a target patient oxygen level. Measurements of other physical conditions of the patient, such as CO₂ level and lung function parameters, may additionally be included. Similarly, additional control of the ventilator to cover breathing frequency, tidal volume, etc., may be provided. Whilst the patent provides a detailed description of the closed-loop control regime, the claims define the invention more straightforwardly.
5. Figure 1 of the patent (reproduced below) provides an overview of the system. I note

¹ Intellivent and ASV are registered trademarks of Hamilton Medical AG

that the figure illustrates a digital processor (10) for analysing the inputs and computing the required outputs, and separately albeit linked, a signal generator circuit (46) for generating the signals (48) necessary to control the ventilator (56). Amongst the inputs to the digital processor is a signal from a patient oxygen sensor (30). The signal generator circuit is linked to an oxygen air mixer (62) for supplying the required concentration of oxygen to the patient.

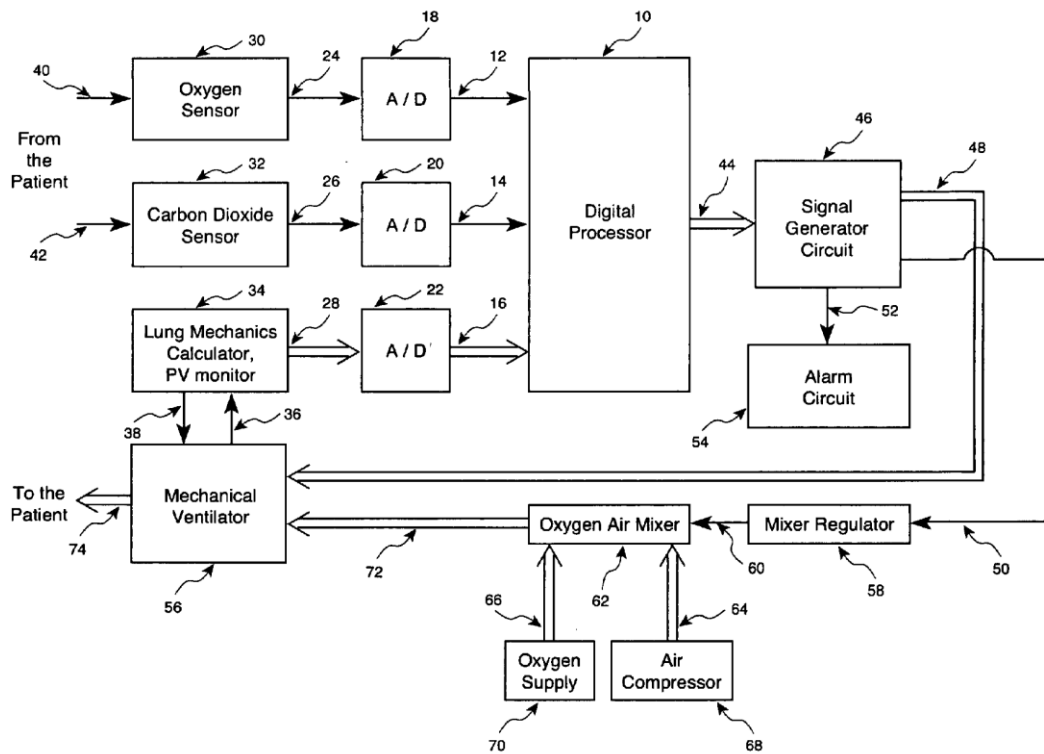


Figure 1

6. The patent provides the following definitions for certain terms:

Ventilator – a device which is used to provide total or assist ventilator treatment to patients, and includes mechanical ventilators (i.e. artificial respirators).

PEEP – Positive end-expiratory pressure

F_iO_2 – Concentration of oxygen in a patient's inspiratory gas (fraction of inspired oxygen). F_iO_2 for atmospheric air is 0.21 (i.e. 21% oxygen)

I:E – ratio of inspiration time to expiration time

7. One further important term which is used is SpO_2 to refer to the blood oxygen saturation percentage. It is a measurement of how much oxygen the red blood cells in the arteries of a person are carrying relative to the maximum amount they can carry. Typical levels in a healthy person are 95-99%.

Claims

8. There are three independent claims (1, 29 and 45) all directed to automatically controlling a ventilator.
9. Claim 1 reads as follows (adopting the formatting used in the request). I note that the primary input to the control system is an indication of the measured oxygen level of the patient (SpO_2). This is used to control the F_iO_2 level and PEEP value. I also note that the claim refers to first means and second means operatively coupled to the first means.

1. *An apparatus for automatically controlling a ventilator comprising:*

first means for processing data indicative of at least a measured oxygen level of a patient,

and for providing output data indicative of required concentration of oxygen in inspiration gas of the patient (F_iO_2) and positive end-expiratory pressure (PEEP) for a next breath of a patient,

wherein F_iO_2 is determined to reduce the difference between the measured oxygen level of the patient and a desired value;

wherein PEEP is determined to keep a ratio of PEEP/ F_iO_2 within a prescribed range and while keeping the ratio within the prescribed range, to keep the measured oxygen level of the patient above a predefined value; and

second means, operatively coupled to the first means, for providing control signals, based on the output data provided by the first means, to the ventilator

wherein the control signals provided to the ventilator automatically control PEEP, and F_iO_2 , for a next breath of the patient.

10. Claim 29 is set out below. It is largely equivalent to the apparatus of claim 1 save that it refers specifically to a programmable controller storing executable instructions rather than a first means.

29. *An apparatus for automatically controlling a ventilator comprising:*

- (a) *means for providing a data signal indicative of the measured oxygen level of a patient;*

- (b) *a programmable controller storing executable instructions that when executed perform the steps of determining;*

- (i) *required concentration of oxygen in an inspiratory gas of the patient, F_iO_2 , based on the data signal indicative of the*

measured level of the patient and to reduce the difference between the measured oxygen level of the patient and a desired value;

(ii) required positive end-expiratory pressure, PEEP wherein a ratio of PEEP/ F_iO_2 is maintained within a prescribed range, and to keep the measured oxygen level of the patient above a predefined value; and

(c) means for providing data signals indicative of the required F_iO_2 and the required PEEP based upon the determining of step (b), for automatically controlling F_iO_2 and PEEP for a next breath of the patient.

11. Finally claim 45 is set out below. It is more complex than the apparatus of claims 1 and 29 in that the carbon dioxide level of the patient, the respiratory elastance and airway resistance are also measured. Furthermore, breathing frequency, ventilation, and inspiration to expiration time ratio are also controlled.

45. An apparatus for automatically controlling a ventilator comprising:

(a) means for providing data indicative of the measured oxygen level of the patient;

(b) means for providing data indicative of the measured carbon dioxide level of the patient;

(c) means for providing data indicative of respiratory elastance, and respiratory airway resistance of the patient;

(d) a programmable controller storing executable instructions that when executed perform the steps of:

I) determining from the data indicative of the measured oxygen level of the patient provided by (a), a required concentration of oxygen in an inspiratory gas of the patient, F_iO_2 , to reduce a difference between the measured oxygen level of the patient and a desired value, and providing a data signal indicative of the required F_iO_2 ;

II) determining a required positive end-expiratory pressure, PEEP, and providing a data signal indicative of the required PEEP, wherein the required PEEP maintains a ratio of PEEP/ F_iO_2 within the prescribed range, to keep the measured oxygen level of the patient above a predefined value;

III) determining, based upon the data provided by (a), (b) and

(c), an optimal breathing frequency, a required ventilation, and a required adjustment in inspiration to expiration time ratio, I:E, for a next breath of the patient, and providing data signals indicative of the same; and,

- (e) means for providing to the ventilator, based upon the data signals provided by (I), (II) and (III), final data signals for automatically controlling: (i) the required F_iO_2 , (ii) the required PEEP, (iii) optimal breathing frequency, (iv) the required ventilation, (v) the required adjustment in I:E ratio, for a next breath of the patient.*

The product

12. The product identified in the request is the Intellivent-ASV system marketed by Hamilton Medical. The evidence provided by the requester comprises an operator's manual for the Hamilton-S1 ventilator titled "Hamilton-S1 Intelligent Ventilation. Operator's manual 624302/02. Software version 2.1X" (the S1 manual). The S1 manual is an extensive description of the features and use of the ventilator running to 600 pages. The S1 ventilator is capable of operating in a number of different modes, one of which is an automatic mode identified as Intellivent or Intellivent-ASV.
13. The introduction to the S1 manual outlines the functionality of the S1 ventilator and includes the following description regarding automatic control:

Fully closed loop control. This device works on the principle known as: "fully closed loop control". The device is intended only for adult and pediatric patients. With the Hamilton-S1 this feature is referred to as "Intellivent".

The physiological inputs come from the patient side. The physician establishes targets and a strategy that are matched with the patient inputs, or where the Intellivent feature has automatically established. Then the ventilator automatically adjusts the ventilator settings (output) to get the patient within the target ranges. This automatic input and output continues, each influencing the other, resulting in a "closed loop" system.

This feature is an improvement on older conventional devices that needed frequent manual intervention to maintain satisfactory ventilation. With this device, when you enter specific patient conditions (with Intellivent) the device uses the data received from sensors (CO_2 , flow and SpO_2) to make suitable automatic adjustments.

In closed loop ventilation, information from the patient is collected and analysed by the device in a continuous manner adjusts the ventilator without frequent human intervention.

The device incorporates three main closed-loop control inputs:

*Automatic minute volume
PEEP
Automatic oxygen adjustment*

14. Appendix D of the S1 manual describes in more detail the Intellivent-ASV system. References to oxygen are to the percentage of oxygen in the air delivered to the patient, i.e. F_iO_2 . Paragraph D.1.2 (page D-4) describes the control of oxygenation as follows:

D.1.2 Oxygenation

The PEEP/Oxygen management operates in two modes, automatic and manual. The automatic PEEP/Oxygen management sets the Oxygen and PEEP values according to the

- *Measured O_2 saturation (SpO_2), hemodynamic state of the patient, and various patient conditions (see Section D.3.5.1)*
- *The patient's conditions and the applied PEEP determine the expected SpO_2 range for the patient.*
- *The optimal relationship between PEEP and Oxygen – used during automatic PEEP/Oxygen management – is based on the ARDSnet guidance when increasing the therapy and the OPEN lung concept when decreasing the treatment (see Section D.13).*

15. Paragraph D.6.1 (page D-65) provides more details of the control of PEEP/ F_iO_2 (my emphasis).

D.6.1 Management of PEEP/ F_iO_2 for passive and active patients

Using the SpO_2 signal, retrieved from the pulse oxymeter, the difference between the actual and the target SpO_2 value is calculated. This calculation, together with the HLI [heart lung index] value and the operator's input, is used to determine the treatment action.

The PEEP/Oxygen automatic management consists of two steps. They are:

- *The operators input and the actual treatment (PEEP) define the SpO_2 target range. **The SpO_2 signal and the SpO_2 target range are used to define the treatment action (increase, decrease, no change of treatment).***
- ***The system decides, depending on the actual combination of PEEP and oxygen on the PEEP/oxygen curve, if PEEP, oxygen or both (when the currently used PEEP/oxygen combination lies already on the PEEP/Oxygen curve) are increased.** The relationship between PEEP and oxygen is based on the ARDSNet guidance for increasing therapy (Figure D-30, target path bold) and the open lung concept for decreasing therapy (Figure D-31, target path bold.)*

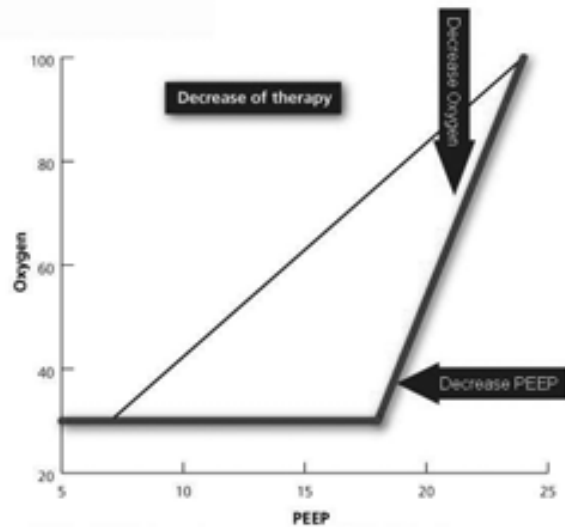
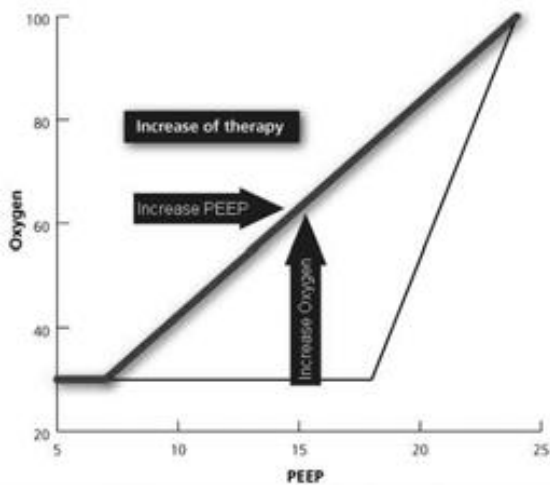


Fig. D-30 – PEEP/oxygen increasing therapy Fig. D-31 – PEEP/oxygen decreasing therapy

16. It can be seen from these paragraphs that the Intellivent system works in generally the same way as the system of the invention. Patient oxygen levels (SpO_2) are measured and the oxygen concentration (F_iO_2) and PEEP are controlled so that the patient's oxygen level approaches a target level whilst also maintaining a desired PEEP/oxygen value.
17. It is however necessary to look in further detail at how the Intellivent system controls F_iO_2 and PEEP.
18. The passage quoted above identifies that the control of F_iO_2 and PEEP differs depending on the actual combination of PEEP and oxygen on the PEEP/oxygen curve. Furthermore there are two different curves used dependant on whether oxygenation treatment is increasing or decreasing and the need for increasing or decreasing treatment is determined by whether SpO_2 is above or below target. Although referred to as curves, the PEEP/oxygen curves are straight lines which represent a ratio of PEEP/oxygen and are equivalent to a ratio of PEEP/ F_iO_2 .
19. Page D-67 describes what happens in the case that the patient's SpO_2 is above target. Oxygen treatment is decreased and the *open lung* PEEP/oxygen curve (figure D-31) is used. If the current value of PEEP and oxygen lies above the curve then oxygen level is reduced until it meets the curve, i.e. F_iO_2 is automatically reduced until the correct ratio of PEEP/oxygen is established. If the current value of PEEP and oxygen is already on the curve, i.e. the correct ratio, then both oxygen and PEEP are automatically reduced. If the current value is above the curve then only PEEP is automatically reduced until the value intercepts the curve.
20. Page D-69 describes the control regime when patient's SpO_2 is below target and oxygenation needs to be increased based on the ARDSnet PEEP/oxygen curve (figure D-30). If the value of PEEP and oxygen is above the curve, then PEEP is increased until the correct ratio of PEEP/oxygen is established. On the curve both PEEP and oxygen are increased, and below the curve only oxygen is increased.

21. Of particular note is that in both cases if the PEEP/oxygen ratio is correct, i.e. PEEP and oxygen on the curve, then both PEEP and oxygen are automatically adjusted.

Infringement

22. Section 60 of the Act states:

(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say-

(a) Where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(b) Where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent

(c) Where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

23. As the claims relate to apparatus only Section 60(1)(a) is relevant.

24. In the Supreme Court in *Actavis v Eli Lilly*² Lord Neuberger stated that the problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, i.e. the person skilled in the relevant art. Those issues are:

(i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not,

(ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

25. If the answer to either issue is “yes”, there is infringement; otherwise there is not.

Does the product infringe as a matter of normal interpretation?

26. I shall start by considering whether the product infringes the patent as a matter of normal interpretation. This means interpreting the claims in the light of the description and drawings as instructed by Section 125(1). In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using

² *Actavis UK Limited and others v Eli Lilly and Company* [2017] UKSC 48

the language of the claims to mean. This approach has been confirmed in the recent decisions of the High Court in *Mylan v Yeda*³ and the Court of Appeal in *Actavis v ICOS*⁴.

27. I have not been provided with any argument about how the claims should be construed. Save for a possible issue with how *determined/determining* is construed, which I consider further below, there do not appear to be any significant issues and I consider that the independent claims may be largely construed as read.
28. The requester has provided claim comparison charts identifying which features of the Intellivent system correspond to the requirements of the claims.
29. Claim 1 essentially requires a first means *suitable for* processing the input data and calculating output data, and second means, operatively coupled to the first means, *suitable for* generating control signals based on the output data.
30. I consider that such an arrangement is illustrated in Figure D-2 illustrating the Intellivent concept in clinical use and reproduced below. In the lower third of the figure a monitoring input in the form of SpO₂ is shown feeding into an *Oxygenation controller*. Data output from the *Oxygenation controller* is then shown feeding into the PEEP and F_iO₂ of the *ventilator output settings* module which are connected to the *ventilation execution* section. The *Oxygenation controller* is considered to be a first means suitable for processing input data and providing output data, and the *ventilator output settings* module is considered to be second means which provide the control signals for ventilation execution.

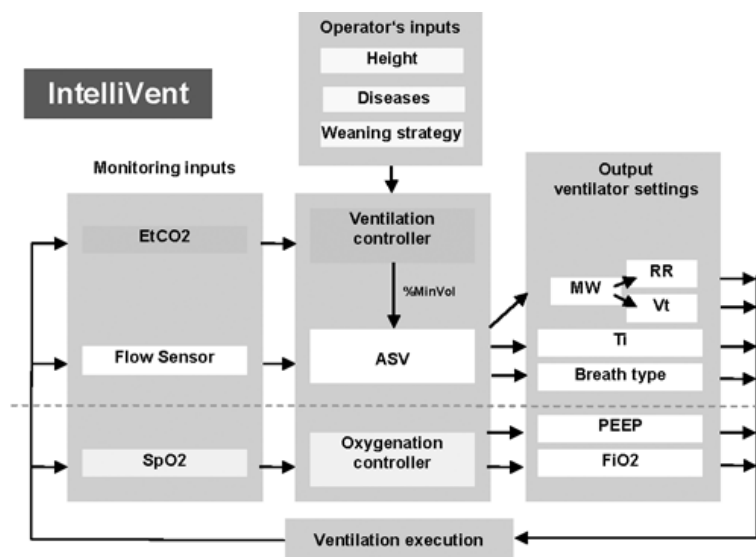


Figure D-2. Intellivent Concept in Clinical Use

31. For the purposes of this opinion, the crux of the infringement issue seems to be whether or not the Intellivent system provides that “F_iO₂ is determined to reduce the difference between the measured oxygen level of the patient and a desired value”

³ *Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor* [2017] EWHC 2629 (Pat)

⁴ *Actavis Group & Ors v ICOS Corp & Eli Lilly & Co.* [2017] EWCA Civ 1671

and “*PEEP is determined to keep a ratio of PEEP/F_iO₂ within a prescribed range and, while keeping the ratio within the prescribed range, to keep the measured oxygen level of the patient above a predefined value*” as required by claim 1.

32. As a preliminary matter I note that *the measured oxygen level of the patient* is referred to twice in different terms. Firstly the difference between it and a desired oxygen level is to be reduced and secondly it is to be kept above a predefined value. Inevitably the desired value will be above a minimum critical value such that the second requirement will be met if the first is met. Additionally, it must be an inherent function of any ventilator to keep the patient’s oxygen level above a minimum critical level.
33. More significantly, I note that the requirement in claim 1 is that a level for F_iO₂ is *determined*. Whilst *determined* could be interpreted narrowly, e.g. *calculated*, I do not consider a narrow construction is appropriate in this instance. In particular, the patent describes two different control regimes which are both considered to be covered by the claim. Firstly, there is a rapid stepwise control scheme (¶¶ [0043], [0044], [0045], [0051]) which sets a slightly high, moderately high or high level of F_iO₂ based on how far SpO₂ falls below a threshold value. Secondly, a proportional, integral, derivative (PID) control procedure (¶¶ [0045], [0051]) is implemented for fine-tuning calculation of F_iO₂ based on SpO₂ when SpO₂ is in a more normal range. In the rapid stepwise control scheme, changes in SpO₂ do not necessarily result in changes in F_iO₂, i.e. there is no direct relationship between F_iO₂ and SpO₂. The system may *determine* that F_iO₂ is not changed. I consider that the skilled person would understand *determined* should be construed broadly in order to encompass the different schemes described in the patent.
34. Similarly, claim 1 requires that PEEP is *determined*, and this should also be interpreted broadly.
35. As discussed in paragraphs 19 to 21 above, the Intellivent system comprises a number of different control regimes (pp. D-65 to D-69). In situations where the PEEP/oxygen ratio (\equiv PEEP/F_iO₂ ratio) is already at the correct value (i.e. where current F_iO₂ vs PEEP is on the *curve*), then both F_iO₂ and PEEP are adjusted to reduce the difference between the measured SpO₂ and the target SpO₂ whilst maintaining the correct PEEP/ F_iO₂ ratio. In these situations the Intellivent system *calculates* values for F_iO₂ and PEEP such that I consider it falls within the scope of claim 1, even on a narrow interpretation of *determined*.
36. In situations when the PEEP/oxygen ratio is not correct, then, depending on the particular circumstances, one only of F_iO₂ or PEEP is adjusted until the correct ratio is reached. The Intellivent system does not therefore necessarily alter the value of F_iO₂. However the overall goal of decreasing the difference between measured and target SpO₂ remains. In circumstances where F_iO₂ is not changed I nevertheless consider that the Intellivent system *determines* F_iO₂ as required by claim 1. In these situations the system *fixes* F_iO₂ and *calculates* a corresponding value of PEEP to keep the ratio of PEEP/F_iO₂ within a prescribed range. The PEEP setting is then

adjusted stepwise to that value. Once the correct ratio of PEEP/F_iO₂ is achieved then control proceeds as above. Such a control regime is considered to meet the requirements of claim 1 based on a relatively broad construction of determined.

37. Having established that the Intellivent-ASV system has a control scheme which meets the requirements of claim 1, I further consider that it meets all the requirements of claim 1 as set out in the claim chart below which is in general agreement with that provided by the requester.

<p>An apparatus for automatically controlling a ventilator comprising:</p>	<p>Page D-3: <i>“Intellivent-ASV offers the operator fully automatic management of ventilation and oxygenation...”</i></p>
<p>first means for processing data indicative of at least a measured oxygen level of a patient, and for providing output data indicative of required concentration of oxygen in inspiratory gas of the patient (F_iO₂) and positive end-expiratory pressure (PEEP) for a next breath of the patient;</p>	<p>Figure D-2 (reproduced above) shows an “Oxygenation Controller” which receives data relating to SpO₂ and outputs data relating to PEEP and F_iO₂.</p>
<p>wherein F_iO₂ is determined to reduce the difference between the measured oxygen level of the patient and a desired value</p>	<p>Section D.6.1 (reproduced above) states <i>“using the SpO₂ signal ... the difference between the actual and the target SpO₂ is calculated...The SpO₂ signal and the SpO₂ target range are used to define the treatment action (increase, decrease, no change of treatment)...The Hamilton-S1 adjusts PEEP/Oxygen and as a result the oxygenation of the patient is affected.”</i></p>
<p>wherein PEEP is determined to keep a ratio of PEEP/F_iO₂ within a prescribed range and, while keeping the ratio within the prescribed range, to keep the measured oxygen level of the patient above a predefined value; and</p>	<p>The example shown on page D-67 shows SpO₂ that is too high and indicates automatic decrease of oxygenation. The example on page D-69 shows SpO₂ too low and indicates automatic increase of oxygenation.</p> <p>When F_iO₂ and PEEP are the correct ratio then both are increased or decreased as appropriate and the ratio is maintained.</p> <p>It is inherent that the oxygen level of the patient is maintained above a critical value.</p>

second means, operatively coupled to the first means for providing control signals, based on the output data provided by the first means, to the ventilator;	As outlined above, Figure D-2 shows "Output ventilator settings" which provides control signals for "ventilator execution" based on the determined values for PEEP and F _i O ₂ .
wherein the control signals provided to the ventilator automatically control PEEP, and F _i O ₂ for a next breath of the patient.	Paragraph D.6.1: " <i>The Hamilton-S1 adjusts PEEP/Oxygen and as a result the oxygenation of the patient is affected.</i> "

38. Similarly for claim 29

An apparatus for automatically controlling a ventilator comprising:	Page D-3: " <i>Intellivent-ASV offers the operator fully automatic management of ventilation and oxygenation...</i> "
(a) means for providing a data signal indicative of the measured oxygen level of a patient;	Page 1-2 states that " <i>the device uses the data received from sensors (CO₂, flow and SpO₂) to make suitable automatic adjustments.</i> " On page 1-6 it further identifies " <i>measurement of arterial O₂ saturation (SpO₂) by one or two pulse oxymeters</i> ".
(b) a programmable controller storing executable instructions that when executed perform the steps of determining;	Page 1-10: " <i>The device's microprocessor system controls gas delivery and monitor the patient.</i> "
(i) required concentration of oxygen in an inspiratory gas of the patient, F _i O ₂ , based on the data signal indicative of the measured level of the patient and to reduce the difference between the measured oxygen level of the patient and a desired value;	Similarly to claim 1, section D.6.1 states " <i>using the SpO₂ signal ... the difference between the actual and the target SpO₂ is calculated...The SpO₂ signal and the SpO₂ target range are used to define the treatment action (increase, decrease, no change of treatment)...The Hamilton-S1 adjusts PEEP/Oxygen and as a result the oxygenation of the patient is affected.</i> "
(ii) required positive end-expiratory pressure, PEEP wherein a ratio of PEEP/ F _i O ₂ is maintained within a prescribed range, and to keep the measured oxygen level of the patient above a predefined	The example shown on page D-67 shows SpO ₂ that is too high and indicates automatic decrease of oxygenation. The example on page D-

<p>value; and</p>	<p>69 shows SpO₂ too low and indicates automatic increase of oxygenation.</p> <p>When FiO₂ and PEEP are the correct ratio then both are increased or decreased as appropriate and the ratio is maintained.</p> <p>It is inherent that the oxygen level of the patient is maintained above a critical value.</p>
<p>(c) means for providing data signals indicative of the required F_iO₂ and the required PEEP based upon the determining of step (b), for automatically controlling F_iO₂ and PEEP for a next breath of the patient.</p>	<p>Figure D-2 shows “Output ventilator settings” which provides control signals for “ventilator execution” based on the determined values for PEEP and F_iO₂. Paragraph D.6.1 specifies that “<i>The Hamilton-S1 adjusts PEEP/Oxygen and as a result the oxygenation of the patient is affected.</i>”</p>

39. Claim 45 requires additional input data and configuration of additional ventilator control settings based on the additional input data to those required by claims 1 and 29. The additional input data comprises patient CO₂ level, respiratory elastance and respiratory airway resistance. The additional ventilator control comprises settings for breathing frequency, required ventilation and I:E ratio.
40. Figure D-2 (see above), illustrating the Intellivent concept of the S1 ventilator, indicates that control of respiratory rate (RR), tidal volume (V_t) and inspiration time (T_i) is available. Control based on respiratory rate and inspiration time is directly equivalent to control based on breathing frequency and I:E ratio. Figure D-2 also indicates that patient CO₂ levels are monitored (EtCO₂ – End-tidal CO₂). However, a flow sensor is shown rather than sensors for determining respiratory elastance and respiratory airway resistance.
41. The requester suggests that references to such parameters as R_{insp} (inspiratory airway resistance), R_{exp} (expiratory airway resistance) and C_{stat} (static respiratory compliance) elsewhere in the S1 ventilator manual are equivalent to the respiratory elastance and airway resistance measurements required by claim 45. Whilst it may be the case that these parameters are equivalent to those identified in claim 45, I do not consider that these parameters are used by the Intellivent-ASV system (being the particular aspect of the S1 ventilator of interest). For example, the requester refers to table A-11 of the S1 manual. However, this table lists configurable parameters and there is no link to the Intellivent-ASV control system. Similarly, the references to R_{insp}, R_{exp} and C_{stat} in tables 7-1 and A-8 do no more than indicate that these are parameters which are monitored and may be displayed by appropriate configuration of the display.
42. Section D.1.1 of the S1 manual indicates that ventilator control in the Intellivent-ASV

mode is based on “The difference between targeted and actual respiratory rate, if the patient is active and EtCO₂ is on or below the target range.” Further details are given in Section D.5. I do not consider that the respiratory rate is equivalent to the respiratory elastance and respiratory airway resistance values. There would be a wide range of these values for any particular respiratory rate.

43. I do not therefore consider that the Intellivent-ASV system uses any of the Rinsp, Rexp and Cstat parameters to control the ventilator as required by claim 45. In particular, the Intellivent-ASV system does not use the data indicative of respiratory elastance or respiratory airway resistance to determine breathing frequency, required ventilation or I:E ratio as required by part (III) of claim 45.
44. In relation to the independent claims, I consider that the Intellivent-ASV system falls within the scope of claims 1 and 29, but it does not fall within the scope of claim 45.

Does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

45. Actavis v Eli Lilly established that equivalents may also infringe if they only vary in ways which are immaterial.
46. Although I consider claim 1 infringes as a matter of normal interpretation, in case I am wrong on that issue I will briefly consider equivalents in relation to it. In particular, claim 1 requires a first means for processing and outputting data and a second means for providing control signals. Although the S1 ventilator manual appears to show such separate first and second means, it seems possible that such separate means may nevertheless be implemented by a single integrated device. As such it would arguably not comprise first and second means. However, I consider that providing a single integrated device would be an immaterial variation from the arrangement claimed in claim 1. Accordingly I consider such a variation would also infringe as being an equivalent.
47. In relation to claim 45 I need to consider whether or not the flow rate data provided by the Intellivent-ASV system is an immaterial variation of the respiratory elastance and respiratory airway resistance data required by the claim. No argument has been provided by the requester and I do not believe on the face of it that this is an immaterial variation. Accordingly claim 45 is not infringed on the basis of being an equivalent.

Dependant claims

48. In relation to the dependant claims I shall only consider whether or not they infringe as a matter of normal interpretation in line with the requesters arguments. The requester has provided arguments in relation to claims 2, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 17, 18, 19, 31, 36, 37, 40, 47, 48, 49, 67, 74, 76, 77 and 79.
49. As I have found claim 45 is not infringed I do not need to consider whether or not claims dependant on it (claims 47, 48, 49, 67, 74, 76 and 77) are infringed; they are not infringed as a consequence of their dependency. (Note claim 79 is dependant on

claim 2).

50. Claim 2 requires that the first means comprises a programmable microcomputer. I consider this is established by virtue of the statement in paragraph 1-10 that “The device’s microprocessor system controls gas delivery and monitors the patient.”

51. Claim 4 is as follows:

4. The apparatus of claim 2, further comprising an alarm unit; wherein the first means further determines whether the measured oxygen levels are outside a prescribed range; and wherein the second means further provides an alarm control signal to the alarm unit to warn of the measured oxygen level of the patient being outside a prescribed range.

52. Section D.6.2 of the S1 manual describes what happens when the measured SpO₂ falls below a critical level as follows:

“The safety feature is activated when the physiologic SpO₂ value of the patient falls below the lowest acceptable value triggering the 100% oxygen response and oxygen control is set to automatic. In this case, an alarm message is displayed indicating that the F_IO₂ value was set to 100% (see Table D-1).

53. Table D-1 also indicates alarms corresponding to “SpO₂ to low” and “SpO₂ too high” as well as other problems with the SpO₂ sensors.

54. However, there is no information regarding how these alarms are handled by the component parts of the Intellivent-ASV system and, in particular, there is nothing to suggest an alarm control signal is provided by the second means to the alarm unit. Accordingly I consider there is no infringement of claim 4.

55. Claim 5 is dependant on claim 2 and further requires an analogue to digital converter connected between a patient oxygen sensor and the first means. Claim 6 is dependant on claim 5 and specifies that the patient oxygen sensor should be a pulse oximeter. Appendix G of the S1 ventilator manual deals comprehensively with pulse oximetry. It is clear that the SpO₂ sensors referred to in the S1 manual are pulse oximeters. The presence of an analogue to digital converter would be inevitable, although typically it would be part of the pulse oximeter. Nevertheless, such an arrangement is considered to fall within the scope of claims 5 and 6, and I consider that both these claims are infringed.

56. Claim 7, which is dependant on claim 2, requires “data indicative of the lower inflection pressure (LIP) point on an inspiratory or expiratory pressure volume curve of the patient is provided to the first means.” Claim 8 which is dependant on claim 7 further requires that the LIP data is supplied by a monitor coupled to the first means. Whilst the S1 ventilator may be capable of monitoring this parameter, there is no information to suggest the data is provided to the oxygenation controller (being the first means) of the Intellivent-ASV system. I do not therefore consider that these claims are infringed.

57. Similarly, claims 9 and 10 require data indicative of PEEP_i (intrinsic PEEP) is provided to the first means, but there is no information to suggest such data is provided to the oxygenation controller of the Intellivent-ASV system. I also consider that these claims are not infringed.

58. Claim 11 reads:

11. The apparatus of claim 2, wherein the programmable microcomputer further comprises a program means for determining from the input data:

*the patient's arterial partial pressure of oxygen;
the required F_iO₂;
the required PEEP;
for a next breath of the patient.*

59. In relation to this claim it should be borne in mind that, according to claim 2, the programmable microcomputer is part of the first means. I have already established that figure D-2 shows that the oxygenation controller determines PEEP and F_iO₂. Arterial partial pressure of oxygen is represented by the symbol PaO₂. The requester states that "Fig. G-4 on page G-5 shows how PO₂ [sic] (arterial oxygen pressure) is obtained from SpO₂". However, figure G-4 is a graph showing the oxygen-haemoglobin dissociation curve, which indicates the imprecise correlation between PaO₂ and SpO₂ when SpO₂ is above 94%. More particularly, at the top of page G-5 it states:

For diagnosis ... an index called PaO₂ /F_iO₂ (P/F) ratio is utilized... SpO₂ /F_iO₂ (S/F) ratio is an approximation of the P/F, which in contrast to P/F can be calculated non-invasively and continuously. S/F ratio correlates well with the P/F ratio ...

Therefore S/F ratio is a useful monitoring value ...

60. My interpretation of these statements is that PaO₂ is not required because the S/F ratio can be used instead of the P/F ratio. I do not therefore consider that the S1 ventilator, and more particularly the Intellivent-ASV system determines the patient's arterial partial pressure of oxygen as required by claim 11. The Intellivent-ASV system does not fall within the scope of this claim and it is not infringed.

61. Claim 14 specifies that the first means processes additional data indicative of respiratory elastance, airway resistance, barometric pressure and carbon dioxide levels and provides digital output based on these data indicative of required ventilation, breathing frequency, and I:E ratio. These additional input and output data are the same as those identified in relation to independent claim 45. I previously determined that claim 45 was not infringed because there was no respiratory elastance or airway resistance data used and I find that this claim is also not infringed for the same reasons.

62. Claims 15, 17, 18 and 19 are dependent on claim 14 and I do not therefore need to consider them further. They are also not infringed.

63. Claims 31 and 36 are largely equivalent to claims 5 and 6 save that they are dependant on claim 29 rather than claim 2. I consider that they are infringed for the same reasons.
64. Claim 37 is dependant on claim 36 and requires that “*an arterial partial pressure of oxygen of the patient is derived*”. As I have determined in relation to claim 11 that the S1 ventilator does not derive arterial partial pressure of oxygen (PaO₂), I conclude that claim 37 is also not infringed.
65. Claim 40 requires stepwise control of F_iO₂. Table D-4 (page D-73) indicates that the Intellivent-ASV system may increase or decrease oxygen levels in a stepwise manner such that it falls within the scope of this claim. I therefore consider that this claim is infringed.
66. Finally, claim 79 is as follows:

79. The apparatus of claim 2, further comprising means for manually entering of an initial value of PEEP.

67. In construing this claim it is necessary to remember that claim 1 requires PEEP to be controlled automatically. Thus claim 79 relates only to the situation where an initial value of PEEP is entered manually, and PEEP is thereafter controlled automatically. This claim is not concerned with apparatus in which PEEP is not controlled automatically. However, in their arguments, the requester has identified that Intellivent-ASV PEEP can be set manual or automatic. I do not consider the manual setting to be relevant to this claim. I can find nothing in the S1 ventilator manual to suggest an initial value of PEEP can be manually set when PEEP is being automatically controlled. The table on page D-11 appears to show that the start-up value of PEEP is set at 5 mbar when PEEP is in automatic mode. I do not consider this claim to be infringed.
68. In conclusion, I consider that dependant claims 2, 5, 6, 31, 36 and 40 are also infringed.

Opinion

69. Based on the evidence and arguments provided, I consider that the Intellivent-ASV system as described and illustrated in the S1 ventilator operator’s manual falls within the scope of claims 1, 2, 5, 6, 29, 31, 36 and 40. Accordingly it is my opinion that the offering for sale in the UK, the actual sale in the UK or importation into the UK of ventilators incorporating the Intellivent-ASV system infringes these claims of the patent.

Matthew Jefferson
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.