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ON THE INTELLECTUAL PROPERTY RIGHTS OF ACADEMIC RESEARCHERS: A CASE STUDY

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This paper is a case study of an academic inventor who has tried to defend her patent rights against a major manufacturer of intensive care unit (ICU) ventilators, Hamilton Medical. In late 2019, the patentee started her litigation battle with the manufacturer in a United Kingdom (UK) court that proclaimed to be a low-cost court focused on intellectual property cases. The manufacturer, which has signed hundreds of millions of dollars of contracts in the U.S. and European countries in the past few years due to the COVID pandemic, was marketing its advanced system in Europe but not in the U.S. due to the regulatory problems. Despite this fact, the manufacturer filed an inter partes review of the U.S. counterpart of the UK patent, and the academic inventor had to fight a major legal battle over her patents in two countries simultaneously. This case study highlights the difficulties faced by individual academic researchers who assert their patent rights in a system that is tailored to fit big corporations and wealthy manufacturers.

Key words: Patent rights; Infringement; Academic inventors

INTRODUCTION

The patent system is established to promote innovation and thereby provide the essential means for continuous progress and betterment of the society. A patent gives the legal right to the inventors to exclusively make use of their inventions or to give licenses to others to make such use for a limited period of time. It is widely believed that without patent rights, there might not be sufficient incentives for innovations, especially by individual or academic inventors or those affiliated with small businesses. It is also a known fact that many inventions that have resulted in major technological advances have been made by individual inventors. At present, a large number of patent applications are filed by individual inventors, many of them affiliated with academia in the U.S. and other countries. For continued innovation, it is of paramount importance to assure that the legitimate patent rights of inventors are respected and can be practically enforced.

Despite the significance of the innovations by the individuals, academics, and small businesses that foster economic growth and technological progress, a procedure called inter partes review (IPR) was instituted by the America Invents Act (AIA) and became available for use as of September 16, 2012. IPR is a proceeding before the United States Patent and Trademark Office (USPTO) in which a third party can challenge the validity of at least one claim of an issued patent. The procedure is conducted by the Patent Trial and Appeal Board (PTAB). Whereas patent invalidity requires a jury trial within the district courts, the

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IPR process allows the PTAB to hold a hearing with the respective parties before a panel of administrative judges. Since its inception in 2012, thousands of U.S. patents have been invalidated through IPR proceedings and while the numbers of IPR applications are on the rise, the rate of invalidity decisions of reviewed IPR applications has been reported as high as 84% (1). In numerous IPR procedures, the wealthy manufacturers and corporations, who can afford the high filing costs and litigation attorneys' fees, file against small businesses and individuals who do not have nearly the same resources to fight the litigations. It should be obvious that the corporations filing the IPRs do not have any reason to spend hundreds of thousands of dollars to invalidate patents that are not useful, and these procedures are bound to be against U.S. patents that are useful to industry. In other words, the real victims of IPRs are good patents and innovative inventors and not patents that do not have much practical use, paper patents, or what is known as patent trolls. In fact, the honorable Randall Rader, a former Chief Judge on the Federal Appeals Court, criticized the IPR process and stated that the small number of administrative judges on the PTAB would be "acting as death squads, killing property rights" (2). The "patent death squad" term has since been used frequently as a reference to the PTAB IPRs.

Among European countries, the United Kingdom (UK) is known as the capital of patent invalidity in infringement procedures (3). In the UK, there is a small-scale court known as the Intellectual Property and Enterprise Court (IPEC). The proclaimed purpose of IPEC is to facilitate the assertion of the patent rights of individuals and small businesses by offering a smooth, low-cost, and streamlined litigation procedure. Believing the stated purpose, the author filed a claim at IPEC in November 2019 against a major manufacturer, which later sued her through the IPR procedure in the U.S. What ensued is the subject of this case study as described below.

BACKGROUND

Due to the COVID-19 pandemic, some of the major manufacturers of intensive care unit (ICU) mechanical ventilators have made unprecedented profits in the past two years. One of those manufacturers is Hamilton Medical, which has signed contracts worth hundreds of millions of dollars to provide ventilator equipment to western governments. The flagships of this corporation are its advanced ventilation systems known as Adaptive Support Ventilation (ASV) and its newer system known as INTELLiVENT-ASV.

The author is an independent academic inventor specializing in biomedicine. Based on her research, she has developed a number of inventions in biomedical engineering, and she is the owner of her patents. She developed a technology for automatic control of ventilation in the 1980s. In her closed-loop ventilation system, the tidal volume and the respiratory rate of a patient on mechanical ventilation are automatically adjusted based on the patient's medical requirements. The amount of ventilation is determined based on the patient's blood chemistry, which can be measured non-invasively and the patient's respiratory mechanics data is used to compute the optimum frequency and tidal volume of the patient's breaths to minimize the work rate of respiration. The rationale for this method is to stimulate the patient's breathing by providing a natural breath pattern and thereby to synchronize mechanical ventilation with the patient's spontaneous breathing and expedite the weaning procedure. The author built a prototype of her invention in the late 1980s (4) and obtained a patent in January 1991 (5). Hamilton Medical had to acquire a license on this patent as a result of litigation and has marketed its ASV system under that license since 2004.

Since then, the author developed new and advanced versions of her previous inventions that could be used for automatic control of a patient's ventilation as well as his/her oxygenation and patented the system in the U.S. (US 7,802,571) (the '571 Patent) (6) and several other countries.

Hamilton Medical started marketing an advanced version of ASV with additional features for automatic control of the patient's oxygenation in many countries around 2010. That system is called the INTELLiVENT-ASV. This system is not yet marketed in an active manner in the U.S. due to regulatory issues. This paper describes the infringement litigation battles between the academic inventor and Hamilton Medical in view of the '571 Patent and its UK counterpart in relation to the INTELLiVENT-ASV system.

The '571 Patent

The detrimental effects of lack of oxygen on the brain cells are rapid and quite grave. Between 30 to 180 seconds of oxygen deprivation causes one to lose consciousness; in only one minute, brain cells start to die; at three minutes, permanent brain damage is likely; and in five minutes, death becomes imminent (7). Bearing in mind that mechanically ventilated patients cannot breathe on their own and rely on the ventilator to provide them with sufficient oxygen, it becomes obvious that the determination of oxygenation parameters of the ventilator in mechanical ventilation needs to be robust, and on a breath-by-breath basis, to be effective.

At the priority date of the '571 Patent on November 21, 2003, there was no automatic system for the determination of a patient's oxygenation in a robust and effective manner on a breath-by-breath basis. At that time, manual look-up tables or semi-manual protocol-driven methods based on look-up tables that could only determine oxygenation parameters intermittently (e.g., every few hours) (8) were used for patient's oxygenation in mechanical ventilation. The system of the '571 patent was developed and tested in different hospital settings for several years to prevent death and brain damage due to oxygen deprivation and poor ventilation among ICU patients (9-12). Figure 1 shows the general system of the '571 Patent.

Detailed description of the '571 Patent and its counterparts is not within the scope of this paper. However, some main points about the invention and the patent covering it are provided here. In brief, the '571 Patent describes the invention of the first fully automatic mechanical ventilation system in which

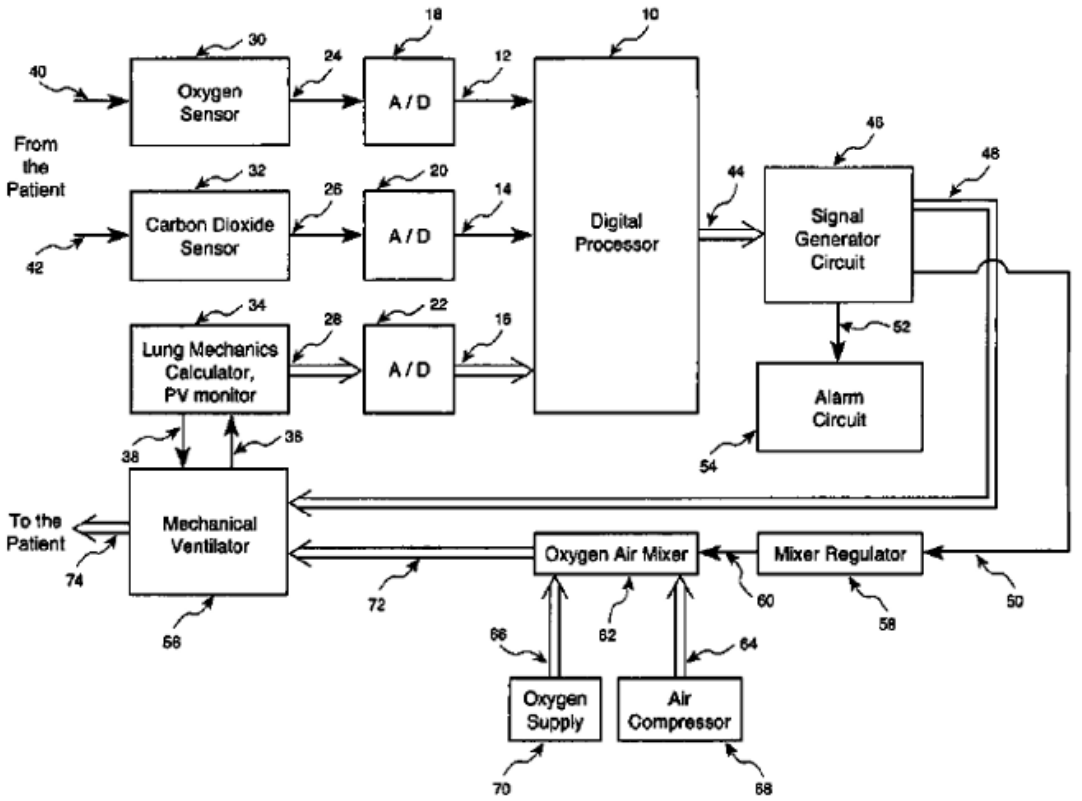

Figure 1. Block diagram of the system in the '571 Patent.

F_{iO2} and PEEP, which are the most important parameters controlling oxygenation, are determined and controlled automatically and for every breath. F_{iO2} is the fraction of the patient's inspired oxygen, and PEEP stands for positive-end-expiratory pressure, which is a pressure applied to the lungs at the end of expiration to keep the alveoli open, prevent lung collapse, and improve gas exchange and oxygenation. Claim 1 of the '571 Patent, covering the basic structure of the invention for automatic breath-by-breath oxygenation, is shown below in Figure 2. This claim is similar to claim 1 of the counterparts of the patent.

In the patented system, F_{iO2} and PEEP are determined for every breath. The claim term "a next breath of the patient" simply means a patient's breath "immediately following in time" or the patient's next breath. None of the ventilator outputs is necessarily changed for every breath, but each one is required to be determined for a next breath. Outputs are determined at a fraction of a second, and changes are made in the parameters through continuous negative feedback algorithms described in the patent. F_{iO2} is determined to reduce the difference between the measured oxygen level of the patient and a set desired value by using interactive stepwise and/or proportional-integral-derivative (PID) negative feedback algorithms for the next breath. PEEP is determined in relation to F_{iO2} and not independent of F_{iO2} to maintain a ratio of PEEP/F_{iO2} within a prescribed range, and while the said ratio is maintained within the range, PEEP is increased if the patient's oxygen level falls below a pre-defined value as recited in the claim. PEEP is not determined independent of F_{iO2} and cannot be controlled by PID. The patent specification advises not to change PEEP unless a minimum time (e.g., four minutes) has passed since the last adjustment in PEEP for patients' safety. The preferred method of oxygen measurement in the patent is by non-invasive pulse oximetry. In its further embodiments, the '571 Patent describes the invention of the first fully

Claim 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 inspiratory gas of the patient (F_{iO2}) and

positive end-expiratory pressure (PEEP) for a next breath of the patient;

wherein F_{iO2} 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_{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

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_{iO2}, for a next breath of the patient.

Figure 2. Claim 1 of the '571 Patent.

automatic mechanical ventilation system, in which all the main outputs of a ventilator for control of oxygenation and ventilation (i.e., F_{iO2}, PEEP, respiration frequency, tidal volume, and the ratio of inspiration to expiration times, or I:E) are determined and controlled in a dynamic system, in relation to each other, affecting each other directly and indirectly, for a next breath of the patient.

Hamilton Medical's Product

Hamilton Medical's product is marketed as INTELLiVENT-ASV, which is an advancement of its ASV system. INTELLiVENT-ASV is the world's first fully automatic ICU ventilation and oxygenation system. In INTELLiVENT-ASV, the system determines tidal volume, breathing frequency, and the I:E automatically, and oxygenation is controlled by automatic determination of PEEP and F_{iO2}. The adjustments of PEEP and F_{iO2} in INTELLiVENT-ASV can be made in seconds (13). The F_{iO2} value is determined to reduce the difference between the patient's measured oxygen level by pulse oximetry and a set target value and is adjusted stepwise in seconds, while PEEP is determined to keep the patient's oxygen level above a minimum value. The relation between PEEP and F_{iO2} is defined by linear curves (14), and it is basic knowledge that on a linear curve, the ratio of two variables is maintained as done in the system of the '571 Patent (6).

THE LITIGATIONS

The UK Case

After Hamilton Medical refused any negotiation in regards to its INTELLiVENT-ASV, the inventor of the '571 Patent (i.e., the author), who is an academic faculty member in the U.S. with modest financial means, had to take legal action against the company in a court known as the Intellectual Property and Enterprise Court (IPEC) in the UK, which as mentioned before, proclaims to be a streamlined, low-cost court designed for small businesses to assert their patent rights. The legal action was initiated in 2019 before the onset of the COVID-19 pandemic. During more than two years of prolonged legal proceedings, Hamilton Medical was given numerous exemptions against the deadlines by the court to submit thousands of pages of filings against the patentee, while the patentee was financially bleeding along the way. The main document focused on by Hamilton in the UK court was a look-up table in a conference presentation (15) for adjustments of oxygenation parameters by trial-and-error in 15-minute to 2-hour intervals. Hamilton Medical claimed that the INTELLiVENT-ASV used the same look-up table for adjustment of PEEP and F_{iO2} to single discrete pairs intermittently. The company further focused on the same look-up table to attack the validity of the UK counterpart of the patent. It should be obvious to anyone with even elementary knowledge on systems control that the manual charts or look-up tables that are basically manual tools for trial-and-error adjustment of parameters intermittently have no place in automatic continuous feedback systems such as the system of the '571 Patent and its counterparts for **breath-by-breath** determination of parameters and can neither be combined with such systems nor describe them. This matter was explained in detail to the court.

The engineering expert of Hamilton Medical in the UK court, Dr. Stephen Edward Rees, who gave testimony at the court, made statements such as *"all closed-loop systems are trial-and-error."* This is despite the fact that continuous feedback control systems cannot function based on trial-and-error. He further testified that *"any system can be run at any timescale,"* which is clearly not true since intermittent systems cannot run continuously and vice versa. However, the basis of his testimony was the definition of a key claim term *"a next breath."* The "claims" in a patent are the legal parts of the patent that are used to provide protection against infringement as well as invalidity challenges to a patentee. It should be clear that if the keywords of any legal document are removed or altered, there can be no legal protection left. In the '571 Patent (6) and its counterparts, the term *"a next breath"* is used to refer to a patient's next breathing cycle. Against the Patent Cooperation Treaty (PCT) conventions, Dr. Rees stated that "*a next breath*" does not mean the same as *"the next breath"* and simply means *"a point in the future"* (16). The UK court completely ignored the PCT conventions and, based on the testimony of someone who was not a patent attorney, decided in its judgment (17) that in the patent claims, *"a next breath"* just means a breath some time in the future "and does not have to be a

patient's next breath (17; paragraph 52). By this baseless definition of a major claim term of the patent, the word "next," which means *"immediately following in time,"* was arbitrarily removed from the claims, and the entire purpose of the patent at issue and its software and hardware details that were designed for a patient's breath-by-breath oxygenation and ventilation became totally meaningless. Still, the court could not justify equating the 60-page patent to a look-up table (15) in the brief non-reviewed conference paper brought in by Hamilton Medical against the patentee. Therefore, in its judgment, the court relied on alleged "evidence" against the patentee that did not exist in the records (17; paragraphs 98-99). The inventor requested the court to revoke its judgment, which was based on alleged evidence that did not exist, but her request was rejected by the court. The UK court even went further against the inventor and, despite the fact that it had found the patent infringed by Hamilton Medical's product in its judgment (17; paragraph 74), it gave an order to make the inventor pay a fine of £50,000.00 to Hamilton Medical, which is the maximum allowable fine in that court.

The U.S. Case

The main documents that Hamilton Medical brought to the courts against the inventor were basically old manual look-up tables for oxygenation. In the U.S. court, the focus was on (a) combining an intermittent look-up table in a conference presentation (18) with a manual chart for adjustment of oxygenation parameters several hours apart (19) and (b) combining the same manual chart in reference 19 with a U.S. patent (20) that presented an unstable positive feedback method against the clinical practice and had been rejected by the patent examiners against the application of the '571 Patent in the past.

The main reference by Hamilton Medical in two scenarios was a manual survey chart in reference 19 for maximum PEEP adjustments at different discrete values of F_{iO2} several hours apart. The inventor explained to the court that there was no ratio of PEEP/F_{iO2} maintained or even mentioned in the reference despite what was alleged by the other side, that a manual chart was not combinable with any of the other proposed references, and that the survey chart was for manual adjustment of parameters several hours apart and not for automatic adjustment of the parameters.

With regard to reference 18, the conference paper presented combining a manual look-up table with PID control, which is a continuous control system. The paper presented **identical** clinical results as presented by Anderson et al. eight years prior (21) by using a manual look-up table only without any PID control, and the presented PEEP results in the paper showed that PEEP was constant for more than ten hours, which was clearly contradictory to PID control of PEEP. The inventor brought all these discrepancies to the attention of the court and further emphasized that a look-up table, which is for intermittent use, could not be combined simultaneously with PID control, that the system of reference 18 was intermittent like any other system based on any look-up table, and also that the system could not be combined with a manual chart in 19. The inventor further emphasized that PID control of PEEP could never be used in the system of the '571 Patent and was against the patented method.

In regard to reference 20, it was explained to the court that (a) the main equations used in that reference to determine PEEP and F_{iO2} were linear functions of the patient's oxygen levels, (b) that such equations would dictate that both PEEP and F_{iO2} would continue to increase unbounded as the patient's oxygen level increased and therefore the system was an unstable positive feedback system against the clinical practice, and (c) that all these matters were discussed in detail with the examiners of the application of the '571 Patent during its prosecution. It was further explained that it was impossible to combine the system of reference 20 with a manual survey chart in reference 19 as was proposed by the other side.

Hamilton Medical's expert in the U.S. court was a biologist who claimed to be a respiratory therapist (RT) despite the fact that he had not renewed his RT certificate for forty years and he had been disqualified as an expert in another case. Based on his testimony, the U.S. court ignored all the evidence and testimony presented by the inventor. The U.S. court concluded in its decision (22) that all the impossible combinations proposed by Hamilton Medical's expert were possible, and a manual survey chart for

adjustment of parameters several hours apart in reference 19 was for automatic control of parameters for a next breath against all evidence (22; pp. 28-29). The U.S. court went even further by ruling that one of the main references of Hamilton Medical, which had been rejected by patent examiners in the past (20) and was admittedly described as a "*fatal*" method, could still be used against the '571 Patent (22; p. 46 footnotes).

DISCUSSION AND CONCLUSION

Critical care is one of the most important areas of medicine that has been revolutionized by numerous technological innovations in the past few decades. Many of the advancements in critical care have been due to the research and dedication of academic scientists, engineers, and clinicians who have tirelessly strived to improve critical care over the years. The '571 Patent (6) and its counterparts are the result of many years of hard work on designing, developing, and testing a fully automatic system for oxygenation and ventilation in ICU settings. This life-saving system was designed to provide safe and robust automatic oxygenation and ventilation to patients who relied on mechanical ventilators and to prevent brain damage and mortalities due to poor ventilation and oxygenation. This system was designed to move away from the ineffective look-up tables and intermittent trial-and-error adjustments of parameters that were available at the priority date of the patent. Hamilton Medical is a major manufacturer of mechanical ventilators that has signed lucrative contracts worth hundreds of millions of dollars with western governments in the past few years during the COVID pandemic. This company has taken advantage of legislation in the U.S. that allows corporations to take legal action against U.S. patentees before administrative judges and away from the U.S. federal courts. For more than two years, it has attacked the '571 Patent (6) and its counterpart in the UK with the aid of many litigation attorneys against the inventor, who is an individual academic patentee. In this battle, Hamilton Medical's documents have been primarily manual charts and look-up tables that do not have any application in the patent at issue and indeed represent the same techniques that the patent is designed to replace and move away from. However, with the help of its paid experts, Hamilton Medical convinced the U.S. court that a manual chart in a survey report is for automatic oxygenation for a next breath, and in the UK court, the court decided to delete the key word "next" from the patent claims altogether and attacked the validity of a patent with 79 claims based on the use of "a" versus "the" in the claim term—a next breath—against PCT conventions. These decisions of the courts show how a corporation can baselessly attack the intellectual property rights of individual researchers and trample on their rights to pave the way for marketing its products. The question is the following: if the same trend, particularly in PTAB IPR proceedings, is continued, is a significant invention a blessing or a curse to its inventor? If the patentee's rights are so easily attacked and violated, are there going to be many more individual academic researchers who have incentives to carry out research work in vital fields of medicine or other impactful areas of research? These are important questions that need to be addressed by all those who care about patent rights and the profound impacts of inventions and innovations on the betterment of society.

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