Patent Law and Global Public Health

Third Edition

Final Examination

Instructions

This is an "open-book" examination. When preparing your answer, you may read or watch any material you wish. However, you may not consult in any way with any other person. Nor may you employ artificial-intelligence tools to write any portion of your answer.

Your answer must constitute original work. Plagiarism is strictly forbidden. Guidelines concerning mandatory attribution of sources and associated citation requirements are available at https://usingsources.fas.harvard.edu/. Any violation of those guidelines will constitute academic misconduct; the exam in question will be rejected and the candidate will be disqualified from the course and from all future editions of the course.

The exam will be distributed at 0900 UTC on Saturday, April 20, 2024. Answers must be submitted by 0900 UTC on Wednesday, April 24. Answers should be submitted, in PDF format, via email, to **pxexams@law.harvard.edu**. You will receive an automated email message confirming receipt of your answer. Any submissions after the deadline on April 20, 2024, will not be considered for grading except in exceptional cases involving either an illness (documented by a medical professional) or a serious extenuating circumstance. The PatentX Advisory Board has complete discretion in determining whether a late submission will be accepted.

When submitting your exam, you must use the following formatting guidelines:

- The subject line of your email must include: PatentX Exam: [Last name], [First name] - Section: [Full Name of Trainer]
    - *For example:* PatentX Exam: Edison, Thomas - Section: Albert Einstein
- Name your exam file as follows: [Last name], [First name] – PatentX Exam
    - *For example:* Edison, Thomas – PatentX Exam
- Include your name and email address at the top of the first page of your submission.

During the examination, all of the course materials (recorded lectures; transcripts, slides, mindmaps; and reading assignments) will remain available at https://ipxcourses.org/patent-law-and-global-public-health/.

Neither the WIPO course team nor your instructors will respond to questions concerning the exam unless those questions involve emergencies. If an emergency does arise, please email harvardpatx@wipo.int, providing details. Someone will respond as soon as possible.

If you find any aspect of the exam's content or instructions to be ambiguous, do not request a clarification. Instead, develop your own interpretation that resolves the ambiguity and make that interpretation explicit in your response.

The exam contains seven questions. You must answer all parts of all of the questions. The word limit for each question and the weight that will be assigned to each of your answers are indicated below.

	Word Limit	Weight
Question 1	200 words	7%
Question 2	200 words	7%
Question 3	400 words	13%
Question 4	400 words	13%
Question 5	300 words	10%
Question 6	500 words	15%
Question 7	1500 words	35%

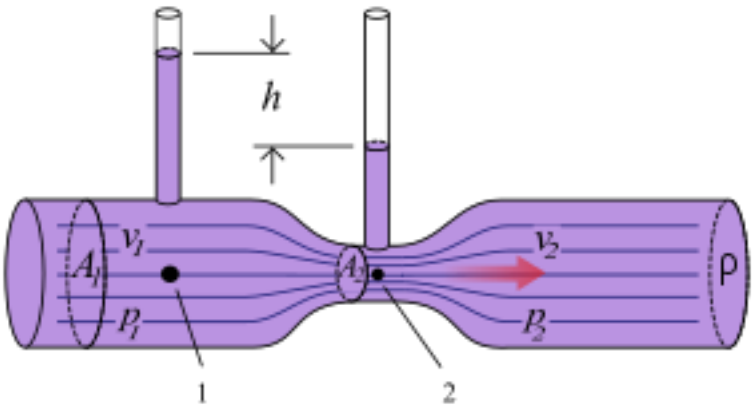
Each student's answers will be graded, using a numerical scale, by a WIPO trainer who did not teach the group in which the student was enrolled. The student's trainer will then have an opportunity to adjust the student's grade (upward but not downward) if, in the trainer's judgment, the quality of the student's participation in seminar discussions manifested greater command of the material than indicated by the exam grade. Answers assigned grades near the borderline between Pass and Fail will be reviewed by Professor Fisher, whose evaluation will be final.

All students who pass the final examination and who actively participated in 10 of the 12 weekly seminars of their groups will receive a certificate from WIPO and Harvard Law School.

A list of the students who passed the examination will be posted on the course website no later than 1200 UTC on May 17, 2024. Certificates will be distributed shortly thereafter.

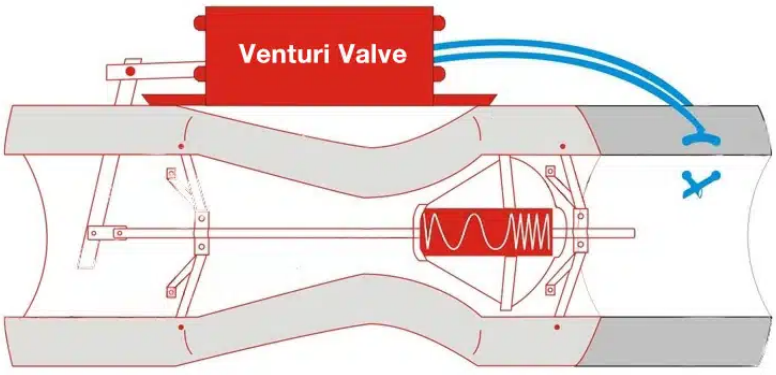
For the purposes of questions 1-4, assume the following facts:

The "Venturi Effect" (named after Giovanni Venturi, an eighteenth-century Italian physicist,) refers to the reduction of pressure that results when a moving fluid or gas accelerates when it passes through a constricted section of a pipe. The following diagram illustrates the effect.



Venturi valves are devices that take advantage of this effect – for example, by using the reduced pressure in the constricted portion of a tube to suck other fluids or gasses into the flow. The following article, published in 2012, describes some of the contexts in which Venturi valves are deployed.

> "Venturi valves are essential components in modern HVAC systems, providing precise airflow control for critical environments such as laboratories, cleanrooms, and healthcare facilities. These valves maintain consistent air pressure and temperature while ensuring energy efficiency and safety….

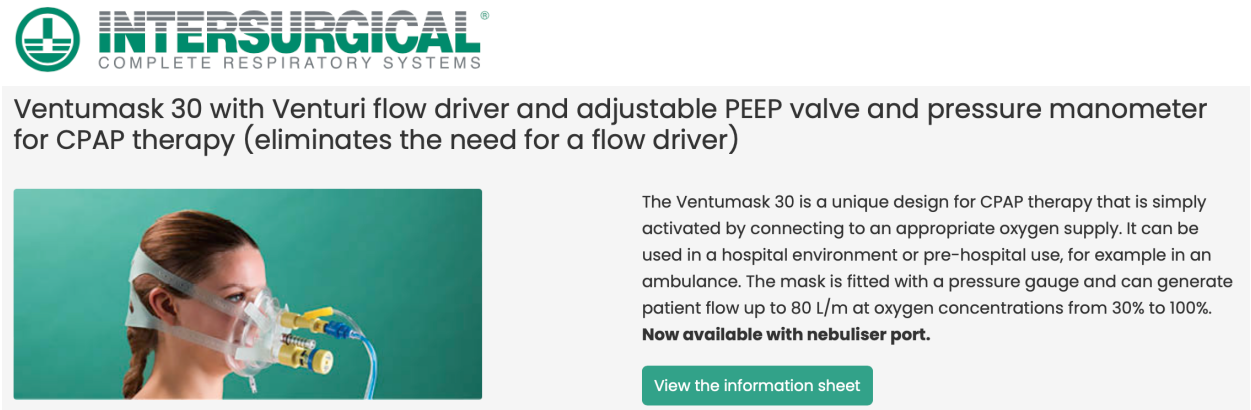


> "Venturi valves operate based on the Venturi effect, a fluid dynamic principle that states that as the velocity of a fluid increases, its pressure decreases. The valve's unique design creates a pressure drop, resulting in a proportional relationship

between the valve's opening and the airflow rate. This allows for precise control of airflow and pressure in critical environments….

"Stainless steel venturi valves (depicted below) are an ideal choice for many industries due to their ability to withstand rust, corrosion, and staining. They are widely used in the food and beverage processing industry, as well as HVAC systems. Stainless steel venturi valves offer a variety of benefits including cost-effectiveness, durability, high-pressure ratings, and low maintenance requirements. These valves are also easy to install and maintain, making them a great choice for any application."

Intersurgical, Inc., based in the United Kingdom, manufactures a variety of medical devices. Most are sold directly to hospitals. In 2014, an employee of Intersurgical invented a valve, which the company then incorporated in a fixed-flow respirator, suitable for use in treating seriously ill patients suffering from respiratory impairments. A photograph of the device, which it called the "Ventumask," appears below. A short video showing how it is used is available at https://youtu.be/BMuGnkinHfw.



On January 1, 2015, Intersurgical filed an application in the European Patent Office, seeking a patent on the valve that is central to the respirator. The relevant portion of the description, the principal drawing, and claim #1 of the application are set forth below.

Description

[0001] The present invention relates to an apparatus for administering oxygen or air with added oxygen, for respiratory therapies.

[0002] As is known, in both hospital and nonhospital environments, respirators are currently employed for emergencies which use apparatuses and/or machines which are designed to deliver adequate flows of air mixed with oxygen to be administered to the patient. With currently available solutions, the apparatus is of the type with fixed installation, since it requires a connection between the air and oxygen sources, and the apparatuses for adjusting the flow and the associated oxygen content.

[0003] Accordingly, such apparatus is scarcely versatile and must be subjected to frequent sterilization operations, since the same apparatus must be used for all patients….

[0006] The aim of the invention is to solve the problems described above by providing an apparatus for administering oxygen or air with added oxygen, for respiratory therapies, which allows to simplify considerably the apparatuses that are currently used ….

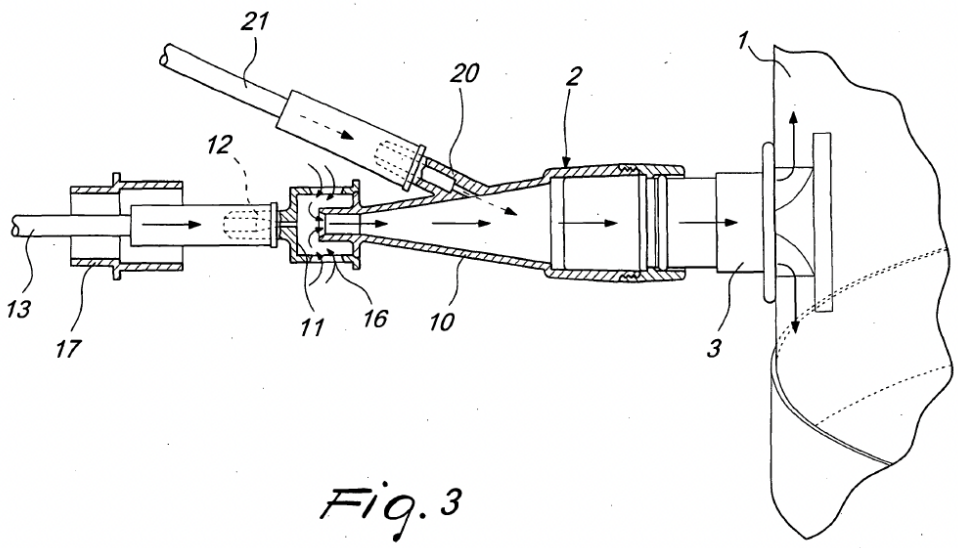


Fig. 3

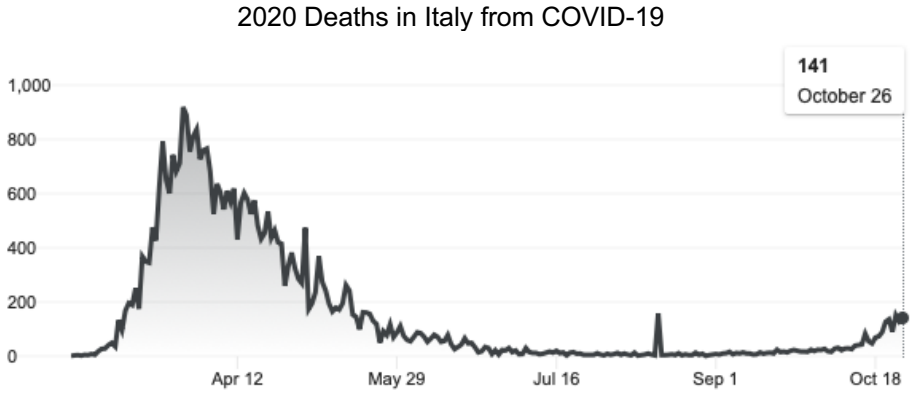
Claims

1. An apparatus for administering oxygen or air with added oxygen, for respiratory therapies, characterized in that it comprises a Venturi meter (2) which is connected to an oxygen source (13), an air intake (16) which can be controlled by a flow control element (17) being provided on said Venturi meter (2), characterized in that said Venturi meter is directly connected to a respirator hood (1)….

On July 1, 2015, Intersurgical filed a PCT application identical to the EPO application, naming a wide variety of PCT member countries, including the United States and China. Between 2017 and 2019, Intersurgical was granted all of the patents for which it had applied.

As of December 2019, the retail price in Italy of the Ventumask was 10,000 Euros. Sales to hospitals were modest.

In March of 2020, the COVID-19 pandemic swept through Italy. As shown by the following chart, the number of deaths rose rapidly.



Doctors in Italian hospitals quickly discovered that the Ventumask was by far the best of the available systems for delivering oxygen to the most seriously ill patients. In response, Intersurgical raised the price of each mask to 20,000 Euros and increased sharply the pace at which it manufactured the valves that are crucial to the operation of the masks. However, the company was unable to keep up with demand. Elderly patients in Italian hospitals that were unable to obtain an adequate number of the devices began dying unnecessarily.

Massimo Temporilli, a professor of engineering at an Italian University, decided to supplement the supply of Intersurgical valves by manufacturing them using 3D printing technology. When Intersurgical refused his request for the CAD ["computer-aided design"] file containing the specification of the valve, Temporilli used a 3D scanner to determine the valve's exact dimensions. He then began using 3D printers in his university laboratory to produce replicas of the valve.

Intersurgical's patents does not specify the kind of material that would be most suitable for constructing the valve, so Temporilli experimented with various substances. After trying 25 candidates, he concluded that "Multijet Fusion PA12" was sufficiently durable – and could withstand repeated the reheating necessary to sterilize valve for multiple uses.

Once he'd settled on the optimal material, Temporilli began producing valves in large numbers – and then distributing them for free to local hospitals. A photograph of a batch of the Temporilli valves appears below.

The hospitals were able to obtain at reasonable prices the other components (all of them unpatented) of the Ventamasks. Quickly, they combined the Temporilli valves with the unpatented components to create replicas of the Ventamasks – and then began using those replicas to treat their most ill patients. The deaths rates in Italian hospitals dropped noticeably.

In April of 2020, the administrators of hospitals in many other countries heard of Temporilli's initiative and began ordering batches of his valves. Temporilli responded by purchasing more 3D printers, hiring some employees, increasing production, and then exporting valves to those hospitals.

In May of 2020, Intersurgical sent Temporilli a cease-and-desist letter. When he did not respond, Intersurgical filed patent infringement suits in three countries: **Germany; the United States; and China**. **You should select one (and only one) of those three countries and answer the following five questions, by applying the law of that country**.

> *[The foregoing narrative is a substantially altered version of a real controversy. If you happen to know or learn about other aspects of that controversy, you should ignore that knowledge when preparing your answers.]*

Question 1: Would Claim 1 of the patent survive a challenge in the jurisdiction you have selected, on the basis of lack of novelty? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 200 words.)

Question 2: Would Claim 1 of the patent survive a challenge in the jurisdiction you have selected, on the basis of non-enablement? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 200 words.)

Question 3: Would Claim 1 of the patent survive a challenge in the jurisdiction you have selected, on the basis of the inventive step requirement? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 400 words.)

Question 4: Would Temporilli escape liability in the jurisdiction you have selected, on the ground that he had not infringed the patent? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 400 words.)

Question 5: If Intersurgical prevailed on all four of the issues discussed above, what remedies would likely be available to Intersurgical in the jurisdiction you have selected? (Your answer may not exceed 300 words.)

* * * * *

Question 6: In the run up to the 13th Ministerial Conference of the World Trade Organization, the TRIPS Council was unable to reach consensus concerning whether the COVID Vaccine Waiver (which had been adopted during the 12th Conference) should be extended to cover COVID-related diagnostics and therapeutics. This issue remains on the Council's agenda.

Should the extension to diagnostics and therapeutics be adopted? Would failure to adopt the extension make a significant difference in the capacity of developing countries to respond to future COVID infections?

Your answer should reflect knowledge of the procedural options already available under other provisions of the TRIPS Agreement for overcoming impediments that patents might pose to ensuring that the residents of low and middle-income countries [LMICs] have access to affordable versions of COVID diagnostics and therapeutics. (Your answer may not exceed 500 words.)

Question 7: The second half of this course examined several strategies that might help alleviate the global health crisis. They include:

1. Improve the procedures in low and middle-income countries [LMICs] for processing applications for marketing authorization;
2. Deploy better systems for detecting and eliminating substandard and falsified medical products [SFMPs];
3. Enable and encourage pharmaceutical firms to employ both international and intra-national differential pricing more often;
4. Facilitate increased use of voluntary licenses;
5. Employ apprenticeship, procurement policies, and limits on clinical trials to increase local production of vaccines and medicines in LMICs;

6. Impose compulsory licenses on the patents pertaining to crucial medical products;
7. Tighten the inventive-step and enablement requirements of patent law in LMICs;
8. Avoid or repeal extensions of the duration of patents on pharmaceutical products;
9. Advise judges in LMICs to minimize the use of injunctions in patent-infringement suits involving pharmaceutical products;
10. Extend the duration of patent protection and/or data-exclusivity protection in upper-income countries [UICs] for (a) vaccines; (b) neglected diseases; and (c) breakthrough drugs of all sorts;
11. Adjust the doctrines of claim construction, equivalents, and remedies in the patent laws of UICs to augment incentives to produce (a) vaccines; (b) neglected diseases; and (c) breakthrough drugs of all sorts;
12. Increase the use of governmental and philanthropic grants to support research and development for vaccines and medicines pertaining to neglected diseases;
13. Impose stricter conditions upon governmental and philanthropic grants of all sorts to increase the availability of their fruits in LMICs;
14. Increase the use of governmental and philanthropic prizes to support research and development for vaccines and medicines pertaining to neglected diseases;
15. Require pharmaceutical firms to achieve each year a social-responsibility index.

Assume that you have been hired by a member of the national legislature of one country in the world. Your employer is considering drafting legislation that would help mitigate the health crisis, both in her own country and in the world at large. She is aware of the 15 options listed above, but is unsure of their relative merits. She asks you to draft a memorandum, containing no more than 1500 words, in which you identify three (and only three) of the options that you consider especially promising. Your memorandum must include a discussion of how the three initiatives would (or would not) interlock and complement one another.

[End of Exam]