Patent Law and Global Public Health

Second 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.

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 09:00 UTC on Friday, December 8, 2023. Answers must be submitted by 09:00 UTC on Tuesday, December 12, 2023. 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 December 12, 2023, 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, 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: Laurie Ann Taylor
- 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	10%
Question 2	400 words	15%
Question 3	100 words	5%
Question 4	500 words	10%
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 participated in 10 of the 12 weekly seminars of their groups will receive a certificate from WIPO and Harvard Law School.

Students who do not pass the final examination will be offered the opportunity to take a similar test in April 2024, following the third iteration of this course.

A list of the students who passed the examination will be posted on the course website no later than 12:00 UTC on January 15, 2024. Certificates will be distributed shortly thereafter.

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

To be effective, most vaccines must remain cold from the time they are manufactured until the time they are injected into patients. Unfortunately, the methods (some of which are depicted below) used to deliver vaccines to remote rural areas in developing countries often result in temperature fluctuations, which causes them to degrade. The result is that residents of those areas frequently receive substandard vaccines.

Mamadou Kassé, 29, travels on a donkey cart to deliver vaccines to the children of Kankelena village, in Mali's volatile region of Mopti.

Yunusa Bawa, a community health worker, rides on a motorbike with a box of AstraZeneca coronavirus vaccines on the outskirts of Abuja, Nigeria.

Isabel Inventor is a faculty member in the Chan School of Public Health at Harvard University. She has long been looking for ways to improve vaccine delivery systems in developing countries. In April of 2022, when preparing for a vacation, Isabel learned that small portable refrigerators designed for use in automobiles had recently become commercially available in the United States and Europe. An example appears below.

Description of Alpicool CF Series Car Freezer

- LCD display panel ,built-in LED light and internal basket.
- Suitable for Car and home using work on 12/24V DC and 110-240V.
- Can freeze down to -4°F(-20°C) for true car refrigeration.
- 3 stage car battery protection system to prevent the car battery run down.
- With portable handles on both sides, easy for moving.
- Vibration resistant design to protect the device safety while driving on road.
- Safe to run on angles up to 45°from horizontal—great for 4WDing!
- High efficiency compressor with adjustable ECO and HH modes.

It occurred to Isabel that an analogous device might be used to deliver vaccines. She quickly concluded that the refrigerators themselves are too large and heavy to be transported on the motorbikes that are often used for deliveries in remote areas. However, she thought that the technologies underlying the refrigerators might be adapted for motorcycle use.

During the next six months, Isabel designed and built a prototype for a set of temperature-controlled panniers. (A pannier is "one of a pair of packs or containers hung over the rear wheel

of a vehicle (such as a bicycle or motorcycle.") A photograph of the panniers, installed on a generic motorcycle, appears below.

Each of the two heavily insulated panniers contains a small, highly efficient compressor, which is powered by the motorcycle's generator. A sophisticated thermostat in each pannier maintains the temperature at the level set by the operator. A loud alarm alerts the operator if the temperature in either pannier deviates from that level by more than 2 degrees centigrade. Inside the panniers, trays made of closed-cell foam prevent vials of vaccines from rattling and reduce the probability that minor collisions would cause them to break. The panniers are shaped so that they can be attached easily to most brands and models of motorcycles.

By October of 2022, Isabel was ready to test the effectiveness of her invention. On October 15, she placed vials of water in the prototype, attached the panniers to her own motorcycle, and spent a day riding, first on highways, and then on bumpy gravel roads in New Hampshire, USA. The temperatures in both panniers remained stable, and none of the vials broke. While she was refueling her motorcycle at a gas station, Isabel was asked by the attendant how the panniers worked. After she explained their function, the attendant, impressed, decided not to charge her for the gasoline.

Encouraged by the performance of the prototype, Isabel reported her invention to the Technology Transfer Office ("TTO") of Harvard University. Working with a local law firm, the TTO prepared an application for a U.S. patent on the invention. The application identified Isabel as the sole inventor. It was filed with the U.S. Patent and Trademark Office on January 1, 2023.

In February of 2023, Isabel sold the prototype for her invention to a network of community health workers in Uganda. Since that time, the network has been using a motorcycle equipped with the panniers to deliver vaccines to rural villages. The system has thus far performed flawlessly.

On March 1, 2023, Isabel established a nonprofit corporation, which she called RFD, Inc. (a reference to "rural free delivery") for the purpose of manufacturing the panniers and then selling them in developing countries. The Harvard TTO promised that, as soon as the patent on Isabel's invention issued, Harvard would grant RFD an exclusive license. To serve as the chief executive officer of RFD, Isabel hired Mark Manual.

On July 1, 2023, Mark gave Isabel some bad news: He had concluded that it would cost at least $300 to manufacture each set of panniers in the United States. If the retail price of the panniers were high enough to cover the cost of making them, sales in developing countries would be sharply limited. However, Mark suggested a plan that could overcome this impediment. He pointed out that motorcycles are popular in western Europe and (to a lesser extent) in the United States, and some of their owners use them to travel to pastoral areas for picnics or overnight camping. (Illustrations of this practice appear below.)

Mark argued that a significant number of these well-heeled motorcyclists would likely be willing to buy the panniers to carry chilled wine and perishable foods. If buyers in the European Union and United States could be induced to pay $600 for a set of panniers, the resultant profit could be used to offset the losses that RFD would incur by selling the panniers at very low prices in developing countries. He pointed out that this plan would require obtaining patent protection in several countries in addition to the United States – and suggested that the Harvard TTO initiate the application processes right away. Isabel quickly endorsed this plan. The following questions concerns its implementation.

Question 1: (a) As noted above, the application for a U.S. patent on Isabel's invention was filed with the USPTO on January 1, 2023. Is the USPTO likely to reject the application on the ground that it lacks novelty?

(b) Suppose that, on September 1, 2023, applications for patents on the same invention are filed with the national patent offices of France, South Africa, and India. Select <u>one and only one</u> of those offices. Is the office likely to reject the application on the ground that it lacks novelty? (Your answer may not exceed 200 words.)

Question 2: Suppose that, among the patent offices that are eventually called upon to evaluate patent applications for Isabel's invention, are the USPTO, the European Patent Office, and the Chinese Patent Office. Select <u>one and only one</u> of those jurisdictions. To determine whether the application would satisfy the inventive-step requirement in that jurisdiction, what additional

information would you need to know? Your answer should make clear why that information would be relevant. (Your answer may not exceed 400 words.)

Question 3: Assume that both that USPTO and the European Patent Office grant applications for patents on Isabel's invention. (a) Will the U.S. patent enable RFD Inc. to prevent a third party from purchasing embodiments of the invention at low prices in developing countries, importing them into the United States, and selling them there for prices less than RFD charges? (b) Will the European patent enable RFD Inc. to prevent a third party from purchasing embodiments of the invention at low prices in developing countries, importing them into the European Union, and selling them there for prices less than RFD charges? (Your answer may not exceed 100 words.)

Question 4: Unfortunately, sales of the panniers in Europe and the United States were less robust than Isabel and Mark had hoped. Accordingly, in November of 2023, Mark suggested an alternative plan. He pointed out that there existed in China, India, and some developing countries in Africa, Latin America, and Southeast Asia companies capable of manufacturing small refrigerators cheaply. Instead of (or in addition to) producing the panniers in the United States and exporting them, Mark suggested that RFD grant patent licenses to some of those manufacturers, authorizing them to produce and sell generic versions of the invention. Draft a memorandum containing no more than 500 words describing how such a voluntary-licensing program might be structured so as to maximize the benefit of the program to the residents of developing countries.

*****

Question 5: What, in your opinion, is the proper function (if any) of the doctrine of equivalents? In light of your view of its function, how (if at all) do you think the doctrine should be modified? (Your answer may not exceed 300 words.)

Question 6: Assume the following:

- A new variant of COVID-19 surges in the first few months of 2024. It is particularly widespread in Latin America but not as yet found in Asia.
- Pharma, Inc., a pharmaceutical firm based in Switzerland, has created and secured regulatory approval of a vaccine that is highly effective against the new variant.
- Pharma, Inc. has been granted patents on the vaccine in many countries, including India and Ecuador.
- The price that Pharma, Inc., currently charges for the vaccine make it unaffordable for most residents of Ecuador.
- Several firms in India have the capacity to produce generic versions of the vaccine, but no firm in Ecuador has that capacity.
- Switzerland, India, and Ecuador are all members of the World Trade Organization, and none is a "least developed country" as defined by the United Nations.

As you know, the TRIPS Agreement limits the ability of the countries that are members of the World Trade Organization to export patented products supplied under a compulsory license. However, contained within (or overlaid upon) the TRIPS Agreement are three distinct mechanisms that temper those limits – specifically, by permitting countries under specified conditions to export a part or all of the supply under a compulsory license. One or more of those three mechanisms

might be employed by the governments of India and Ecuador to enable generic versions of Pharma's vaccine to be manufactured in India and then exported to Ecuador. In an essay containing no more than 500 words, describe those three mechanisms and summarize the principal differences between them.

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. Increase the use of governmental and philanthropic prizes to support research and development for vaccines and medicines pertaining to neglected diseases;
14. 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 14 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 two of the options that she should not consider and two of the options that she should consider – and then explain your selections. Your memorandum should of course indicate the country in which your employer is a legislator and thus would be adopting your recommendations.

[End of Exam]