



## Patent Law and Global Public Health

April 2023

Final Examination

### *Instructions*

This is an “open-book” examination. When preparing your answer, you may read, watch, or rely on any material you wish. However, you may not consult in any way with any other person concerning any aspect of the test, and you must abide by the PatentX Policy on Academic Honesty, which is available at <https://ipxcourses.org/patent-law-and-global-public-health/> and is reprinted in the Appendix to this exam.

The exam will be distributed at 09:00 a.m. UTC on Thursday, April 20, 2023. Answers must be submitted by 09:00 a.m. UTC on Tuesday, April 25, 2023. Your answer should be submitted, either in MSWord or PDF format, as an attachment to an email message sent to [ipx@cyber.harvard.edu](mailto:ipx@cyber.harvard.edu).

Answers submitted after 09:00 UTC on April 25 will be accepted only if timely submission was prevented by illness (documented by a medical professional) or serious extenuating circumstances. Determination of whether a particular examination meets these criteria will be made by the PatentX Advisory Board.

### **When submitting your exam, please adhere to the following formatting guidelines:**

- The subject line of your email should include: [Last name], [First name] - Section: [Full Name of Trainer]
  - *For example:* Edison, Thomas - Section: Samiksha Ramesh
- 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 instructor will respond to questions concerning the exam unless those questions involve emergencies. If an emergency does arise, please email [harvardpatx@wipo.int](mailto: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 nine questions. You must answer all of them. 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	8%
Question 2	200 words	8%
Question 3	400 words	12%
Question 4	200 words	4%
Question 5	200 words	8%
Question 6	1 word	4%
Question 7	100 words	4%
Question 8	400 words	12%
Question 9	1500 words	40%

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 satisfied the participation requirement but do not pass the final examination will be offered the opportunity to take a similar test in December 2023, following the second iteration of this course.

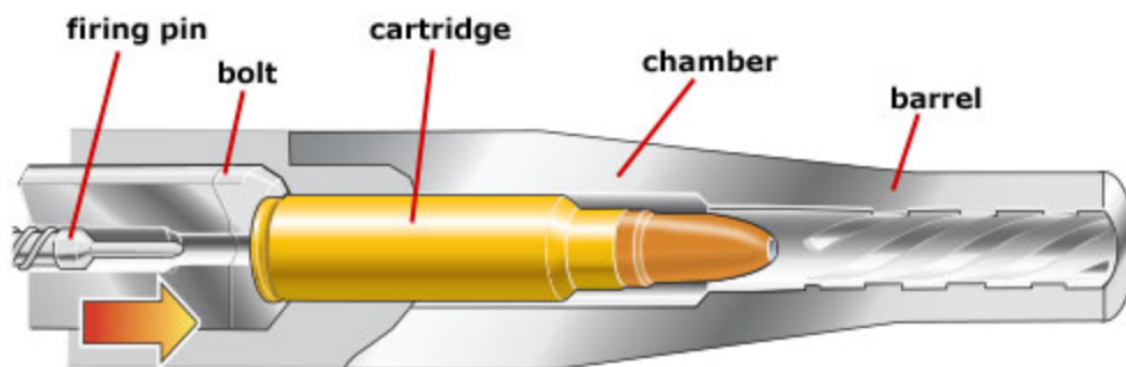
Students will be notified of their final course grades no later than 1200 UTC on May 24, 2023. Certificates will be distributed shortly thereafter.

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

John is a chemist, employed by Acme Chemical Corporation in the United States. For several years, he has been a member of a team of Acme employees responsible for developing new heat-resistant, non-metallic materials. In 2019, the team developed an extremely hard non-metallic compound, which they called “tenalon.” Acme applied for and obtained a U.S. patent on tenalon.

In his spare time, John enjoys collecting and using firearms. He has a small machine shop in his garage, where he repairs guns and produces ammunition.

A group of gun aficionados in the United States has long sought to produce a firearm that contains no metallic parts and thus cannot be detected by the machines currently used to screen airline passengers, visitors entering public buildings, and so forth. Although the members of the group have succeeded in producing most of the essential components of such a gun (barrel, stock, trigger, bullets, etc.) using carbon-fiber and other nonmetallic materials, they have failed to develop reliable non-metallic firing pins and cartridges. (A diagram, showing how a firing pin, cartridge, and chamber interact in the operation of a firearm, appears below.)



Source: [https://www.hunter-ed.com/pennsylvania/studyGuide/How-the-Rifle-and-Handgun-Fire/20103901\\_88408/](https://www.hunter-ed.com/pennsylvania/studyGuide/How-the-Rifle-and-Handgun-Fire/20103901_88408/)

In July of 2022, it occurred to John that firing pins and cartridges made from tenalon might be sufficiently durable and heat-resistant to replace the metallic versions of those parts. He spent many evenings in his shop, making and testing tenalon prototypes. After several failures, he finally produced a firing pin and a related cartridge that could shoot bullets reliably. Because the new parts were somewhat thicker than their metallic counterparts, John was obliged to fabricate a new, larger chamber to accommodate them. Finally, in November of 2022, he combined the new parts with other readily available non-metallic components to create a complete gun, which he called the “Ghost.” A photograph of the gun appears below.



For several months, John kept his invention secret. Then, on March 25, 2023, he displayed the Ghost in a booth at the Wichita Gun Show, a large gathering of gun manufacturers and distributors, held every few months in Wichita, Kansas, in the United States. A photograph of the event appears below.



Although the new tenalon components were concealed inside the gun and thus not visible to persons who visited his booth, when asked John described their composition and dimensions precisely.

Many visitors expressed skepticism concerning the quality and usefulness of the Ghost. In response, John freely admitted that the Ghost is less accurate and powerful than metallic firearms and is more expensive to fabricate, but he argued that it has a crucial advantage: it evades metal detectors and thus may be taken many places where guns are forbidden.

One of the people who visited John's booth was Karl, who himself had long tried to develop a nonmetallic firearm. On April 1, 2023, without informing John, Karl filed a patent application with the United States Patent and Trademark Office [USPTO] on a combination of: (a) a firing pin made of tenalon; (b) a cartridge made of tenalon; and (c) a chamber that could accommodate (a) and (b). The claims recited in the application included the exact dimensions of the parts that John had created and that John had disclosed to Karl at the Wichita show. On April 2, Karl posted a copy of his application on his personal website: [ksguns.org](http://ksguns.org).

On April 15, 2023, John filed with the USPTO a patent application of his own on a combination of: (a) a firing pin made of tenalon; (b) a cartridge made of tenalon; and (c) a chamber that could accommodate (a) and (b). The claims in John's application were very similar to the claims in Karl's application. On the same date, John filed with the USPTO a Patent Cooperation Treaty [PCT] application that was substantively identical to his US patent application. In his personal blog, John expressed his tentative intent to use his PCT application to pursue patent protection in many countries and regions.

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**Question 1:** Suppose that, among the patent offices that are eventually called upon to evaluate John's patent application, are the USPTO, the European Patent Office, and the Chinese Patent Office. Select one and only one of those offices. Is the office likely to reject John's application on the ground that the invention at issue is pernicious? (Your answer may not exceed 200 words.)

**Question 2:** Suppose that, among the patent offices that are eventually called upon to evaluate John's patent application, are the USPTO and the national patent offices of France, South Africa, and India. Select one and only one of those offices. Is the office likely to reject the application on the ground that the application lacks novelty? (Your answer may not exceed 200 words.)

**Question 3:** Suppose that, among the patent offices that are eventually called upon to evaluate John's patent application, are the USPTO, the European Patent Office, and the Chinese Patent Office. Select one and only one of those offices. To determine whether John's 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 4:** Would John's status as an employee of Acme affect his US patent application? If you need additional information to answer the question, say what that information is and why it matters. (Your answer may not exceed 200 words.)

**Question 5:** When interpreting patent claims, courts in all countries now rely primarily on the principle of peripheral claiming. Occasionally, however, they employ claim-construction principles that draw upon the principle of central claiming. Provide an example of a legal doctrine that incorporates aspects of central claiming and explain how it functions. (Your answer may not exceed 200 words.)

**Question 6:** The Beta Corporation, based in the United States, manufactures widgets, which it sells throughout the world. Beta holds a U.S. patent on its widgets. The packaging of the widgets that Beta sells outside the U.S. contains the following text: “*This product may not be imported into or sold in the United States.*” Some of the packages bearing this label were sold in Nigeria at prices below the prices that Beta charged in the U.S. In 2022, Arthur Arbitrageur purchased some of the packages of Beta widgets sold in Nigeria, shipped them to New York, and sold them in the United States. Has Arthur violated U.S. patent law? (Your answer may not exceed 1 word.)

**Question 7:** As of April 20, 2023, are any of the member countries of the World Trade Organization free to deny patent protection to all pharmaceutical products? Substantiate your answer. (Your answer may not exceed 100 words.)

**Question 8:** The approaches used by courts to determine whether a patentee, who has prevailed in an infringement suit, is entitled to injunctive relief, rather than only compensatory damages, vary by country. In your view, in which of the following three countries is the approach taken by the courts the most sensible: Germany; the United Kingdom; or the United States. Your answer should reflect a clear understanding of the ways in which the three approaches differ. (Your answer may not exceed 400 words.)

**Question 9:** 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, authorizing either local production or importation of the products in question;
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) drugs directed at 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) drugs directed at 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. The country is a member of the World Trade Organization. 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 which is most promising. She asks you to draft a memorandum, containing no more than 1500 words, in which you select three of the 14 options and explain why, in your judgment, they would be best. Your memorandum should of course indicate the country in which your employer is a legislator and thus would be adopting your recommendations. If you believe that, in addition to the three options you have selected, your employer should consider another strategy not included in the list, you should also describe that strategy and explain its merits.

## **Appendix: PatentX Policy on Academic Honesty**

In any work for PatentX, including the final examination, students must attribute the ideas of others properly, so as to avoid plagiarism. When a student directly copies the words of another, those words must be enclosed in quotation marks. Such quotations must be attributed to their original author. When a student paraphrases the words of another, quotation marks are not appropriate. However, the student must still attribute the ideas to their original author. Students are not required to use a particular style of citation. Students seeking additional guidance about proper attribution may wish to consult the [Harvard Guide to Using Sources](#). Failure to quote and attribute the ideas of others properly, as described above, will result in a failing grade on the work in question as well as a failing grade in the course. Failure to abide by the instructions for an examination will also result in a failing grade both on the exam and in the course as a whole.

Students are not permitted to use artificial intelligence/machine learning software (e.g., ChatGPT) to perform, in whole or part (including initial drafts), any work assigned in this course or any part of the course's final examination. (For this purpose, the systems included in most word-processing programs for detecting errors in spelling and grammar are not considered artificial intelligence/machine learning software.)