Patent Law and Global Public Health

Sixth Edition

Final Examination

Instructions

This is an "open-book" examination. When preparing your answer, you may read, listen to, or watch any material you wish. However, you must abide by the following rules:

(1) When preparing and drafting your answer, you may not consult in any way with any other person.
(2) Plagiarism is strictly forbidden. Guidelines concerning mandatory attribution of sources and associated citation requirements are available at https://usingsources.fas.harvard.edu/harvard-plagiarism-policy.
(3) Although you are permitted to use artificial intelligence when preparing your answer, you must abide by the following constraints:
   a) As you likely know, large language models (LLMs), such as "ChatGPT" or "Claude," sometimes "hallucinate." In other words, they fabricate material and then present it as real. If, as a result of using such a model, your answer contained false information, you would be penalized – in much the same way that a journalist who included false information in an article, or a lawyer who included false information in a brief, would be penalized. Thus, if you consult a LLM when preparing your answer, you should certainly verify the accuracy of the information it provides you.
   b) Appropriate attribution of material obtained from a LLM is just as essential to academic integrity as it is for any other source. Thus, if you derive an idea or an argument from such a model, you must include in your answer a footnote clearly identifying the model in question.
   c) If any of the text you include in your answer consists of material generated by artificial intelligence (or a paraphrase of such language), you must underline the text at issue in addition to providing an appropriate footnote.
   d) If you write all or some of your answer yourself, but then employ artificial intelligence to correct your grammar or to clarify your prose, you must acknowledge doing so in an appropriate footnote.

Any violation of these 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 12:00 UTC on Thursday, January 15, 2026. **Answers must be submitted by 12:00 UTC on Monday, January 19, 2026**.

Answers must be submitted via the CopyrightX/PatentX portal; email submissions will not be accepted. To submit your answer, please follow these steps:

(i) log in your PatentX account;
(ii) click on the "Exams" option in the main menu;
(iii) click on "PatentX – 6th Edition";
(iv) click on the "Choose File" button and then select your answer file; and
(v) click "Upload."

Please note that only one (1) file in **PDF format** can be uploaded. You should receive an **email confirmation** shortly after the submission of you answer file; if you do not receive it, please reach out to pxexams@law.harvard.edu as soon as possible.

If you fail to submit your exam prior to the deadline on January 19, you may send an email message to pxexams@law.harvard.edu, explaining the reason for your failure and attaching your answer. However, you should be aware that late submissions will be considered for grading only 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:

- 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 both harvardpatx@wipo.int and pxexams@law.harvard.edu, 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 eight questions. You must answer all. 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	300 words	9%
Question 3	400 words	10%
Question 4	400 words	10%
Question 5	400 words	10%
Question 6	400 words	10%
Question 7	500 words	14%
Question 8	1500 words	30%

The word limits are strict; you will be penalized if you exceed them. When counting the number of words in your answers, you must include the words used in the footnotes or other citations.

Each student's answer 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 12:00 UTC on February 20, 2026. Certificates will be available for download through the CopyrightX/PatentX portal shortly thereafter.

[The following is a fictionalized composite of several events. Many of the statements made in the narrative are true, but others are "alternative facts" – i.e., either distortions of true events or outright fabrications. If you happen to know (or learn) about aspects of the actual events that are inconsistent with the narrative, you should ignore that knowledge when framing your answer.]

Many children throughout the world lack hands. As a result, their ability to perform many functions is limited. In addition, they often find it difficult to participate in social activities.

This situation has two main causes. First, "congenital upper limb differences occur in up to 1 in 500 live births…. These children will have one typical upper limb and one that ends below the elbow, at the level of the proximal or mid-forearm."[1] Second, roughly 500 children lose hands each year to land mines or other war-related injuries.

In recent years, the technology associated with prosthetic arms and hands has advanced rapidly. Many companies now produce and sell devices that enable users, by activating nerves in their arms, to control the movement of mechanical hands and even individual fingers. The current state of the art is summarized below:

> Standard-of-care pediatric prostheses provide limited functionality, typically offering only a single degree-of-freedom open/close grasping function. This is a stark departure from the immense dexterity of an intact hand that moves with 27 degrees of freedom, and the 6–9 common hand grasp movements (pulp pinch, cylindrical grasp, among others) that have been shown to account for nearly 80% of grasping movements when performing activities of daily living. In recent years, multi-articulating motorized prosthetic hands for adults have become increasingly available. These assistive devices offer adults significant functional benefits by providing a multitude of hand grasp configurations. Beyond their added function, an additional advantage inherent to their handlike designs is the anthropomorphic or more life-like appearances when compared to their hook or grasper-style counterparts.[2]

Such devices are gradually approaching natural hands in functionality, although many decades will likely elapse before they are truly comparable.

One of the major disadvantages of the current generation of multi-articulating motorized prosthetic hands (also known as "multi-grip myoelectric hands" or MGMHs) is cost. Retail prices can approach USD 100,000. As a result, for most people lacking comprehensive health insurance, these devices are unaffordable.

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[1] Marcus A. Battraw et al., "A Multiarticulate Pediatric Prosthetic Hand for Clinical and Research Applications," *Frontiers in robotics and AI* 9 (2022): 02.

[2] Ibid.

Open Bionics, a British company, has developed a line of MGMHs (which it calls "Hero Arms") that cost less than most. The savings have been achieved in part by using components that can be manufactured using 3D printers. In the following photograph, the father is wearing one of Open Bionics' early products.

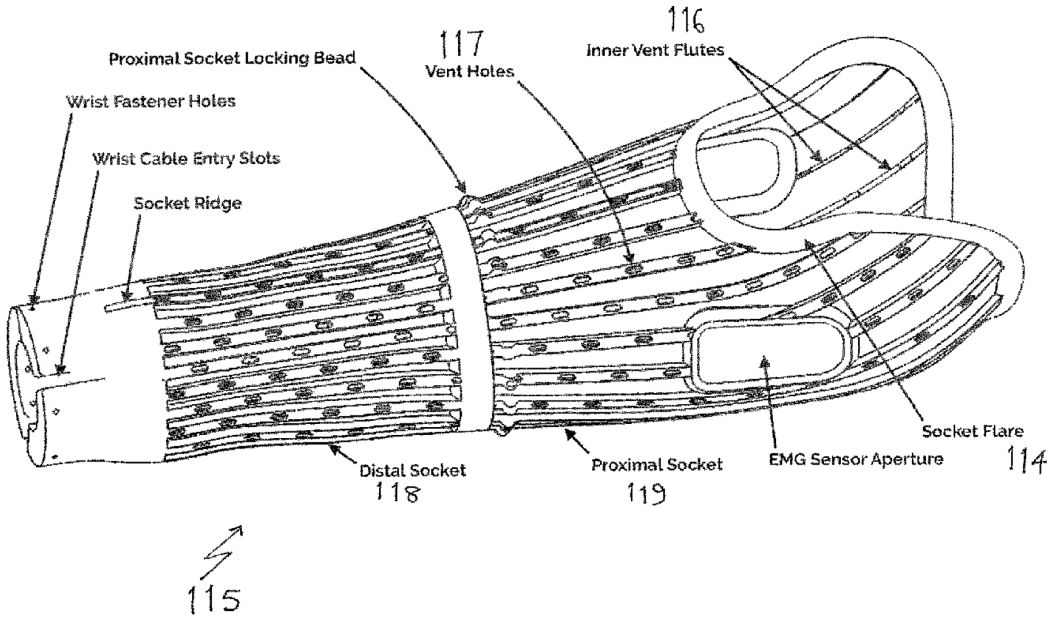
Among the many current models of Hero Arms are some that are specially designed for children. These are smaller, of course, than the arms for adults; they also are available with special covers:

> At Open Bionics, we turn children with limb differences into bionic heroes and make science fiction a reality. As if cutting-edge bionic arms weren't cool enough, we're incredibly fortunate to be working with Disney to develop a range of Hero Arm covers, starting with designs from the Star Wars, Marvel and Frozen universes. We've also worked with Eidos-Montreal to bring you super slick Deus Ex covers for the Hero Arm.

Retail prices for Hero Arms start as low as USD 6000, but the total cost of a Hero Arm is typically closer to USD 15,000.

Starting in 2019, Open Bionics began applying for patent protection in many jurisdictions on some of the components of the Hero Arms. In 2023, the Patent and Trademark Office in the United States granted one of those applications. The technology in question involves a forearm

exoskeleton, which is used in all of the current generation of Hero Arms. The crucial figure in the patent application – and the primary claim – are set forth below.[3]



The invention claimed is:

1. A prosthetic limb comprising:

an inner socket formed from a flexible material and comprising a plurality of fluted channels, each of the plurality of fluted channels having a plurality of air flow openings in series with one another along the plurality of fluted channels, wherein the plurality of airflow openings extends only a thickness of the flexible material at the plurality of fluted channels; and

an outer frame formed from a rigid material and having an open lattice structure.

In 2024, the European Patent Office and the national patent offices of China and Thailand issued identical patents to Open Bionics.

A drawbacks of all MGMHs, including Hero Arms, is that they frequently break. Repair costs can be substantial.

Sarah Jones lacks a hand on her left arm. Her family does not have a health-insurance policy that would cover a MGMH. However, in January of 2025, her parents managed to save enough money to purchase one of the Hero Arms for her. She quickly came to love the device.

John Jones, Sarah's father, is an engineer. He is reasonably skilled with computer-aided design techniques and owns a scanner and a 3D printer.

[3] The full patent is available at https://patents.google.com/patent/US11696841B2/en?oq=11696841.

Last week, Sarah fell and broke the exoskeleton of her prosthetic arm. John is currently considering how he might replace it. Searching for information on the website Reddit, he found the following post:

> One of my friends just got his hero arm after about a year long process and about 12k in cost. He's from the US, and so far he's had it a month and really likes it. It's doesn't seem to be as durable and some of the components probably aren't going to last long. But with a 3d printer he's going to see if he can scan, model and manufacture his own replacements.[4]

Intrigued, John removed the broken exoskeleton from Sarah's Hero Arm, taped the pieces together, scanned it, created a replica using his 3D printer, and used the replica to repair the device. The rebuilt arm worked perfectly.

It then occurred to John that parents of other children with Hero Arms may be confronting the same challenge. He posted on Reddit a willingness to provide them replacement exoskeletons – and quickly received requests from parents in several countries. If he charged each parent half the amount that Open Bionics charges for a replacement exoskeleton, he could earn a modest profit. He is currently considering doing so.

Select one and only one of the following countries: Germany, the United Kingdom, China or the United States. Assume that John Jones lives and works in the country you have selected. Answer the following questions, based on the patent law applicable in the jurisdiction you have selected.

Question 1: Is Open Bionics' patent vulnerable to challenge on the ground that it does not pertain to patentable subject matter? (Your answer may not exceed 200 words.)

Question 2: It has recently come to light that, prior to filing any of its patent applications, Open Bionics provided several prototypes of the Hero Arm to children in Afghanistan who had lost hands to land mines. Would that information support a successful challenge to the patent (in the jurisdiction you have chosen) on novelty grounds? What additional information, if any, would you need to know to answer this question confidently? (Your answer may not exceed 300 words.)

Question 3: Is the patent (in the jurisdiction you have chosen) vulnerable to challenge on the ground that it fails the inventive-step requirement? What additional information would you need to know to answer this question confidently? How would that information be analyzed by a court in the relevant jurisdiction considering such a challenge? (Your answer may not exceed 400 words.)

Question 4: Read the principal claim in the patent carefully. Would it be possible for John to "invent around" the patent – i.e., to develop a variant of the exoskeleton the manufacture of which

[4] https://www.reddit.com/r/amputee/comments/eqffe0/hero_arm_from_openbionics/

would neither constitute literal infringement nor run afoul of the doctrine of equivalents? (Your answer may not exceed 400 words.)

Question 5: One of the parents who responded to John's Reddit post lives in a low-income country. She explained that Hero Arms are not available for sale there – and that, even if they were, they would be too expensive for most residents. She pleaded with John to establish a small business that would address the desperate need for such devices in many low and middle-income countries (LMICs). Specifically, she suggested that he use his engineering skills to produce, not just exoskeletons, but complete generic replicas of Hero Arms – and then export those generics to LMICs, charging only enough to cover his costs and earn a modest profit. She volunteered to help distribute those products. John is considering her suggestion. If he does, and if Open Bionics prevails in a patent infringement suit against him, what remedies would a court (in the jurisdiction you have selected) be likely to grant? (Your answer may not exceed 400 words.)

Question 6: During the past 10 years, the Ministry of Public Health in Thailand has purchased from Open Bionics a modest number of Hero Arms and then distributed them for free to children lacking hands. Dismayed by the rapidly increasing numbers of people requesting such devices, the government of Thailand is considering overriding Open Bionics' Thai patent in some way and thereby making it possible for a local company to begin producing the devices and providing them to the government at a low price. Advise the Thai government concerning its options. (Your answer may not exceed 400 words.)

* * * * *

Question 7: The four dominant theories of intellectual property are summarized in William Fisher, "Theories of Intellectual Property," which is included in the readings for Module 103 of this course. Select one (and only one) of those four theories. Then select one of the major sectors of the legal regime relevant to the global health crisis – examined in Modules 201 through 205 of the course.

Does the theory that you have selected point toward any amendments of the sector of the legal regime that you have selected? (To illustrate, you might discuss how the Welfare Theory illuminates the question of how the set of "TRIPS flexibilities" should be modified, or you might discuss how the Fairness Theory illuminates the set of laws governing differential pricing of pharmaceutical products.) (Your answer to this question may not exceed 500 words.)

Question 8: Modules 202 through 205 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;

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 regulatory-exclusivity protection in high-income countries [HICs] for (a) vaccines; (b) drugs addressing neglected diseases; and (c) breakthrough drugs of all sorts;
11. Adjust the doctrines of claim construction, equivalents, and remedies in the patent laws of HICs to augment incentives to produce (a) vaccines; (b) drugs addressing 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. (You should select and specify the country.) 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 two (and only two) of the options that you consider especially promising and one (and only one) that you consider especially misguided – and explain your recommendations.

[End of Exam]