Patent Law and Global Public Health

Fourth 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 through the online library of the University of London.
(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 or other citation clearly identifying the model in question.
   c) Finally, if any of the text you include in your answer consists of language generated by artificial intelligence (or a paraphrase of such language), you must double underline the text at issue in addition to providing an appropriate citation.

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 1300 UTC on Friday, December 6, 2024. **Answers must be submitted by 1300 UTC on Tuesday, December 10, 2024**.

Answers can be submitted only via the CopyrightX/PatentX Portal (https://hlscopyrightx.com/). Submissions by email will not be accepted. To submit your answer, you should:

1) save your answer in PDF format;
2) log in your account on the portal;
3) click on the "Exams" tab in the main menu;
4) click on " PatentX – Fall 2024";
5) click on the "Choose File" button and select your answer file;
6) click "Upload."

Please note that you may submit only one answer to your exam. Once you have submitted your answer, the system will not permit you to submit another. You should receive an email confirmation shortly after the submission of your answer file; if you do not receive it, please reach out to pxexams@law.harvard.edu as soon as possible. In the unlikely event that the portal malfunctions and does not permit you to upload your answer prior to the deadline, you should immediately contact Tomas Felcman at tfelcman@law.harvard.edu.

If you fail to submit your exam prior to the deadline on December 10, 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 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 eight 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	300 words	7%
Question 2	200 words	6%
Question 3	400 words	10%
Question 4	400 words	10%
Question 5	400 words	10%
Question 6	300 words	7%
Question 7	500 words	15%
Question 8	1500 words	35%

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 actively participated in 10 of the 12 weekly seminars of their groups will receive certificates 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 13:00 UTC on January 15, 2025. Certificates will be available for download through the CopyrightX/PatentX Portal shortly thereafter.

For the purposes of questions 1-6, assume the following facts:

John Smith is a surgical oncologist employed by the Massachusetts General Hospital, which is based in Boston. In addition to his medical degree, Smith has a Ph.D. in computer science and a master's degree in electrical engineering. Most of Smith's time in the hospital is spent removing malignant tumors from patients' lungs. In the evenings, at home, he often relaxes by tinkering in his workshop or by experimenting with recently developed forms of artificial intelligence.

One of the longstanding challenges in lung-cancer surgery is determining how much tissue to excise when removing tumors. If the surgeon cuts out too little, the patient's cancer is likely to recur. If the surgeon cuts out too much, the patient's postoperative lung function may be impaired. For many years, surgeons have sought to determine whether they have removed the right amount by rapidly freezing and then analyzing thin slices of tissue from the edges of their excisions. This method, however, is time-consuming and imperfect.[1]

In May of 2024, Smith came across an article by J. Everett Knudsen, describing the state of the art concerning uses of artificial intelligence to facilitate surgery.[2] The following passages caught his attention.

> Since its inception and widespread adoption, artificial intelligence (AI) has revolutionized nearly every aspect of human life. AI is the study and development of algorithms that give machines the ability to reason and perform cognitive functions such as problem-solving and decision-making. From finance to agriculture, manufacturing to education, AI has fundamentally altered our ability to understand and respond to complex problems. Perhaps the most impactful adoption of AI on human life is in the field of medicine where AI is being used to help physicians make more precise decisions and predict patient outcomes with a higher degree of certainty.
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> Within the medical field, surgery has experienced one of the largest impacts with the adoption of AI as more and more surgeries are performed using robotic assistance. Current surgical robots are controlled by a "master–slave" dynamic where the robot itself does not have any autonomy if it does not have a human operator. However, recent advances in AI and machine learning (ML) are beginning to expand the capabilities of surgical robots and augment the surgical experience in the operating room. Surgical robots may soon rely on data captured through sensors and images to operate, and this plethora of data capture is likely to be the key driver behind AI innovations in robotic surgery….

[1] See, e.g., Pan Yin et al., "Optimal Margins for Early Stage Peripheral Lung Adenocarcinoma Resection," *BMC cancer* 21, no. 1 (2021).

[2] J. Everett Knudsen et al., "Clinical Applications of Artificial Intelligence in Robotic Surgery," *Journal of robotic surgery* 18, no. 1 (2024). [The text of the essay has been modified slightly to make it more accessible to non-physicians.]

> Robotic surgery allows for operation in deep anatomical spaces (e.g. abdominal and pelvic cavities) using small incisions for cameras and instruments. Real-time AI image enhancement allows for enhanced identification of anatomical structures and instruments. Intraoperative visual environments are constantly changing as dissection or repair tasks progress, which can lead to marked changes in intraoperative image quality. To combat these changes, Shahnewaz Ali and his colleagues have developed an online preprocessing framework capable of denoising, deblurring, and color-correcting real-time camera imaging to enhance intraoperative visualization in knee arthroscopy.[3] Their method outperformed existing image enhancement with significantly reduced computation time to image display….
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> One of the major differences between traditional and robot-assisted surgery is tactile sensation. Traditional approaches allow surgeons to palpate anatomical structures or feel changes in tissue resistance during dissection and suturing tasks, something that has not yet been developed for robotic surgery. The newest generation of surgical robots can display force measurements in the surgical console…. Johanna Miller et al. have developed important refinements of this technology….[4]
>
> Another area of interest where AI promises advancement is surgical oncology, particularly in the realm of margin minimization to prevent cancer recurrence. In the field of oral surgery, Marsden et al. presented a variety of AI models that utilize fluorescence imaging to guide intraoperative dissection tasks.[5] Model features allowed researchers to generate and overlay a heatmap of probable cancer location within the oral cavity to guide surgeons during cancer excision…. Intraoperative deployment of these tissue models can help surgeons to resect malignancies while preserving as much healthy neural tissue as possible.

Intrigued, Smith contacted Shahnewaz Ali (at the QUT Centre for Robotics in Australia) and Johanna Miller (at the Tübingen University Hospital in Germany), asking if each would be willing to provide him one of the devices with which he or she had been experimenting. Both quickly complied.

Smith then spent all of his evenings during the months of June and July, 2024, designing and building a prototype of an augmented scalpel, which he hoped could be the centerpiece of a combination of these emerging technologies. A photo of his creation appears below.

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[3] See Shahnewaz Ali et al., "One Step Surgical Scene Restoration for Robot Assisted Minimally Invasive Surgery," *Scientific reports* 13, no. 1 (2023).

[4] See Johanna Miller et al., "Impact of Haptic Feedback on Applied Intracorporeal Forces Using a Novel Surgical Robotic System—a Randomized Cross-over Study with Novices in an Experimental Setup," *Surgical endoscopy* 35, no. 7 (2021).

[5] See Mark Marsden et al., "Intraoperative Mapping of Parathyroid Glands Using Fluorescence Lifetime Imaging," *The Journal of surgical research* 265 (2021).

The purpose of this device is to provide a surgeon real-time assistance in determining precisely how much tissue to excise when removing a tumor. It functions as follows:

(a) A tiny camera mounted on the underside of the device transmits to a computer (via Bluetooth) a close-up image of the tissue that the blade is poised to cut.
(b) Using the technology refined by Miller, the device measures the amount of force that the surgeon is applying to the blade at any given moment and then transmits that information to the same computer.[6]
(c) Cameras mounted in the ceiling over the operating table transmit to the computer real-time images of the zone of the body upon which the surgeon is operating.
(d) The computer enhances the images derived from (a) and (c), using the technology developed by Ali and his colleagues. The enhancements provide additional detail concerning the textures of the tissues and the exact location of the surgeon's hand and scalpel during the operation.
(e) The computer then uses these various inputs and a cloud-based AI system (also developed by Smith) to determine with precision the contours of the tissue that the surgeon should remove.
(f) The computer's recommendations are transmitted to the device (again, using Bluetooth), which guides the surgeon by illuminating lights located in the console. If the computer determines that the surgeon has not yet removed enough material in the zone immediately adjacent to the scalpel blade, a green light is illuminated. When the amount removed approaches the optimum, the light changes to orange. When the surgeon has removed just

[6] The reason that this information is useful in the present context is that the amount of force necessary to make an incision provides clues concerning the nature of the tissue being cut.

the right amount – and is thus on the verge of excising healthy tissue, the light changes to red.

In September, Smith used this new device – and the complementary technologies – when operating on ten patients (after obtaining the patients' permission). Those operations went well. Their success prompted Smith to make some minor adjustments to the device and to the AI model, but he is now satisfied that the system is ready for release to the public.

In October, Smith drafted an article describing the new device and the various technologies that it integrates. On November 1, he submitted the draft to the Journal of Robotic Surgery. The editors of the journal eagerly accepted the article. It is scheduled to be published on December 15, 2024.

Carla Jones is another surgeon working at Mass General. Like Smith, she is interested in the ways in which artificial intelligence might be harnessed to improve surgery. Recently, Jones suggested to Smith that he consider patenting his innovation – and then establish a company that would manufacture the enhanced scalpels and license access to the accompanying cloud-based AI model. She argued that experimentation in AI-augmented health care currently is especially intense in **Germany, China, and the United States**. Thus, Jones suggested, Smith should at least consider obtaining patents in those three jurisdictions. Unfamiliar with patent law, Smith has come to you for advice.

Select one (and only one) of the three countries highlighted by Jones and answer the following questions, by applying the law of that country.

Question 1: Would it be possible to describe Smith's invention – and to draft claims embodying the invention – in a way that would enable the invention to qualify as patentable subject matter? (Your answer may not exceed 300 words.)

Question 2: If the answer to question 1 is yes, would the patent satisfy the novelty requirement in the jurisdiction you have selected? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 200 words.)

Question 3: If the answer to question 1 is yes, would the patent satisfy the inventive-step requirement in the jurisdiction you have selected? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 400 words.)

Question 4: Would Shahnewaz Ali, Johanna Miller, or the Massachusetts General Hospital likely have any claims against Smith or an enforceable interest in any patent he obtains on his invention? What additional facts, if any, would you need to know to answer confidently. (Your answer may not exceed 400 words.)

Question 5: Assuming that the answer to question 4 is no, how much protection would a patent provide Smith in practice? To answer this question, you should consider at least: (a) How easy would it be for another doctor to "invent around" the patent? and (b) What remedies would be available to Smith if he prevailed in an infringement suit against a competitor? What additional

facts, if any, would you need to know to answer confidently. (Your answer may not exceed 400 words.)

Question 6: Would it be immoral for Smith to obtain or enforce a patent on his invention? (Your answer may not exceed 300 words.)

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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.)

In preparing your answer, you might consider asking the "IP Theory AI Chatbot" (also included in the readings for Module 103) to provide insight into the guidance that could be gleaned from one or more of the IP theories. If you choose this approach, then you must of course abide by the procedural instructions set forth in the introduction to this exam concerning uses of AI. In addition, you should indicate the respects in which you disagree with the response you receive from the "IP Theory AI Chatbot."

However, you are certainly not required to solicit assistance from the chatbot. At least as valuable would be a response to the question derived entirely from your own knowledge and thought.

(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 data-exclusivity protection in upper-income countries [UICs] 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 UICs 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) of the options that you consider especially unpromising – and explain your recommendations.

[End of Exam]

References

Ali, Shahnewaz, Yaqub Jonmohamadi, Davide Fontanarosa, Ross Crawford, and Ajay K. Pandey. "One Step Surgical Scene Restoration for Robot Assisted Minimally Invasive Surgery." *Scientific reports* 13, no. 1 (2023): 3127-27.

Knudsen, J. Everett, Umar Ghaffar, Runzhuo Ma, and Andrew J. Hung. "Clinical Applications of Artificial Intelligence in Robotic Surgery." *Journal of robotic surgery* 18, no. 1 (2024): 102-02.

Marsden, Mark, Shamira Sridharan Weaver, Laura Marcu, and Michael J. Campbell. "Intraoperative Mapping of Parathyroid Glands Using Fluorescence Lifetime Imaging." *The Journal of surgical research* 265 (2021): 42-48.

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Yin, Pan, Bingqing Yue, Ji Zhang, Dong Liu, Dongyu Bai, Guang Zhao, Chutong Huang*, et al.* "Optimal Margins for Early Stage Peripheral Lung Adenocarcinoma Resection." *BMC cancer* 21, no. 1 (2021): 533-33.