Patent Law and Global Public Health

Fifth 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) 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 underline the text at issue in addition to providing 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 21:00 UTC on Friday, May 9, 2025. **Answers must be submitted by 21:00 UTC on Tuesday, May 13, 2025**.

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 – Spring 2025";
(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 May 13, 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. 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	8%
Question 2	400 words	10%
Question 3	400 words	10%
Question 4	400 words	10%
Question 5	300 words	8%
Question 6	400 words	10%
Question 7	500 words	12%
Question 8	1500 words	32%

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 13:00 UTC on June 15, 2025. Certificates will be available for download through the CopyrightX/PatentX portal shortly thereafter.

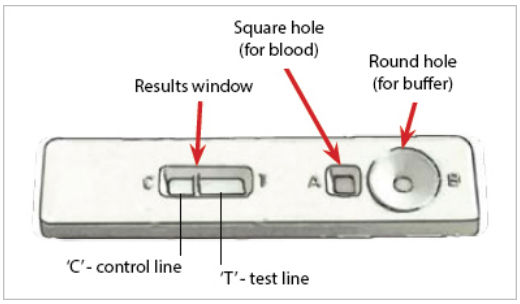
[The following is a fictionalized composite of several events. Many of the statements made in the narrative are true, but others are "alternative facts" – i.e., either distortions of true events or outright fabrications. If you happen to know (or learn) about aspects of the actual events that are inconsistent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

Rapid diagnostic tests (RDTs) are commonly used in rural areas in poor countries to diagnose infectious diseases. Malaria RDTs, for example, work as follows:[1]

Malaria rapid diagnostic tests (RDTs) assist in the diagnosis of malaria by providing evidence of the presence of malaria parasites in human blood. RDTs are an alternative to diagnosis based on clinical grounds or microscopy, particularly where good quality microscopy services cannot be readily provided.

Variations occur between products, such as targets and formats, though the principles of the tests are similar. Malaria RDTs detect specific antigens (proteins) produced by malaria parasites in the blood of infected individuals. Some RDTs can detect only one species (*Plasmodium falciparum or P. vivax*) while others detect multiple species *(P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*). Blood for the test is commonly obtained from a finger-prick.

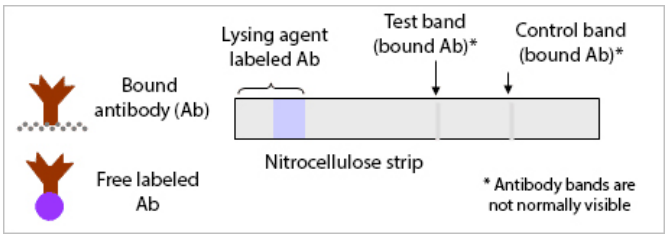
RDTs are lateral flow immuno-chromatographic antigen-detection tests, which rely on the capture of dye-labelled antibodies to produce a visible band on a strip of nitro-cellulose, often encased in plastic housing, referred to as cassettes. With malaria RDTs, the dye-labelled antibody first binds to a parasite antigen, and the resultant complex is captured on the strip by a band of bound antibody, forming a visible line (T - test line) in the results window. A control line (C- control line) gives information on the integrity of the antibody-dye conjugate, but does not confirm the ability to detect parasite antigen.



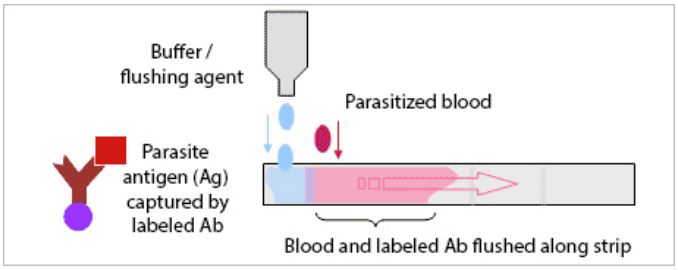
Inside the cassette is a strip made of filter paper and nitrocellulose. Typically, a drop of blood is added to the RDT through one hole (A; sample well), and then a number of drops of buffer usually through another hole (B; buffer well). Buffer carries the blood along the length of the RDT.

1. The first step of the test procedure involves mixing the patient's blood with a lysing agent [a solution used to break open blood cells] in a test strip or well. This ruptures the red blood cells, releasing more parasite protein.

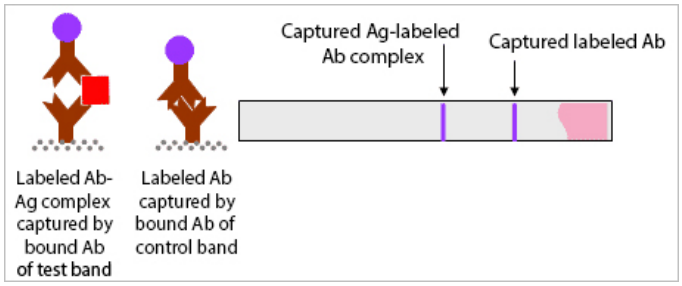
[1] Source: World Health Organization, https://www.who.int/teams/global-malaria-programme/case-management/diagnosis/rapid-diagnostic-tests/how-malaria-rdts-work.



2. Dye-labelled antibody, specific for target antigen, is present on the lower end of nitrocellulose strip or in a plastic well provided with the strip. Antibody, also specific for the target antigen, is bound to the strip in a thin (test) line, and either antibody specific for the labelled antibody, or antigen, is bound at the control line.



3. Blood and buffer, which have been placed on strip or in the well, are mixed with labelled antibody and are drawn up the strip across the lines of bound antibody.



4. If antigen is present, some labelled antibody-antigen complex will be trapped and accumulate on the test line. Excess-labelled antibody is trapped and accumulates on the control line. A visible control line indicates that labelled antibody has traversed the full length of the strip, past the test line, and that at least some free antibody remains conjugated to the dye and that some of the capturing properties of the antibodies remain intact.

5. The intensity of the test band will vary with the amount of antigen present, at least at low parasite densities (antigen concentration), as this will determine the amount of dye particles which will accumulate on the line. The control band intensity may decrease at higher parasite densities, as much of the labelled antibody will have been captured by the test band before reaching the control.

RDTs have a few disadvantages. Because their results are sometimes equivocal and because they must be interpreted by humans, they sometimes generate false-positive or false-negative results. Second, they are ephemeral; their results last only a few hours, which impedes verification of test interpretations. Third, aggregation of their results for the purposes of public health is time-consuming and expensive.

Starting in 2011, Professor Aydogan Ozcan and a team of researchers at the University of California sought to develop a technology that would overcome these longstanding limitations. The system they eventually created is described in the following article, published on May 9, 2012:[2]

> In poor and remote areas of the globe, rapid diagnostic tests (RDTs) are helping to make disease screening quicker and simpler. RDTs are generally small strips on which blood or fluid samples are placed. Specific changes in the color of the strip, which usually occur within minutes, indicate the presence of infection. Different tests can be used to detect various diseases, including HIV, malaria, tuberculosis and syphilis.
>
> But conventional RDTs are currently read manually by eye which is prone to error, especially if different types of tests are being used by a health care worker.
>
> To address such challenges, Aydogan Ozcan, a UCLA professor of electrical engineering and bioengineering, and his colleagues from the UCLA Henry Samueli School of Engineering and Applied Science and the California NanoSystems Institute at UCLA developed the new cell-phone based system.
>
> Their RDT-reader attachment, which clips onto a cell phone, weighs approximately 65 grams and includes an inexpensive lens, three LED arrays and two AAA batteries. An RDT strip is inserted into the attachment, after which an image of the strip is taken by the cell phone camera.
>
> Software then rapidly reads the digitized RDT image to determine, first, whether the test is valid and, second, whether the results are positive or negative, thus eliminating the potential errors that can occur with a human reader.
>
> Because the color changes in RDTs do not last more than a few hours in the field, the ability to store the digitized image indefinitely provides an added benefit.
>
> After this step, the RDT-reader platform wirelessly transmits the results of the tests to a global server, which processes them, stores them and, using Google Maps, creates maps charting the spread of various diseases and conditions -- both geographically and over time -- throughout the world.

On May 31, 2012, the University of California filed a US patent application on this technology – claiming priority to a US Provisional Application that had been filed on February 6, 2012. The principal figures and the primary claim of the application are set forth below. [3]

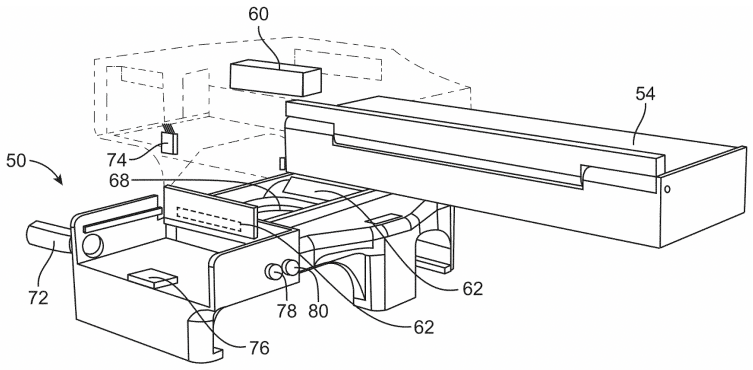


FIG. 4B

[2] "Cell phone imaging system makes light work of diagnostic tests," https://www.vision-systems.com/non-factory/life-sciences/article/16747310/cell-phone-imaging-system-makes-light-work-of-diagnostic-tests.

[3] The full application is available at https://patents.google.com/patent/US8916390B2/en.

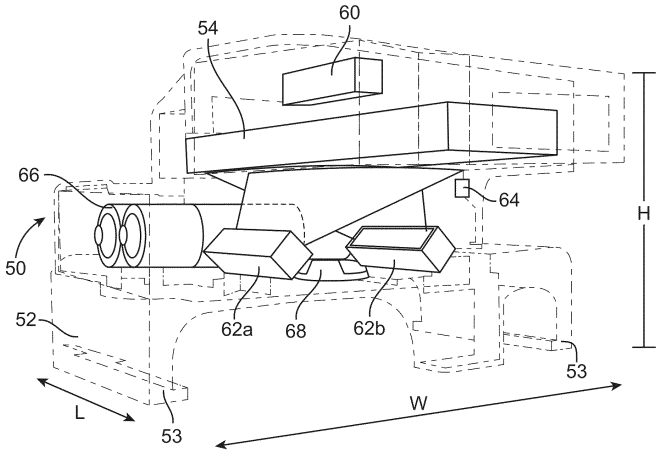


FIG. 3

What is claimed is:

1. A portable rapid diagnostic test reader system comprising:

a mobile phone having a camera and one or more processors contained within the mobile phone, the mobile phone containing imaging software thereon executable by the one or more processors;

a modular housing configured to mount to the mobile phone, the modular housing including a receptacle configured to receive a rapid diagnostic test or a sample tray holding a rapid diagnostic test, the rapid diagnostic test comprising a test location and a control location;

at least one illumination source disposed in the modular housing and located on one side of the rapid diagnostic test;

an optical demagnifier disposed in the modular housing, the optical demagnifier demagnifying the image of the rapid diagnostic test to place the test location and control location in a field of view of the mobile phone camera; and

wherein the imaging software extracts regions of interest from the test location and the control location in an image of the field of view and compares respective regions of interest with respective threshold values and characterizes the rapid diagnostic test.

The University of California filed substantially identical applications at the same time in the European Patent Office, the China Patent Office (CNIPA), the Patent Office of Brazil (INPI), and many other jurisdictions. The US patent was granted on December 23, 2014. Patent grants in all of the other jurisdictions followed soon thereafter.

On June 15, 2015, the University of California granted five-year renewable licenses to Acme Diagnostics (based in the United States), Bentham Diagnostics (based in Germany), and Chronos Diagnostics (based in China) to manufacture and distribute the devices described in the patents. The royalties were nominal. On June 15, 2020, the University of California renewed all three licenses without altering their terms.

Relying on these licenses, for the past 10 years, Acme, Bentham, and Chronos have been manufacturing large quantities of the devices and selling them (for a modest profit) to the Health Ministries of low and middle-income countries in Africa, Latin America, and Southeast Asia. The Ministries, in turn, have been using the devices to improve and expedite diagnoses of infectious diseases. They have worked remarkably well. They have only one disadvantage: they wear out rapidly and thus need to be replaced on a regular basis.

In February of 2025, the University of California was notified by the Government of the United States that research funding for the University was being substantially reduced. Since then, the leaders of the University have been looking for ways to reduce expenses or to increase revenues. On March 1, the Technology Transfer Office of the University notified Acme, Bentham, and Chronos that their five-year licenses to manufacture the patented RDT readers would be renewed on June 15, but that the royalties would increase sharply. The executives of the three licensees are currently considering their options.

Select one and only one of the three licensees. Answer the following questions, based on the patent law of the jurisdiction in which the licensee that you select is based.

Question 1: It has recently come to light that, in October of 2011, Professor Ozcan supplied prototypes of the devices to the Health Ministries of Namibia and Malawi in hopes of learning whether community health workers in those countries found the devices easy to use. Would that information support a successful challenge to the patent (in the jurisdiction in which the licensee is based) on novelty grounds? What additional information would you need to know to answer this question confidently? (Your answer may not exceed 300 words.)

Question 2: Should the licensee consider challenging the patent (in the jurisdiction in which the licensee is based) on the ground that it fails the inventive-step requirement? What additional information would you need to know to answer this question confidently? (Your answer may not exceed 400 words.)

Question 3: Read the principal claim in the patent carefully. How might the licensee "invent around" the patent – i.e., develop a variant of the device the manufacture of which would neither constitute literal infringement nor run afoul of the doctrine of equivalents? (Your answer may not exceed 400 words.)

Question 4: Aware of the intensifying health crisis throughout the world and the demonstrated benefits of the technology, the licensee is considering continuing to manufacture and distribute the device without paying the increased royalties demanded by the University of California – in other words, daring the University to bring suit. If the licensee adopted such a confrontational stance,

and the University brought suit and prevailed, what remedies would a court in the relevant jurisdiction be likely to grant? (If the licensee you selected is Bentham Diagnostics, you should bear in mind the remedial options that the recently activated Unified Patent Court makes available to the recipients of European patents.) (Your answer may not exceed 400 words.)

Question 5: Suppose that Professor Ozcan, when he learned of the University's plan, objected. His purpose was to promote global public health, not to augment the revenues of the University. Would Ozcan be able in any way to disrupt the plan – and thus enable the licensee to continue to manufacture the devices while paying the nominal royalties? (Your answer may not exceed 300 words.)

Question 6: During the past 10 years, the Ministério da Saúde of Brazil has purchased from Acme many of the patented devices. Dismayed by the impending price increase, the government of Brazil is considering overriding the Brazilian patent in some way and thereby making it possible for a Brazilian company to begin producing the devices and providing them to the Ministério at a low price. Advise the 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.)

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 three (and only three) of the options that you consider especially promising – and explain your recommendations.

[End of Exam]