Patent Law

Fall 2021

Professors William Fisher and Ruth Okediji

1. This is a three-hour, open-book examination. It will be available for download starting at 9:00 a.m. EST on December 14. It must be electronically submitted 3 hours after it is downloaded, or by 12:30 p.m. EST on December 14, whichever time is earlier.

2. The exam mode is <u>TAKEHOME</u>. When preparing for and taking the exam, you may consult any material you wish. The only thing you may not do is consult in any way with any other person after 9:00 a.m. EST on December 14.

3. The exam contains two parts. Your answers to the two parts will be given equal weight when determining your final grade.

4. Exam4 will automatically print your Anonymous ID and word count on the exam copy. Do not write your name on any part of your response. To preserve the anonymity of your response, avoid including any information that would enable the instructor to identify you.

Part I

Question 1:

In 2020, Kara is awarded a U.S. patent on an innovative corkscrew. In 2021, Kara enters into a license agreement with Laurent, under which Laurent is authorized to manufacture and sell the patented product in Italy, but is forbidden to export the corkscrews to the United States. Laurent manufactures corkscrews in a plant in northern Italy and then sells some of them to Max, a retailer in Rome, without informing Max of the content of the license agreement. Max enters into a contract to resell some of the corkscrews to the Wine Enthusiast, a retailer based in the United States. Can Kara enjoin the importation of the corkscrews into the United States? [Word limit: 100 words]

Question 2:

Nathan invents an improved mousetrap on January 1, 2010. Olivia is Nathan's neighbor. Olivia's house is infested with mice. On February 1, 2010, Nathan sells 10 versions of the improved mousetrap to Olivia, but asks that Olivia keep the sales secret. She uses the traps to purge her house of the pests, but tells no one how. On March 1, 2011, Nathan applies for a U.S. patent on the improved trap. Will the application be granted? [Word limit: 100 words.]

Question 3:

In September 2021, John files for a patent on a "sandwich" of diagnostic assays[1] using monoclonal antibodies.[2] He claims:

"An immunometric assay to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to the solid carrier or the amount of unreacted labelled antibody, the improvement comprising employing monoclonal antibodies having an affinity[3] for the antigenic substance of at least about 108 liters/mole for each of said labelled antibody and said antibody bound to a solid carrier."

---

[1] A diagnostic assay is a test to determine the presence of infectious antigens (molecules capable of stimulating an immune response in the body).

[2] Antibodies are proteins released from specific cells that function like a "search" battalion of the human body's immune system. They look for and find foreign invaders (like bacteria or viruses) and mark them for destruction. Monoclonal antibodies are man-made (usually by cloning) proteins that can be traced to the same parent cell.

[3] Affinity refers to the capacity of an antibody produced by the immune system to "bind" (capture) a foreign invader in the body.

The scope and content of the prior art comprises:

- An article in *Nature* that teaches a technique for the in-vitro production of monoclonal antibodies by using hybrid cell lines;
- A YouTube lecture that teaches the use of one monoclonal antibody in a conventional radioimmunoassay technique;
- 3 other patents disclose the use of sandwich assays using polyclonal antibodies[4];
- A textbook that teaches the use of sandwich assays, but not to detect the presence of antigens (i.e., a toxin or other foreign substance in the body) but, rather, to determine the amount of a specific antigen in the body;
- An unpublished PhD dissertation at Harvard University that teaches the production of monoclonal antibodies having an affinity of 10^{10} liters/mole.

Can John overcome a § 103 challenge? [Word limit: 500 words]

Question 4:

To support the claims that they submit to dental insurance companies, dentists are required to include photographs or x-rays showing the teeth of the patients that the dentists treated and the improvements that were made to those teeth. An example of such an image is set forth below.

One of the ways in which dentists sometimes defraud dental insurance companies is by submitting claims for dental services that were never actually provided to patients. To support these false claims, the dentists sometimes submit images showing treatments that they had previously provided to real patients – and for which the dentists had already been reimbursed. To reduce the probability that they will be caught, the dentists typically modify the images – not just by changing the name of the patient, but also by distorting slightly the photograph or x-ray. Fraudulent

---

[4] Polyclonal antibodies are produced naturally in the body by different types of B cells. They are a complex mix of antibodies which are able to address different types of invaders in the human body.

substitutions of this sort can sometimes be detected by human examiners employed by the insurance companies. However, the insurance companies lack the funds to employ enough examiners to catch a significant number of fraudulent claims. The net result: U.S. insurers pay millions, perhaps billions, of dollars each year in false dental-insurance claims.

In 2018, Fraudbusters [FB], a startup company based in Palo Alto, California, developed a technology designed to detect fraud of this type. In brief, the technology generates a digital signature of each image submitted in support of a dental-insurance claim and adds that signature to a digital library. Each time another image is submitted in support of another claim, its digital signature is compared to all of the signatures already included in the library. A computer program using artificial intelligence then ascertains the probability that the new image is fraudulent. If the probability is high enough, the program flags the claim for investigation by a human examiner.

In September of 2019, Frank, the President of FB, approached Samantha, the President of San Francisco Dental Insurance Company [SFDIC], hoping to persuade her to adopt the technology. Samantha concluded that the system would be too expensive and declined the offer. However, she promised to keep their conversation confidential. At an industry conference in January 2020, Samantha broke that promise. In a presentation devoted to the topic of "Fighting Fraud," she described the FB system in detail, but explained why she thought it would not be cost effective.

On February 1, 2020, Frank learned of Samantha's speech. The following day, FB filed a U.S. patent application on the technology. Claim 1 of the application recited, in pertinent part:

1. A computer system comprising:

> memory; and a processor in communication with the memory and configured with processor-executable instructions to perform operations comprising: obtaining, for a first insurance claim, a first radiograph image, wherein the first radiograph image has been submitted by a healthcare provider to an insurance carrier as supporting evidence of a medical service; generating a digital signature representing the first radiograph image through the use of a feature-extraction process, wherein the feature-extraction process comprises providing the image data within the first radiograph image as input to a convolutional neural network[5]; comparing the digital signature generated for the first radiograph image to previously generated digital signatures of other images that have been submitted in association with [other] insurance claims; identifying a match between the digital signature generated for the first radiograph image and one or more of the previously generated digital signatures; determining, based on the match identified between the digital

---

[5] "A Convolutional Neural Network (ConvNet) is a Deep Learning algorithm which can take in an input image, assign importance (learnable weights and biases) to various aspects/objects in the image and be able to differentiate one from the other. … The architecture of a ConvNet is analogous to that of the connectivity pattern of Neurons in the Human Brain and was inspired by the organization of the Visual Cortex." Sumit Sasha, "A Comprehensive Guide to Convolutional Neural Networks — the ELI5 way" (2018), https://towardsdatascience.com/a-comprehensive-guide-to-convolutional-neural-networks-the-eli5-way-3bd2b1164a53.

signature and the previously generated digital signatures, that the first radiograph image is a duplicate or variant of at least one radiograph image previously submitted to the insurance carrier for a different insurance claim; determining that the first insurance claim is associated with potential fraud based on the identified match between the digital signature and the previously generated digital signatures; and based on the determination that the first insurance claim is associated with potential fraud, generating user interface data that enables a user to review whether to approve or deny the first insurance claim.

In November of 2021, the Patent and Trademark Office granted FB a patent that included this claim.

You represent Boston Dental Insurance Company [BDIC]. Brian, the President of BDIC, disagrees with Samantha. He believes that the FB technology could save BDIC a great deal of money. But he is reluctant to pay the high licensing fee that FB has demanded. Brian knows a bit about patent law. He asks you to address the following questions:

  a) Would Claim 1 survive a challenge based on 35 U.S.C. 101?
  b) Would Claim 1 survive a challenge based on 35 U.S.C. 102?
  c) If we were to challenge Claim 1 based on obviousness, what kinds of prior art would we look for and why?
  d) If we used FB's technology without permission, and the patent survived all three of the challenges set forth above, what remedies would be available to FB?

Write Brian a memorandum containing no more than 1300 words, answering his questions.

[This question contains a fictionalized composite of real events and a real patent. Most of the statements made in the question are true, but a few 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 set forth above, you should ignore that knowledge when framing your answer.]

Part II

Select (from the set of materials assigned in this course) a judicial opinion, an article, or a segment of one of the recorded lectures with which you disagree. In an essay containing no more than 2000 words, explain how and why you disagree.

When choosing your target and when drafting your essay, you should strive to demonstrate a critical understanding of the policy basis of the patent system.

You must identify the sources of any quotations or ideas you present in your essay. However, you need not employ any formal citation system; simple parentheticals identifying your sources will suffice.

End of Exam