

FALL '02

15.615/15.647

LAW FOR THE ENTREPRENEUR AND MANAGER

FIRST TAKEHOME EXERCISE

Material Covered:

From Class 1 (“Introduction”)
Through Class 9 (“Setting up a new company”)

INSTRUCTIONS AND ADVICE

- 1. Schedule and timing.* Make arrangements with the TA to have the exam e-mailed to you at a mutually convenient time, and then within **three hours** e-mail back to the TA the completed exam. Keep a hard and computer-readable copy of your exam.
- 2. Sources and communication among students:* During the period the exercise is available, students may not consult with each other about the course. For the exercise, you may consult the text, the readings, and any notes prepared by you, but no other sources. (Since your answers will be evaluated in terms of the course readings and the lectures, especially the readings, consulting other sources would not likely do much good.)
- 3. Weighting and strategy:* There are two questions. Answer both. They will be weighted equally. Each particular point you should address appears in a sentence ending with a “?” Don’t neglect to respond to each “?”
- 4. Format and submission of answers:* Your answer should have a cover sheet which includes your name, “ESL” if English is your second language, and the exact word count for the entire document. Start the answer to each question on a fresh sheet. **Your entire submission should not exceed 1,000 words.**
- 5. Some general advice (READ THIS CAREFULLY):* You are not supposed to be a lawyer, and I don’t expect you to have definite answers to legal questions. You are supposed to be a manager with the ability to make a **preliminary** assessment of legal problems. Each question will ask you to address legal issues in a business context from the point of view of a manager. It doesn’t matter much if I don’t agree with your judgment as to how serious a risk or problem is, so long as you spot it and understand the legal and managerial implications of it. Your answers should demonstrate your understanding of and ability to express broad legal concepts, and your ability to spot where and how the law will have an impact on a business problem and the individuals involved. It will not be necessary to cite specific cases or statutes. **Make sure that your answer focuses on how general legal principles apply to the facts you have been given.** To the extent that the facts are not as specific as you would like them to be for your assessment, point that out. You shouldn’t concern yourself with implausible possibilities. I don’t try to “trick” people in these exams. Look for the main issues suggested by the facts, and get right to them. **Be responsive in your answer; that is, answer the specific questions that have been asked from the perspective you have been asked to assume.** (For example, if you are asked to

provide some alternative courses of action, do so. If you are asked to assess risk from the perspective of a particular party, do that.) Your answers should be well-organized and clearly written. The length limit is tight, so you will probably have to edit your answers carefully to cover the necessary points in the limited space allowed.

6. Grading: If your exam is over the length limit, or submitted late, there will be a downward adjustment to your grade.

QUESTIONS

Question 1. You are Smarty Aleck, a senior manager at Device Inc., a leading manufacturer of medical diagnostic equipment. You report to the CEO, Ms. Top Dog. Top is a brilliant engineer whose main strength is product design, but she is a bit heavy-handed and combative. You are a stronger general manager, and Top relies heavily on your advice.

Device's main product is a scanner that produces cross-sectional images of the human brain. Brain tissue requires especially sensitive readings. Device is working on a new model which will be even more sensitive and which may permit the early diagnosis of Alzheimer's disease.

Device has also been trying to build a relationship with Dr. Look at Metropolis Teaching Hospital (MTH). Dr. Look is a leading authority on the early diagnosis of Alzheimer's.

Device's main competitor is WestCoast Co., a California manufacturer. WestCoast has never marketed a scanner designed specifically for the brain. However, WestCoast has recently brought out a new model of its general use scanner, and it is a big advance. Some neurologists are saying it might be a substitute for the current Device machine, and Device is worried that it might even be as good as the newest Device scanner that is still in the development stage.

Device would like to get a good look at the new WestCoast machine, but WestCoast sells machines only to health care providers under contractual arrangements which discourage resale, so there is no secondary market. WestCoast would not sell a machine directly to Device.

Top came up with the idea of entering into a contract with with MTH and Dr. Look for a "sponsored research project." The contract for the project provides that Device will make payments to MTH for a total of \$2 million, and MTH will use some of those funds to purchase the latest model WestCoast machine for use in Dr. Look's research at MTH. Dr. Look's lab already has a Device machine, and Device technicians are frequently in Dr. Look's lab. Under the terms of the sponsored research contract, Dr. Look will give Device access to "all research data" (other than data which would violate rules of medical confidentiality). Top is hoping that Device technicians will get a good look at the new WestCoast machine.

Dr. Look understands what Device is doing, but the MTH managers are not aware of the competitive implications of Device gaining access to a WestCoast machine through Dr. Look.

Device has made a first payment to MTH of \$1 million. MTH has ordered the WestCoast machine. MTH has signed a purchase agreement with WestCoast which specifies that the machine is to be used "exclusively for medical diagnosis and research." The machine costs

\$700,000. The machine is delivered and installed in stages. Most of the heavy hardware is already in Dr. Look's lab, but certain key parts including the computer "brain" have not yet been delivered or installed. MTH has paid \$500,000 to WestCoast, with the remainder due when the machine is fully installed and operating.

You and Top just learned that yesterday Dr. Look received what he described as a "nasty phone call" from an executive at WestCoast. The WestCoast executive cited the contract language about "exclusively for medical diagnosis and research" and asked if Dr. Look was "working for Device." He also said he would need more information about how the machine would be used by Dr. Look. Dr. Look said "I just told him that I didn't know what was bothering him, and that if he had questions about the research he should take that up with MTH." The WestCoast executive implied that the remaining components would not be delivered or installed until this was cleared up. Dr. Look is very worried that "This isn't going to look very good to MTH."

Against that background you receive the following memo from Top. How are you going to respond to the questions in her memo?

MEMORANDUM

To: Smarty
From: Top
Re: WestCoast

I've called in our lawyer for a meeting tomorrow morning. I'd like to sit down with you this afternoon to think through this WestCoast problem so that we are primed for that meeting.

Assume MTH decides to insist that WestCoast deliver the machine, that WestCoast refuses, and that MTH sues WestCoast on the sales contract. If WestCoast says MTH was in breach of the "research and treatment" clause, what are the arguments each side is going to make? If MTH does win the lawsuit, does that mean MTH gets the machine? If MTH only gets damages, how large are they likely to be? (Because I'm going to want all our money back.) What can MTH do if WestCoast says "We will give you your money back and we will come pick up the machine"?

Assume MTH is not inclined to push WestCoast on delivering the machine, and we try to push MTH by threatening that we will sue MTH under the sponsored research contract. What are the arguments for and against us in that suit?

Question 2. You are still Smarty Aleck and working for Device. It is three years later. The dispute over the WestCoast machine got settled without much fuss when Device backed down. WestCoast soon developed serious financial problems. WestCoast struggled along for about two years, and was then acquired by Device. That acquisition closed 6 months ago. Device kept the main WestCoast production facility working for about 3 months after the acquisition, and then phased it out by shifting all production to the main Device plant.

There will be a meeting of the executive committee of the Device Board of Directors in one week, and the main topic is a review of the acquisition of WestCoast and any problems from that acquisition that need attention.

To get ready for that meeting, you and Top have been meeting with Device personnel who have key responsibilities in implementing the acquisition. One of these is Snoopy Sam, who was in charge of shifting all production to the Device facility. Snoopy has just reported to you some troubling information. Manufacturers of medical devices must make periodic reports to a government agency, the US Food and Drug Administration (“FDA”) about production line quality control and the results of any internal product quality audits. The FDA’s regulations are not completely clear as to when a problem is serious enough that it must be reported. According to Snoopy, it appears that during the year right before WestCoast was purchased by Device, and when WestCoast was in financial distress, WestCoast’s reports to the FDA became less complete, and were not as complete as would be expected in accordance with general industry practice. WestCoast seems to have omitted data on certain quality problems. However, these quality problems were small, and very likely had no impact on the safety or efficacy of the machines. It is not yet clear whether the pattern of non-reporting continued during the 3 months after the purchase of the company, while the WestCoast facility (then owned by Device) was still in operation.

Like all medical device manufacturers, Device worries a great deal about products liability lawsuits. Reports about quality problems to the FDA are a public record, and can encourage products liability lawsuits against the company and make these lawsuits easier for plaintiffs to win. On the other hand, the FDA has been known to bring criminal charges for failures to report.

When Snoopy leaves, Top says to you: “This reporting problem can become a huge legal mess. You and I should talk about it first thing tomorrow morning. I’m putting you in charge. Put together an outline of what we need to worry about and how we are going to approach this problem.” What are you going to suggest?