PHARMACEUTICAL PATENT LAW

PIERCE LAW IPSI 2009

Final Exam

This is an open note final. Computers may not be used, however, notes and class materials may be printed and referenced. You will have one hour for this exam.

Short Answers
Please provide a one-word to one-sentence answer for the following questions

1. As counsel for a brand/innovator company, what type of studies will you recommend to be carried out in order to obtain an additional 6 months of exclusivity to all of the companies Orange Book listed patents?

2. As counsel for a brand company, when will you request patent term restoration?
   a. On which patent will you request such extension?
   b. How will you calculate the time given back to the patent?

3. How does a generic company receive the entitlement to 180-days of exclusivity?

4. As counsel for the brand company, what questions will you ask the inventors to obtain the greatest patent protection?
   a. What types of patents will you file?
   b. Will all of these patents be eligible for listing in the Orange Book?

Fact Pattern

You are a patent counsel for a generic drug company. Your company is interested in filing an ANDA to the popular drug Pierceitril®. The generic name for Pierceitril® is Studious HCl. This drug has the useful indications of helping students study harder, for longer periods of time, and to increase their concentration. Below you will find the Orange Book listing for Piercetril®.

Patent Number	Claims	Expiration
8,800,800	The compound	January 1, 2013
8,900,900	Polymorph A of Studious	September 1, 2017
9,000,000	A method of increasing concentration	December 1, 2017
9,100,100	Formulation	February 1, 2018

This product was approved on June 2, 2009 and received 5 year NCE protection until June 2, 2014.

Questions:

1. When will you advise your client to file their ANDA application?

2. How will you advise that your client certifies to each of the listed Orange Book patents?

3. If any of the patents will be certified with a paragraph IV or viii certification, how GENERALLY will you argue? What additional information do you want to know? How will you obtain this information?

4. What date will you tell the client is a reasonable time to expect a product approval?

5. When will you advise that your client launch the product? What might this depend on?

6. What other concerns will you advise your client of?

7. If you are the brand company being served the notice letter of the above filing, how will you respond?

8. As a brand company, what other tactics will you use to delay the generics entry?