

University of Arkansas Microelectronics-Photonics Graduate Program

PhD Candidacy Exam – March 2008

Bio-Chemistry Area of Emphasis Exam

PROBLEM TO BE SOLVED

Diabetes mellitus (DM) is a metabolic disorder suffered by a large percentage of the population around the world. In North America, the majority of DM cases are *type 2*, caused by defective insulin secretion and/or insulin resistance. Insulin is a peptide hormone secreted by the pancreatic beta cells. The early stage of *type 2* DM is characterized by elevated levels of insulin in the blood. If this condition is detected early, *type 2* DM can potentially be reversed by improving the patient's insulin sensitivity or reducing the glucose production.

You are the CTO of a small biomedical company in charge of developing a nanotechnology based sensor for fast-detection of insulin level in a blood sample. Currently, immunoassay is the most popular method for measuring human insulin. In this method, anti-insulin antibodies are used to illuminate insulin particles in the sample, and the result is measured by an optical reader. Your sensor can consist of some components found in immunoassay, but the sensor output must be an electrical, instead of an optical, signal. In addition, the response time and sensitivity level of your sensor must be at least close to what an immunoassay can provide and must provide some identified product characteristic that would create an opportunity to compete for existing or new market share.

Your proposed sensor must also be portable, capable of being deployed rapidly in a non-laboratory environment, and able to operate continuously in a stand-alone mode for a minimum of 12 hours without recharge.

YOUR DELIVERABLE

Your task is to write an internal proposal for your corporate officers describing your approach to this issue. In this document you should lay out the development of a nanotechnology based portable sensor for insulin level detection. Be sure that you address all of the following in detail:

Current technologies – What is currently available on the market? What are the sensing mechanisms; time response; sensitivity level; and cost for available products? The current state-of-the-art for both the science and the implementation should be described, making use of diverse resources such as science literature, journals, conference proceedings, the internet, patents or other sources of existing public knowledge. **Be sure to cite all references that you use and to quote any word-for-word transfer to your report.**

Your design – What is the basis for the chosen sensing mechanism? What is the estimated response time, repeatability, and sensitivity level? Why is your sensor better than the existing test kits and what product attribute or attributes will allow suitable market penetration for profitability? Be sure to address both the scientific and engineering issues of the question.

Other Issues – Address any other issues of major importance

Manufacturing flow – provide a detailed step-by-step process flow for manufacturing the sensor in your company.

Testing and Qualification - Describe a set of tests and demonstrations that you will use to demonstrate the effectiveness and reliability of your sensor and instrumentation in typical field usage conditions.

Cost Analysis -

At least in qualitative terms, describe the factors that will enter into the cost analysis for developing your sensor and instrumentation unit; then extrapolate that to describe the cost factors involved in fabricating 10,000 units of your sensor on an annual basis. Use this as an introduction to then discuss your expectations of the competitiveness of your product and what would be the expected return on investment, fully explaining your assumptions.

Intellectual Property - List in rank order of importance all commercial, academic, and governmental IP sources that were consulted while formulating the answer, including key important reference data, as an appendix to this exam. For instance, if the IP source is a patent, include the patent number; title; inventor name; and assignee name. (The full list will not be counted as part of the 15-page limit.) The three that are the most significant threats to your solution should be discussed within the 15-page document, making comparisons of strengths and weaknesses of these approaches relative to your own.

Most importantly - this is just a minimum list of issues you might consider. There may be many more. The point is that your report *should contain the evidence* needed to make an effective and compelling case to your CEO in order to insure that she makes the right decision.

Hint - Your report should read like a story – one logical step followed by another. This will help you stay focused! Re-read along the way to be sure that you have one logical step followed by another.