“Man vs. Nature: *Monsanto* and Genetically-Modified Soy Beans” – Sam S. Han, Ph.D.

In addition to the Plant Patent Act (PPA) and the Plant Variety Protection Act (PVPA), the law affords protection to man-made plants through 35 USC 101 (Utility Patent). Indeed, with a Utility Patent, protection extends beyond plants, and includes other man-made organisms such as bacteria and mammalian life forms. In ruling that "anything under the sun that is made by man" is patentable subject matter, the Supreme Court in Diamond v. Chakrabarty carved out three exceptions: abstract ideas, products of nature, or natural phenomena are not patentable subject matter.

Monsanto Company owns Utility Patents to genetically-modified (GM) soybeans and other GM organisms (GMOs). With its GMO patents, Monsanto employs aggressive marketing and legal strategies to maximize its market-share and, hence, its profits. Monsanto's aggressive tactics have led to numerous patent-infringement lawsuits where some organic farmers have been sued out of business. Many legal theories (including patent exhaustion and antitrust) have been argued in Monsanto's cases. However, one question that has not been addressed is whether or not the second-generation Monsanto seeds are patent-eligible subject matter.

Once the GM-soy seeds mature into a GM-soy plants, those plants pollinate biotically (by bees) and abiotically (by wind). Thus, while the first-generation GM-soy plant may be "made by man" in a laboratory through genetic engineering, subsequent generations of GM-soy plants are the product of biotic and abiotic pollination, which is a natural phenomena that has existed since the dawn of time. Similar self-propagating mechanisms exist in animals as they do in plants.

The question that we examine in this presentation is whether or not second-generation genetically-modified organisms are outside of patent protection because they are "products of nature" (or naturally-occurring phenomena).

“Making Sensible Patent Investments” – Bob MacWright

In these challenging economic times, many companies and universities are looking for ways to reduce the cost of protecting their inventions and products with patents. Of course, many are economizing by looking for discounted attorney's fees; but since attorneys have to run their businesses too, this is a self-limiting strategy. A more far-reaching strategy is to view patenting costs as investments, just like investments in the stock market. Although there are always incalculable risks, you want to invest your patenting dollars in those applications that have the best potential to provide value in the long term, and hopefully limit the overall cost. Evaluating the down-stream economic potential of each application relative to others you have can be difficult, especially for early-stage technologies, but there are a number of key questions you can ask to guide your thinking. For example, is this a patent you will be willing to license or enforce against infringers? How easy might it be for a competitor to evade infringement? If it is a process invention, could you tell from looking at a competitor's products that they have infringed, or would you need to look at their factory - which may be impossible to do? If it is a fast-moving field, will the invention be obsolete before the patent issues? Considering the strength of competing products, is there room in the market for this product? Will using your invention require a licensee to tear down its factory and build a new one, which is unlikely? These and

other key questions can help you decide what inventions to patent, and importantly, which ones not to spend the money on. In addition, since downstream patenting costs can compound year-after-year, these same questions can help you evaluate the older applications in the portfolio, and decide which ones you can live without.

"How Statements to the FDA Can Create Some Real Challenges in Patent Prosecution and Enforcement" – Tom Irving

In prosecuting a patent application covering an FDA approved product, clients will have made representations to FDA. Particularly interesting can be pre-IND and IND submissions. In those, the applicant tries to get FDA to require minimal testing for approval. As you can imagine, the IND applicant may try to convince FDA that the literature proves up both the safety and efficacy of the IND candidate. We will examine real life experiences of interplay between such submissions, patentability, and Rule 56.

"USPTO's Green Technology Initiative" – Esther Kepplinger

Esther will be providing a summary of the Patent Prosecution Highway (PPH) and its practical uses. Under the PPH, an applicant receiving a ruling from the Office of First Filing (OFF) that at least one claim in an application filed in the OFF is patentable may request that the Office of Second Filing (OSF) fast track the examination of corresponding claims in corresponding applications filed in the OSF. PPH will leverage fast-track examination procedures already available in the OSF to allow applicants in the OSF to obtain corresponding patents faster and more efficiently. As of May 25, 2010, the USPTO has eliminated the fee for the petition to make special under the PPH programs. The elimination of the petition fee will simplify the PPH requirements and is expected to encourage greater PPH participation.

Since 2006, the USPTO has implemented the Patent Prosecution Highway (PPH) programs with a number of patent offices as part of efforts to pursue work sharing to avoid duplication of work among patent offices, and for reducing its own pendency and backlog. The PPH applications have proven, on average, to take significantly less time to prosecute than non-PPH applications. Using the PPH process also increases the sharing and re-use of information (primarily search and examination results) between the USPTO and its partner patent offices. Improving the PPH framework to make it more user-friendly, and thereby encourage greater participation by applicants, would support the Office's goal to optimize both the quality and timeliness of patents. Therefore, the USPTO has determined that all PPH applications will now be advanced out of turn for examination under 37 CFR 1.102(a) in order to expedite the business of the Office. Applications that are advanced out of turn under 37 CFR 1.102(a) do not require the petition fee set forth in 37 CFR 1.17(h).

Esther will also be providing information on the USPTO's Green Technology Pilot Program for our practitioners. Under the Green Technology Pilot Program, an applicant may have an application advanced out of turn (accorded special status) for examination, for applications pertaining to green technologies including greenhouse gas reduction (applications pertaining to environmental quality, energy conservation, development of renewable energy resources or

greenhouse gas emission reduction). Currently, an application pertaining to environmental quality, or energy conservation, development of renewable energy resources or greenhouse gas reduction will not be advanced out of turn for examination unless it meets the requirements of the accelerated examination program. Under the Green Technology Pilot Program, applications pertaining to environmental quality, energy conservation, development of renewable energy, or greenhouse gas emission reduction, will be advanced out of turn for examination without meeting all of the current requirements of the accelerated examination program (e.g., examination support document). The USPTO will accept only the first 3,000 petitions to make special in new applications, provided that the petitions meet the requirements set forth in the notice published on December 8, 2009, in the Federal Register, as modified by the Federal Register notices published on May 21, 2010, and November 10, 2010.

"IP Considerations for Medical Devices from Start-ups to Fortune 500 Companies" – Panel discussion moderated by Mary Beth Privitera featuring Dan Kincaid, Joseph E. Topmiller, and Sam Privitera

This panel discussion will provide perspectives of attorneys, entrepreneurs, and those that have worked with a broad range of companies dealing with a broad range of issues centered around the development and marketing of medical devices. The panelists will provide insight as to the challenges, best practices, and other considerations that come into play as they work together to develop, fund, license, and acquire the technology. They will also discuss patent and licensing issues, including deal killers, partnering with other organizations, and the determination of market potential in the context of their respective experiences.

"FDA Regulation for Medical Devices" – Elsa Abruzzo

The medical device market changes frequently in terms of technology, risk potential, marketing, and reimbursement. The rate of change intensifies for the fast-paced world of startups and emerging growth companies. For this reason it is vital for entrepreneurs, management, and regulatory professionals to be aware of existing requirements and new developments in the medical device market. The course is intended to enable participants to ask the right questions and adapt the course concepts within their own organizations.

This course will provide a basic understanding of US regulatory strategy for medical devices. Participants will learn the value of establishing a sound regulatory strategy with executive management, director, and investor buy-in early in the development process. The instructor will present guidelines for developing successful strategies for medical devices, including definitions and classifications, elements of regulatory strategy, sources of competitive and regulatory intelligence, and product approval pathways in light of pending FDA regulatory reform. Participant will also gain a general understanding of US the regulations, including guidelines, practical steps, and strategic considerations for determining a product's regulatory route to market. The course will examine:

- How to determine device classification as well as electing the appropriate FDA application for the device, including labeling, establishment registration, and listing;
- How to identify predicate devices for, plan and assemble a 510(k) submission;
- When and how to effectively use preIDE and other early collaboration meetings with FDA;

- What clinical data maybe be required to support a particular device or type of submission;
- How to create a viable clinical plan and obtain IDE approval for US clinical trials;
- What is involved with other type of submissions, including HDEs, various types of PMAs, and PDPs;
- How to interact with FDA during the review process and deal with post-market clearance or approval issues; and
- How to most effectively and efficiently integrate your US regulatory strategy into your global regulatory strategy.

"Biosimilars Legislation and the Biosimilar Approval Pathway" – Kevin Noonan, Esq., Ph.D.

As part of the comprehensive health care reform bill passed last year and signed into law by the President, the U.S. now has a regulatory approval pathway for "follow-on biologic" drugs (also called "biosimilars"). The law has several important features that constitute challenges to the biotechnology community. These include:

- Indeterminate requirements for "biosimilarity": the law leaves to the FDA the principal responsibility for determining how similar a "biosimilar" drug needs to be, and the criteria required for such a drug to be "interchangeable" with the innovator biologic drug (important because interchangeability permits a pharmacy to fill a prescription with the biosimilar drug without physician approval each time). The Agency has had one public meeting on the criteria it should adopt, but it may be some time before final regulations are promulgated

- Patent infringement litigation under this scheme is discouraged by a complex set of provisions requiring the innovator and the biosimilar applicant to exchange information, both regarding the biosimilar drug application and the innovator's patent position, intended to narrow the issues and patents involved in litigation. In addition to creating delays (of about 280 days) between notice that the biosimilar application has been filed and when litigation can commence, the regime established by the statute has several time-intensive periods (some less than 30 days) where a patentee innovator is required to respond with specific, detailed information to the biosimilar applicant, where failure to do so can cause serious damage to the innovator's position. As a result, there is an increased need not only for vigilance, but for proactive portfolio management for patentee innovators to be prepared for responding to a biosimilar applicant's challenge.

While many of the details of the new biosimilars regime are still to be worked out, we will discuss the most likely contours of biosimilar approvals under the new law.