Serendipity, Inc. is a medium-sized biopharma company. It has had great success marketing biologic and small molecules therapies in a diverse number of therapeutic areas due to its own R&D efforts, as well as strategic partnerships and acquisitions. Currently, however, it needs to double down on its efforts to get two lead candidates in strategic growth areas through Phase III trials in the next 1-5 years.

Serendipity's management has decided that it needs to winnow down the number of therapeutic areas of Serendipity's involvement to focus on these growth areas.

Serendipity's management calls in a consulting group to evaluate its various divisions and to make recommendations for divestiture.

The consulting group recommends, among other things, that Serendipity should not place further efforts on its diabetes business and instead sell it off. The diabetes treatment division consists of two approved drugs for diabetes, a proprietary metered dosage delivery device and method, as well as some earlier stage programs that have not received regulatory approval.

Specifically, Serendipity’s diabetes business portfolio consists of:
1) a marketed small molecule, glipancide (NALITYA®), administered orally;
2) an extended release form of glipancide, also oral, which is in development;
3) a marketed biologic, pancrezumab (POURITON®), which cannot be delivered orally;
4) a painless, dial-a-dose injection delivery device (PAINFREE®) optimized for pancrezumab; and
5) several early stage small molecule compounds aimed at targeting various aspects of a novel pathway implicated in the pathogenesis of disorders, other than diabetes, related to insulin resistance (such as liver cirrhosis, atherosclerosis etc.)

Serendipity is considering several potential avenues for divesting this business from its main operations. To that end, it has recently made preliminary contact with three “suitors”.

Register Now: AmericanConference.com/IPDueDiligence | 888.224.2480
MegaPharm, an established, international biopharmaceutical company, is interested in assuming the diabetes portfolio as it has experience in developing and marketing diabetes drugs, but, as the injection devices could enhance the patient experience with some of its existing drugs, is particularly interested gaining access to that technology. MegaPharm is not interested in the early stage work.

Biovol 2, a small privately-held company, is interested in obtaining access to IP and the compounds surrounding the novel pathway, so that it can progress the existing candidates through clinical trials, and using what it learns about the trial design, expedite the development of new candidates using its platform discovery process that targets the same pathway.

Additionally, Moneybags, a venture capital company has approached Serendipity about forming a spinout of the diabetes portfolio as a whole, as a co-investor along with Serendipity and other VC’s. In an effort to buttress the strength of Serendipity's diabetes portfolio, Mark Deviousberg, Serendipity’s CEO, is in discussions with Wampum Pum, Chief of the Native American Ute Nation. Deviousberg’s proposal would convey to Ute title to the patents of Serendipity that cover FDA approved diabetes products and devices, reserving for Serendipity an exclusive license to the patents as well as the obligation to pay for any enforcement of the patents and any challenge to their validity. Ute would have the obligation to maintain title to the patents and to take all steps needed to maintain them in force but will be required to consult with Serendipity prior to taking any such action and to adopt Serendipity’s suggestions about how to proceed. Wampum is willing to enter into such a transaction but wants to be paid many millions of dollars.

In more detail, the IP and development history of each component of the Serendipity diabetes business is as follows:

Glipancride (NALITYA®) and Glipancride XR (Extended Release):

Glipancride (NALITYA®) was approved in 2016 in the US for treating type II diabetes. There is no composition of matter per se patent, as the compound was previously known for use as a food preservative, and the patent to the glipancride molecule expired decades ago. Scientists at Serendipity speculated that, because glipancride kept the level of sugar constant in various foodstuffs, it might help stabilize sugar levels in a person’s bloodstream. Tests in animal models indicated that glipancride did stabilize sugars in the blood with a reasonable safety profile and soon enough, Serendipity was testing it in humans. As Serendipity progressed glipancride through clinical trials for use in treating diabetes, it was able to obtain patents covering the method of using glipancride to treat diabetes and a pharmaceutical formulation containing glipancride. These patents are listed in the Orange Book and glipancride was granted a 5-year (NCE) marketing exclusivity by the FDA.

Serendipity has also developed an extended release technology in-house, and filed on March 15, 2013 two provisional patent applications: a first provisional patent application covering the extended release technology as a platform, and a second provisional patent application directed to the specific embodiment of the lead molecule combined with the extended release
technology, and also encompassing formulations containing the lead molecule as well as means for providing a specified pharmacokinetic profile. Serendipity followed up one year later with PCT applications. The PCT applications contained additional information on certain aspects of the extended release platform and on a broader effective dosage range for glipancride within the extended release formulation and also contained claims encompassing these newly added features.

Serendipity has recently discovered the existence of a potential blocking portfolio of patents directed to some aspects of the manufacture of the extended release technology. It has been weighing its options as to whether to seek only a search and noninfringement/invalidity opinion, or file an IPR (assuming close prior art was developed in the search and/or a flaw in entitlement to priority was identified in the opinion) or PGR (on any grounds that might be available) against some or possibly all of the patents. Serendipity is also seeking advice about the risk that the owner of the blocking patents will seek to enter into an agreement with a Native American Nation similar to that contemplated by Deviouberg.

Pancrezumab (POURITON®):

Pancrezumab was discovered by another company, Bankrupt Biologics, in collaboration with the University of Technology, in 2000. A precursor to panreuzumab was identified by a massive screening program of pancreatitis patients. The program yielded only a handful of active antibodies and only one with high affinity. Bankrupt and the University filed an application in 2000 on the composition of matter, as well as potential general methods of use, including diabetes. The purification processes by which clinical/commercial grade panreuzumab is prepared to high yield and efficiency were kept as a trade secret by Bankrupt. Bankrupt brought the drug through to phase I trials. Despite borrowing much money, Bankrupt found itself struggling to fund and perform phase II trials, so it entered into collaboration with Serendipity for its late-stage development and commercialization expertise, and its FTEs/money. During this collaboration, a patent whose claims most closely track the current label for the dosage regimen of panreuzumab to treat diabetes in the US was filed by Serendipity and names only Serendipity inventors. The drug was brought through phase III trials to approval for use in treating type II diabetes in 2014.

Upon approval, Serendipity exercised an option in the agreement to develop and market panreuzumab globally. As part of the option exercise, Bankrupt exclusively licensed its interest in all its underlying patents and patent applications to Serendipity, putting Serendipity in control of the prosecution of the patent applications worldwide but retaining a right to review all papers to be filed in patent offices around the world, and also exclusively licensed to Serendipity its know-how.

The PAINFREE® technology:

The PAINFREE device is a pen-type injector for administration of medicinal products from a multidose cartridge. The device permits users (typically patients with no medical training) to set the delivery dose, to correct inadvertently set inappropriate doses and to conveniently and painlessly self-administer the medication and manage their condition.
Patent applications resulting in **Patents A and B** were filed by Bankrupt and later exclusively licensed to Serendipity, with Bankrupt retaining a right to review all papers to be filed in patent offices around the world, and issued from the same ancestor non-provisional application filed on **March 3, 2004**.

**Patent A** would normally expire on **March 3, 2024** but has received three years of patent term extension because of regulatory delay of approval of panrezumab and will expire on, **March 3, 2027**. Patent A is directed to the overall pen injector in which a piston mechanism cooperates with a dose dial sleeve located between the pen injector’s housing and the injector’s piston rod. The dose dial sleeve has a helical thread; a drive sleeve interposed between the dose dial sleeve, and the piston rod has a helical groove. The lead of the thread and the lead of the groove are the same, allowing the two sleeves to move and/or rotate relative to each other at the same rate. This reduces the pressure required to be exerted by the user to push the piston and makes the injection practically painless. This fact pattern does not state whether Patent A contains any claims to a dosage form comprising the claimed pen injector loaded with panrezumab nor whether panrezumab is even mentioned in the specification of Patent A.

**Patent B** has a non-provisional filing date of **March 2, 2004** and will expire on **March 2, 2024**. It is directed to aspects of the drive mechanism for use in the foregoing pen injector, specifically that a drive sleeve is releasably connected to the dose dial sleeve (they are to be connected only during dose selection and loading). A piston rod is also provided threadedly engaged with the drive sleeve; and a clutch mechanism is provided and located between the dose dial sleeve and the drive sleeve. The clutch serves to release the drive sleeve from the dose dial sleeve during injection of the loaded dose.

**Patent C** has a non-provisional filing date of **March 3, 2004** and an expiration date (with PTA) of **March 17, 2025**. The patent application resulting in Patent C was filed by Bankrupt and later exclusively licensed to Serendipity, with Bankrupt retaining a right to review all papers to be filed in patent offices around the world. It is directed to additional aspects of the drive mechanism, namely certain features of the piston rod and the drive sleeve. However, unbeknownst to Serendipity but known to and considered highly material by Bankrupt, these features are disclosed in a prior art reference that was not before the Examiner who examined the application for Patent C. Also, Patent C contains one working example reporting false data as demonstrated by a post-filing publication authored by a third party.

**Early stage portfolio:**

The founding research and development work that elucidated the novel biochemical pathway was done at State Institute of Technology (“State), within a large laboratory run by Professor. Kribster. Professor. Kribster collaborated with the laboratory of Professor Synthesis at Chemistry University (“Chemistry”), who had synthesized various novel scaffolds, to see if any compounds could be inhibitors of the new pathway. Both Professors. had received federal grant funding for their work. as a result, the U.S. government has a license to as well as “march-in rights” in any patents they obtain on the work. Sure enough, several promising candidate species of the scaffolds were discovered based on their ligand binding properties to various proteins along the pathway.
Professors. Synthesis and Krebster submitted an abstract describing the scaffold compounds of interest
to the Annual Meeting of Sugar Metabolism Researchers, which abstract was accepted for a poster and
oral presentation. Chemistry’s tech transfer office learned of the presentation two days prior to the
meeting, but after the abstract had been published online, and filed a provisional patent application on
the scaffold compounds. The applications were filed naming only Professor Synthesis as an inventor;
no assignments were executed.

Professor. Krebster’s graduate student, Ms. Ina Genius, who generated much of the target binding data,
subsequently reported the data in her dissertation, a hard copy of which was filed at the State library. 12
months after the filing of the provisional patent application, Chemistry filed a PCT application, naming
Chemistry and State as Applicants that included some additional data from Professor Krebster’s lab
since the filing of the provisional application, which supported better some of the use claims to the
compounds. The target binding data of Ms. Genius was also included in the PCT application but not in
the provisional applications.

It is at this stage that Serendipity obtained an exclusive license to all of these patent applications and
foreign and domestic applications claiming priority to them, as well as all Chemistry “technology” related
to the compounds. Serendipity filed patent applications stemming from the PCT application globally and
began a research and development program, which it conducted through its European division,
Serendipity GmbH.

Serendipity GmbH synthesized some additional compounds based on the original Synthesis scaffolds,
and found that they had unexpectedly better properties in animal models of diabetes, as well as
unexpectedly good properties in models of some other indications such as polycystic ovarian, an orphan
disorder.

Serendipity’s in-house legal department filed a U.S. provisional application for the new compound
species and data, as the species were not disclosed in the original scaffold filing, and plans to file
additional patent applications on this discovery that include updated data and information from the
clinical trials. Serendipity’s species invention disclosure names its employees or contractors as
inventors, including three other scientists (an American, a German and a UK inventor). Serendipity has
not yet converted the U.S. provisional application into a global filing.

Because there is so much competition in the diabetes marketplace, Serendipity is considering a
regulatory strategy whereby approval is first obtained for the orphan disorder.

From an IP due diligence point of view, what advice would you provide to Serendipity, in the first
instance as a target. And assuming you are advising the suitors, what would you tell each of
them?