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NEGOTIATING LICENSING AGREEMENTS – ROLE PLAY

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[*] The views expressed in this document are those of the authors, and not necessarily those of the WIPO Secretariat or its Member States.

INTRODUCTION

1. To illustrate the issues which arise in the negotiation of a licence we will be presenting a Rôle Play, in which the two presenters will each play the part of one of the key protagonists – the representatives of the Licensor and the Licensee.

2. The Rôle Play will cover all of the stages of the negotiation of the Licence from the first contact, in which the Licensor must meet the Licensee and persuade him that he wishes to consider a licence to the technology, through all stages of discussing and agreeing a project which will prove the technology through to the licence itself.

3. During these discussions and negotiations the protagonists will have the opportunity to demonstrate the typical characteristics and conflicts of priorities which often arise between universities and research institutions and business. (Whilst many licences arise between businesses there are fewer issues which tend to arise because the priorities of the organisations are more similar).

THE TECHNOLOGY – BACKGROUND INFORMATION

4. The technology to be licensed is described below as it might be described by a university. This is the description which has been received by the Licensee and which has given rise to the first meeting.

Technology Description

5. This technology, combining the use of a light-producing gene from the American firefly and a chemical bromide, is developed as a broad-based therapeutic approach to the treatment of cancers and infections. Concept: in recent years, photodynamic therapy (PDT) has emerged as a promising tool in both antiviral and cancer chemotherapy. In the presence of light of the appropriate wavelength, a photoactive molecule absorbs light and inactivates the virus or destroys tumor cells. Hypericin is an example of a photactive chemical that has shown these properties. However, PDT cannot treat regions of the body impenetrable to light. Thus, two needs exist: (1) a method for targeting PDT at viral-infected cells and or tumor/cells, and (2) an energy source connected to photoactive molecules so that PDT can work in all regions of the body. Luciferin is an effective photoactive energy source which emits light in the 520-68nm range. Hypericin is photactivated by light in the 540-660nm range. Therefore, luciferin and hypericin are a suitable pair of an energy source and a photoactive molecule.

Potential Applications and/or Markets

6. Example Use in HIV treatment: T-Cells from an HIV infected host are isolated and transformed with a plasmid construct containing the luciferase (light-activating) gene from the North American firefly and a promoter sequence that is transactivated by virus replication. HIV TAR and EAIV LTR are examples of such promoters. Once transformed, the T-cells are reintroduced into the infected host. The host is also injected with tethered protein, which increases the efficiency of the following reaction. After the introduction of the transformed T-cells and injection of the luciferin -hypericin tethered protein, the HIV virus replicates and activates the transgene, causing luciferase production (1). The luciferase enzyme then

activates the injected luciferin protein, resulting in light emission (2). The injected photo-active hypericin absorbs light and singlet oxygen is produced. The singlet oxygen, in turn, inactivates HIV replication.

Stage of Development

7. The technology has been proven in vitro using Equine Infectious Anemia Virus (EIAV) which has similar genetics to HIV. Four US patents have been issued (5,780,287; 5,786,198; 5,952,311 and 6,160,024 issued on 7/14/98; 7/28/98; 9/14/99; and 12/12/2000) and applications have been filed in other countries using the PCT.

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