



TECHNOLOGY LICENSING OPPORTUNITIES

STEM CELL TOOLS FOR DRUG DEVELOPMENT

Cytiva have a broad patent portfolio spanning a range of stem cell related technologies including, but not limited to, cellular compositions, culturing and expansion methods, differentiation protocols, and uses of stem cells and stem cell-derived cells in various non-therapeutic assays.

Cells derived from human pluripotent stem cells (PSCs) can have similar attributes to their counterparts in the body, and can therefore be used to predict many pharmacological characteristics of a drug candidate. Cardiotoxicity and hepatotoxicity are the most common causes of drug safety liabilities and withdrawal of drugs during development. Derivation of functional cell types from pluripotent stem cells, in particular hepatocytes of the liver and cardiomyocytes of the heart, could provide a reliable supply of cells to perform metabolism, biodistribution and toxicity testing of drug candidates.

Background

In 2009, Cytiva (formerly GE Healthcare) entered into an alliance agreement with Lineage Therapeutics (formerly Geron Corporation) that provides an exclusive license under a number of patents that relate to development and commercialization of cellular assay products derived from PSCs (human Embryonic Stem Cells (hESC) cells and induced Pluripotent Stem Cells (iPSC) cells) for use in drug discovery, drug development and toxicity screening. Subsequently, in 2012, Cytiva expanded its license to obtain exclusive global rights to the intellectual property (IP) and know-how for the development and sale of cellular assays derived from stem cells. This gives Cytiva exclusive sub-licensing rights within this field of use.

Technology

The technology covered by the IP portfolio relates to hESC; their culture & differentiation, as well as non- therapeutic uses such as in vitro screening of drugs and toxicological agents. At the time of some of the initial patent filings, iPSC were not discovered, but many of the patents refer to pluripotent stem cells that would also encompass iPSC. The patent portfolio spans a range of stem cell related technologies including, but not limited to, cellular compositions, culturing and expansion methods, differentiation protocols and uses of stem cells and stem cell-derived cells in drug and toxicity screening.

The technology portfolio can be divided into the following categories:

- Culture and proliferation of pluripotent stem cells
 - Methods and Materials for growth
 - Conditioned media
- Differentiation
 - Methods of providing differentiated stem cells
- Screening
 - Use of human pluripotent stem cells for drug screening and toxicity testing

- Stem cell-derived differentiated cell models for assays
 - Compound Screening Using Cardiomyocytes
 - Hepatocyte Lineage Cells Derived from Pluripotent Stem Cells
 - Neural Progenitor Cell Populations
 - Islet cells

The portfolio can be summarized as below against the different cell types:

	Cell Bank	Culture and proliferation	Differentiation protocol	Screening assays
Pluripotent stem cells	Yes (hESC & pPS on ECM)	Yes	n/a	Yes (from hESC & pPSC)
Cardiomyocytes	Yes (hESC)	No	Yes	Yes (from hESC & pPSC)
Hepatocytes	Yes (hESC)	No	Yes (from hESC & pPSC)	Yes (from hESC & pPSC)
Neuronal cells	Yes (hESC & pPSC)	No	Yes (from hESC & pPSC)	Yes (from hESC & pPSC)
Islet cells	No	No	Yes (from hESC & pPSC)	No

Licensing this technology

Being able to develop different cells and tissues from human pluripotent stem cells enables availability of more physiologically relevant cell models for drug discovery and development, access to this technology will allow users to operate in the areas covered by the Lineage /Cytiva license field of use. The main applications covered are:

- differentiating pluripotent stem cells into another cell type (e.g. cardiomyocytes, hepatocytes or neuronal cells) and/or
- using those cells in an in vitro cell-based assay*

A variety of licenses are available to accommodate most commercial needs and there is flexibility to modularize the license, to reflect the licensee’s evolving needs.

There are typically two type of licenses available:

- Commercialization: right to develop, manufacture and sell stem cell derived cell products for use in vitro assays. These products could be cell models, kits or services used in drug development (including toxicity and efficacy testing).
- Screening: right to develop and use stem cell derived cell products for screening or testing the effect of compounds.

Patent Portfolio

A list of the patents licensed to Cytiva can be provided on request.

Anyone interested in obtaining more information regarding a license or wanting to know if their chosen supplier is a licensee should contact LSLicensing@cytiva.com stating their areas of interest.

*Note that Lineage retained the rights to applications outside of in vitro cell-based assays (e.g. therapy).