

	MOREHOUSE SCHOOL OF MEDICINE	POLICY NUMBER	
	INTELLECUTUAL PROPERTY COMMITTEE	EFFECTIVE DATE	
	EXHIBIT C	PAGE (S)	9
	<u>SUBJECT</u> <b>INTELLECTUAL PROPERTY DUE DILIGENCE FORM</b>	SUPERSEDES	

**SECTION 1: To be completed by IP Committee**

1. Check all contractual agreements such as employee agreements, contract research and consultancy agreements, license agreements, Non-Disclosure Agreements, assignments and third party funding terms.
  - a. Who currently owns the intellectual property?
  - b. Are there prior claims to the technology?
  - c. If the IP is jointly owned by the MSM and one or more other party(s), has an agreement been reached on the relative ownership proportions and the responsibilities of the parties in terms of commercial exploitation of the IP?
  - d. If the IP is not owned by the inventors or the MSM, have arrangements been made to use the IP? Is the IP subject to any opposition, re-examination or revocation proceedings? Is a patent ownership opinion letter required from a patent attorney? Have all past attorney opinion letters regarding validity and confirming that rights do not infringe those of others been checked? Have there been any infringement proceedings by or against the patentee in relation to the patent(s) in the past? What is the likelihood that future claims can be put forward? Will the existing IP provide adequate cover against these claims? Have any warranties been sought? Has the third party patented all or only some of the IP associated with the invention?
  - e. Does the invention currently have any license agreements associated with it? What is the nature of these agreements (in- or out-licensed; whole or part of invention etc.)?

2. Check the CVs and do a background investigation on the inventor(s) and interview the inventor(s)

Is the inventor in the forefront of his/her field of research and internationally known?

3. Assess the science/thinking behind in the invention, using experts in the field if necessary. Investigate the additional steps in the value chain required for commercialization, what is needed for them, how long they will take and how much they will cost.

- a. Is the invention scientifically sound and feasible? How certain is it that it will work, i.e. what are the technical risks? Have the conceptual framework, experimental design, methods, analyses and development options been adequately assessed? How feasible/appropriate is the R&D methodology employed?

- b. Would it be possible to demonstrate the invention to a potential licensee or investor or convince them that it will work? Is it easy to demonstrate the technology? Is there a functioning prototype?

- c. At what stage of development is the invention (idea only; some research done; some development done; prototype available; fully developed and market ready)? Will a potential licensee have to fully develop the invention? What steps are necessary for commercialization? How long will it take and how much will it cost for development and commercialization? Is this technology useful without substantial further investment in development?

- d. Will the invention require any additional/new infrastructure or facilities not currently available to the inventors? What other facilities does the inventor have access to?

- e. Are there any significant concerns or problems with the invention (technical, commercial, market, regulatory issues etc.) that may result in failure to commercialize it? Does it need government approval or certification?
  
- f. What is the level of technical innovation of the invention? Is the technology still state-of-the-art?
  
- g. Does the invention have a value-adding element? Are the benefits identifiable and significant?
  
- h. Does the invention have a single application or are broad-based applications possible? Does it offer the possibility of alternative deliverables, if commercialization fails?

## **SECTION 2: To be completed by IP Risk Assessment Consultant**

Literature and patent searches for novelty and prior art. Check Patent Office Register and databases for names of the patentee or applicant and for records of assignments, licenses and securities. Check all relevant "prior art" publications, evidence of prior use, results of prior art and infringement searches, reports and opinions supplied by the inventor. Consult with a patent attorney to determine patentability, broadness of claims, infringement on other patents etc.

- a. Is the invention or part thereof currently protected by an issued or pending patent or some other form of IP? Have all key patents and patent applications been identified?
  
- b. Are the rights owned by the MSM or a third party or both?
  
- c. Are the rights strong and enforceable? Have all US and foreign issued and pending patent applications been obtained? What are the status and fee payments of all patents and patent applications? What are their remaining terms? Has the scope of all claims been checked in order to determine the risk of them being "invented around"? Is there any scope for filing further patent applications?
  
- d. Are any third party rights infringed?
  
- e. What territories are covered? Do the territories covered impact negatively on the ability to commercially exploit the invention?
  
- f. Are there dominating patents? If so, are they available for license?

- g. Is patenting the best option for protection of the IP? Is patenting the right route to maximize societal access to the technology? Are the invention so early and the time to develop it so long that the patents will expire before products reach the market? Is the field moving so quickly that patents are irrelevant: by the time the patent issues, the invention will be obsolete? Would the patent affect the novelty/obviousness of a planned future development? Will the patent be supported by future developments?
  
- h. What are the prospects of obtaining a valid patent? What would the patent protect (e.g. a specific product, a new method of using an existing product, a way of developing a product, etc.)?
  
- i. Has the invention been published or used commercially? If so, when?
  
- j. Did a novelty search (patent and/or literature search) identify any relevant prior art that may impact on the ability to patent the invention?
  
- k. What is the potential extent of the patent protection that could be sought, i.e. are broad claims possible? Is there a risk of the claims being "invented around"?
  
- l. Is there a possibility of an overlapping portfolio of patents?
  
- m. Will foreign patents be necessary/desirable? Have countries where patent protection may be required been identified?

- n. If a patent is issued, can it be enforced? Are there enough funds available for enforcement?
  
- o. Could infringement of the patent be easily detected?
  
- p. Does commercial potential or return justify the cost of possible enforcement?
  
- q. Has all confidential information and know-how been identified and is it secure?

### **SECTION 3: To be completed by IP Commercialization Assessment Consultant**

1. Assess the market and competition as thoroughly as possible through preliminary market research studies, existing market reports and any other publications or website information. Do a preliminary SWOT analysis on any competitors. Calculate potential future revenues.
  - a. Who are the customers for this invention? What are the different markets for which this invention might be used? Does the invention address a defined, identifiable, unsatisfied market need/niche? What specific need does it fulfill? Is this a major, well-recognized need or a minor one? Is this need being filled now? If so, how?
  - b. Does the invention improve on an existing product/process that is currently satisfying market needs? Does the technology represent a marginal or significant product improvement/cost reduction?
  - c. Is the invention easy for buyers to adopt? Will people easily grasp its utility? Does the technology conform to relevant industry standards?
  - d. Does the product have a long product cycle?
  - e. How big is the potential market for the invention both locally and globally?
  - f. What are the characteristics of the market? Is the invention premature for the current market? Is this an established market, or one that will need developing? Is this a growing field, or a dying one? What is the market acceptance/public perception of the product? Is the market accessible (no blocking patents or overwhelming dominant player)

g. Have prospective licensees/customers been identified or secured? Has there been any commercial interest in the invention?

a. Are there any directly competitive products or technologies currently on the market or in the pipeline? If yes, how do they compare with this invention? Is the invention likely to be able to compete in the market against these products? Does the competition have the market "sewn up", i.e. do their IP rights dominate? Are there any specific aspects of the technology which could be used to market it? Does the invention represent a technical revolution in its market? Is it a lot cheaper, better, and/or faster than the competition? How does this product rate in terms of product differentiation when compared with similar products? Does the invention confer a sustainable competitive advantage?

2. Assess the potential commercialization routes for the invention.

a. What is the most appropriate commercial route for the invention? Should the rights be sold outright for an immediate large return? Should the rights be licensed? Do possible licensing opportunities exist? Will the licensee have to make a major investment to bring the technology to market? Can transfer of invention to the licensee be achieved solely by reference to a patent? Are there any additional requirements such as technical support? Will the invention give the licensee a market lead? Is the technology the basis for a spin-out company? Does the organization/inventor have the capability and intention to commercialize the invention itself?

b. Is significant investment required to take the invention to market? Should the MSM commit funding to the development and commercialization of the invention?

c. What is the availability of complementary funds for development and commercialization? Will it be necessary to raise external funding for development and commercialization of the invention? What is the likelihood of being able to raise external funding for development and commercialization?

d. Are we likely to recover and exceed commercialization costs and effort from the invention? Is the market large enough to justify the risk? If patented, will this invention likely attract a license or investment for commercialization, with enough return to the institution to justify the patenting expense?

#### **SECTION 4: RESPONSIBLE OFFICE**

The Office of the Intellectual Property Committee is responsible for the the Intellectual Property Due Diligence Policy. Questions regarding the review process should be directed to

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