Republic of the Philippines
DEPARTMENT OF SCIENCE AND TECHNOLOGY

FEB 1 3 2018

DOST Memorandum Circular No. 004
Series of 2018

Subject: DIRECT LICENSING AND SPIN-OFF TERMS UNDER THE PHARMACEUTICAL INDUSTRY THAT WOULD BE CONSIDERED AS "FAIR" TO THE GOVERNMENT FUNDING AGENCY (GFA) AND/OR RESEARCH AND DEVELOPMENT INSTITUTE (RDI) FOR FAST TRACKED ISSUANCE OF FAIRNESS OPINION REPORT (FOR) UNDER REPUBLIC ACT NO. 10055, OTHERWISE KNOWN AS THE "PHILIPPINE TECHNOLOGY TRANSFER ACT OF 2009"

ARTICLE I
RATIONALE AND OBJECTIVE

Section 1. This Guideline setting up the Standardized Direct Licensing and Spin-off Terms are formulated pursuant to Articles II, III and IV of Memorandum Circular No. 007 series of 2016 dated 26 April 2016 and Memorandum Circular No. 003 series of 2015 dated 15 September 2015, per the recommendation of the Industry-based FOB duly constituted for the Pharmaceutical Industry pursuant to DOST Special Order No. 174 s. 2016 dated 21 March 2016.

Section 2. The intention of this guideline is to fast track the release of a fairness opinion by the Department of Science and Technology (DOST) Secretary as regards the proposed transaction between the Government Funding Agency (GFA) or a Research and Development Institute (RDI) as the Licensor and the individual entity that has an interest to commercialize a technology as the Licensee.

ARTICLE II
TERMS FOR DIRECT LICENSING

Section 1. Coverage. For this particular industry, we shall be considering pharmaceuticals, biotechnology and medical devices. Pharmaceuticals include medicaments, botanicals, chemicals, cosmeceuticals, compounds or mixtures primarily for the treatment of human ailments and diseases; Biotechnology refers to any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use; and a medical device refer to any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Section 2. Basic Requirements. The following requirements must be satisfied before the proposed transaction shall be assessed:

2.1 *Cost of technology:* Not exceeding P5,000,000. Valuation of the technology shall be based on the comparable market approach or income approach valuation to be made by technology valuators duly accredited by the Secretariat.

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2.2 *Types of Intellectual Property (IP):* Patents, Utility Models (UMs), *Industrial Design (*ID), Trade Secrets and Know Hows

**confined to medical and biotech devices only*

2.3 *Eligibility of Licensee:*

a. If Sole Proprietor:
- Registered with the Department of Trade and Industry (DTI);
- Filipino citizen;
- Equity at least equivalent to the cost of the technology but not below P1,250,000.00;
- With existing facilities; and
- At least three (3) years in the business for exclusive licensing agreements or at least one (1) year in the business, for non-exclusive licensing agreements; good reputation.

b. If a corporation, partnership or a cooperative:

- Registered at the Securities and Exchange Commission (SEC) or the Cooperative Development Authority (CDA);
- Domestic stock corporation;
- Must not be a general professional partnership, if applicable;
- Capitalization twice the cost of the technology but not below P5,000,000.00;
- With existing facilities; and
- At least three (3) years in the business, for exclusive licensing agreements, or at least one (1) year in the business, for non-exclusive licensing agreements; good reputation; good reputation.

2.4 *Additional Requirements:* For Sole Proprietors, Cooperatives, Partnerships or Corporations, the following documents must be submitted to the FOB upon application for fast tracked issuance of FOR.

- Original or certified copy of the Freedom to Operate (FTO) opinion (to operate the potential IPRs or IPRs) issued by a third-party expert;
- Valuation Report;
- Business plan/Marketing Plan;
- R&D cost;
- IP Registration; and
- Financial Report/SEC Registration/Business Registration
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Section 3. Ideal terms in the proposed transaction. The following terms shall be the basis in the determination whether the proposed transaction is fair or not fair to the GFA or to the RDI:

3.1 *Financial terms:*

a. Acceptable royalty rates based on gross sales for Pharmaceuticals (novel technology) (Based on the guidelines by Harold A. Meyer III, March 2001):

- A raw idea is worth virtually nothing, due to an astronomical risk factor.
- A patent pending with a strong business plan may be worth 1% of gross sales.
- An issued patent may be worth 2%.

- A patent with a prototype, such as a pharmaceutical with pre-clinical testing may be worth 2-3%.
- A pharmaceutical with clinical trials may be worth 3-4%.
- A proven drug with FDA approval may be worth 5-7%.
- A drug with market share, such as one pharma distributing through another, may be worth 8-10%.

b. The acceptable royalty rates for novel Pharmaceuticals shall likewise apply to Medical Devices *mutatis mutandis*.

c. Acceptable royalty rates for health supplements and herbal medicines unless covered by a patent:

- 3-5 % of the gross sales

d. Acceptable royalty rates for Biotech (based on gross sales):

	Royalty Rates
• Research Reagents (e.g. expression vector, cell culture, media supplements)	*1 - 5%*
• Diagnostic products (e.g. monoclonal antibodies, DNA probes)	*1 - 5%*
• Therapeutic products (e.g. monoclonal antibodies, cloned factors)	*5 - 10%*
• Vaccines	*5 - 10%*
• Animal health products	*3 - 6%*
• Plant/agriculture products	*3 - 5%*

Royalty rates below the approved rates as above-stated shall be required to undergo full blown FOB.

3.2 *Licensing fee:* At least 0.5% of the cost of technology. However, the FOB may also impose different fees per field of use or other considerations.

Note: Payment other than royalty fees may be an option

3.3 *Exclusivity:*
a. Field of use: One or two fields of use
b. Geographic territory: Limited.

3.4 *Sub-licensing:* With consent/upon the discretion of the Licensor

3.5 *Effectivity / Term:*
a. For patents and industrial designs: Five (5) years renewable
b. For UMs: Life of the UM

3.6 *Addition requirements for corporations*

- Certified copy of: a) Articles of Incorporation (AOI); and b) latest General Information Sheet (GIS);
- Other additional documents/records that may be required by the FOB.

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RECORDS OFFICER
DEPARTMENT OF SCIENCE AND TECHNOLOGY

3.7 *Addition requirements for partnerships*

- Certified copy of: a) Articles of Partnership (AOI); and b) latest General Information Sheet (GIS);
- Other additional documents/records that may be required by the FOB.

3.8 *Additional requirements for cooperatives:*

- Certified copy of: a) Articles of Cooperation (AOC); and latest financial statement of the Cooperative.
- Other additional documents/records that may be required by the FOB.

ARTICLE III
TERMS FOR SPIN-OFFS

Section 1. Basic Requirements. The following requirements must be satisfied before the proposed transaction shall be assessed:

1.1 *Cost of technology:* Not exceeding P5,000,000. Valuation of the technology shall be based on the comparable market approach or income approach valuation to be made by the secretariat or thru its authorized evaluator.

1.2 *Types of IP:* Patents, UMs, IDs, Trade Secrets and Know How

1.3 *Eligibility of Licensee:* Who can spin-off?

- Researcher or any member of the research team
- Employee / still in the service
- The RDI that developed the technology. Provided however, that the RDI has a corporate personality or it has fiscal autonomy.

1.4 *Type of spin-off:* Corporation, cooperative with or without government support, provided however that for entity receiving government support, the amount of government support should not be more than 50% of its capitalization limited to office area, facilities and equipment for a period of one year.

1.5 *Capitalization equity:* Twice the amount of technology but not less than P5,000,000.

1.6 *Additional Requirements:* For Spin-offs, the following documents must be submitted to the FOB ***upon application for fast tracked issuance of FOR.***

- Original or certified copy of the Freedom to Operate (FTO) opinion (to operate the potential IPRs or IPRs) issued by a third-party expert;
- Valuation Report;
- R&D cost;
- IP Registration; and
- Financial Report/SEC Registration/Business Registration

1.7 *FOR* request should also contain secondment/leave form, and an indication from RDI that (researcher) its employee involved in the spin-off will be allowed to be on secondment or on leave. Said employee to present leave of absence and waiver by RDI of conflict of interest.

If the spinoff company is owned by the RDI, the researcher should not take a leave during the initial three (3) years of operation.

If the RDI employee is a mere stockholder of the spin-off entity without any management responsibilities, he or she shall submit a certificate of limited practice of profession in lieu of secondment/leave from the RDI issued by the DOST Secretary.

Section 2. Ideal terms in the proposed transaction. The following terms shall be the basis in the determination whether the proposed transaction is fair or not fair to the GFA or to the RDI:

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a. Acceptable royalty rates for Pharmaceuticals: (Based on the guidelines by Harold A. Meyer III, March 2001)

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b. Acceptable royalty rates for health supplements and herbal medicines:

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c. Acceptable royalty rates for Biotech based on gross sales

	Royalty Rates
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Royalty rates below the approved rates as above-stated shall be required to undergo full blown FOB.

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2.2 Exclusivity:
a. Field of use: One or two fields of use
b. Geographic territory: Limited

2.3 Effectivity / Term: For patents and industrial designs: Five (5) years renewable. For UMS: Life of the UM

ARTICLE IV
EFFECTIVITY/SEPARABILITY/AMENDMENT/REPEALING

Section 1. Effectivity. This Circular shall take effect immediately after its complete publication in the Official Gazette or newspaper of general circulation and upon filing at the UP Law Center in accordance with law.

Section 2. Separability. If any part of provision of this Memorandum Circular is held invalid or unconstitutional, the other provisions not affected thereby shall remain in force and in effect.

Section 3. Amendment/Repealing. All existing orders and guidelines inconsistent herewith are deemed repealed and provisions not affected thereby shall remain in force and in effect.

FORTUNATO T. DE LA PEÑA
Secretary

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