World Health Organization

UNDP

Briefing note on access-oriented technology licensing

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Contents

HIV and Health Group
United Nations Development Programme
304 East 45th Street, FF-10116A
New York, NY, 10017
United States

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Introduction

As outlined in WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and in UNDP's HIV and Health Strategy (2022–2025), ensuring access to health technologies calls for integrated, equitable solutions, including licensing approaches to meet urgent public health needs.

Technology licensing is a common feature of the research and development (R&D), production and distribution landscape in the health sector. Technology licences provide the legal framework pursuant to which intellectual property (IP) associated with technology (e.g. patents and trade secrets) is shared or transferred between parties. Such licences often address additional subject matter, such as obligations regarding regulatory compliance and technical assistance. IP that identifies products by brand name (i.e. trademarks) may also be addressed in a licence agreement. Technology licensing facilitates innovation through the sharing of discoveries and their further development, and it enables the transition from innovation to the production of health products such as therapeutics and vaccines. The sharing enabled by licensing is often referred to as 'technology transfer'.

Technology licensing can cover any subject matter field, and the specific terms of individual licences are likely to be different depending on the subject matter involved. For this reason, among others, it is problematic to prescribe a standard 'one-size-fits-all' model technology transfer licence, or even to provide a menu of pre-drafted provisions from which to select. At the same time, by looking at licences that have been previously negotiated for a given field, one may obtain a good idea of the types of provisions that should be included, and what they might say.

This Briefing Note is in two parts. The first is a brief discussion of subject matter that negotiators and drafters of licences should address, particularly from the standpoint of promoting wide access to the products based on the transferred technologies. The second is a more detailed checklist of the subject matter—presented in outline form—that should be addressed by a technology transfer licence.

Technology licensing from an access-oriented perspective

The development, production and distribution of health products (including vaccines, diagnostics, therapeutics and medical equipment/supplies) often entails the transfer of technology between parties. These transfers are typically from a party providing the technology (e.g. a licensor) to a party receiving and using the technology (e.g. a licensee), though there may well be reciprocal transfers between recipients and providers (e.g. 'cross-licensing'). The arrangements between technology providers and recipients are generally formalized in 'licence agreements'.

Much of the global system of technology transfer takes place among commercial enterprises whose objective is to generate (and maximize) returns on investment from the technology and its implementation. However, in the sphere of public health, there are various circumstances in which technology providers and/or recipients are not seeking to maximize returns on investment but are seeking to maximize access to their products or services among health product users, whether individual patients, health systems or otherwise (i.e. social returns). The latter parties may be seeking to craft 'access-oriented' licences.

This document (including its associated annexes) is intended to provide basic guidance for technology providers and recipients in negotiating and drafting access-oriented licence agreements. The elements to be addressed in technology licences are largely the same whether the parties involved are primarily seeking to maximize financial return on investment or are primarily access-oriented. However, the objectives that the parties are seeking to achieve will influence how the terms and conditions in individual cases are structured—for example, what terms are more likely to maximize financial returns or accomplish an access-oriented purpose.[1]

Perhaps the most common type of technology licence involves IP subject matter, such as patents or trade secrets, which involves ownership or control by a party over a specific technology. Licences may also cover trademarks, designs, copyrights and other IP. The recipient of the technology (licensee) often pays a fee (such as a royalty or stage payment) to the technology owner (licensor) for use of the IP.[2] An access-oriented technology licence may involve royalties, stage payments or other fees (such as fees for providing technical assistance), but payments are likely to be lower than for a licence aiming to maximize financial returns, and in some circumstances may be zero (e.g. royalty-free) or negligible. A technology licence in the health sector will likely address other detailed subject matter, such as rights and obligations regarding compliance with regulatory requirements, permitting use of regulatory data that might otherwise be restricted, use of newly developed technologies, and how potential liabilities arising from use of the licensed technology will be addressed.

Another type of technology licence is referred to as 'open source'. Open-source licensing is common in the computer software and digital sectors. There are various types of open-source licence, but the basic idea is that the owner of the IP (such as a copyright interest in software code) makes it freely available to anyone wanting to use it, but often subject to conditions. For example, an open-source licence might require that any improvements or modifications to the software also be made freely available under an open-source licence. There are open-source patent licences, usually meaning that the patent owner has decided (or pledged) that anyone can use the covered patented technology without risk of being sued for infringement, though there might be associated conditions—for example, that improvements to the patented technology must similarly be made available under an open-source patent licence (i.e. a pledge to refrain from infringement action).

[1] Financial return-oriented providers of health technologies and products provide access to patients, health systems, etc., just as access-oriented providers do. This Briefing Note does not suggest otherwise. Financial return-oriented providers are generally seeking to satisfy the interests of investors (e.g. shareholders) with interests in rates of return, and they engage in pricing and other behaviours intended to satisfy those investor interests.

[2] 'Stage payment' refers to an obligation on a licensee to pay a lump sum when a contingency occurs or a defined milestone is reached. For example, a pharmaceutical patent licensee may be obliged to make a lump-sum payment when regulatory approval has been granted for the patented product in a licensed territory.

A patent (or other IP) owner may decide to license its technology under especially favourable terms and conditions for purposes such as making health technologies available at low cost in developing countries. 'Voluntary' preferential licences are distinguished from 'compulsory' patent licences. The latter may be granted or issued by governments without the consent of the patent owners, such as to address important public health needs.[3] Compulsory licences may be granted to governments for their own use or for use by third parties (e.g. government contractors) on their behalf. Such 'government use' licences are accorded supplemental flexibility under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) compared with compulsory licences granted for private use.[4] Also, compulsory (including government use) licences issued in circumstances of national emergency, other circumstances of extreme urgency or for public non-commercial use are exempt from certain procedural conditions in order to expedite action.[5]

Much of the world's stock of knowledge is not owned by anyone. Rather, it is part of the 'public domain'. This knowledge has accumulated over the centuries, and a good deal of it is today freely available on the Internet. The use of information and knowledge in the public domain does not require a licence or other permission. However, there may be provisions in technology licences—for example, regarding associated technical training programmes—that will make use of knowledge in the public domain. The fact that knowledge is in the public domain does not mean that a licensor may not charge a service fee to a licensee for help in using that knowledge, much as a university may charge a tuition fee to its students who are being instructed predominantly with public domain knowledge. But a fee for training services should not be confused with ownership of IP rights, which do not attach to knowledge in the public domain.[6]

Traditionally, licence agreements are assessed under competition law as implemented by national and/or regional jurisdictions. Certain types of licensing agreements and terms raise competition or antitrust concerns *'per se'*,[7] or otherwise may be subject to a balancing assessment by competition authorities. This publication is not specifically designed to provide guidance on licensing conditions from a competition law standpoint, but it does point to certain areas where concerns can be raised.[8]

1. Technology subject matter and exclusivity

The principal purpose of the technology licence is to enable the licensee to undertake certain activities making use of the licensor's technology. It is essential that the licensee identify and secure rights to the technologies held by the licensor that it requires. If the technology is covered by a patent or patents owned by the licensor, those patents need to be specifically identified and listed. Also, the licensor may have applied for patents that have not yet been granted but that may be granted during the term of the licence. If the technology covered by such applied-for patents will be necessary or useful for undertaking its activities, the licensee should also have rights to use the relevant patents when issued. The licensee additionally may seek to secure rights to use patents for improvements to the covered technology by the licensor that may not yet be developed but may later be developed and may be the subject of a patent application.

In addition to patent subject matter, other technology necessary or useful in the development and manufacture of products in the health sector—often referred to as 'technical know-how'—should be included within the scope of a licence. There is a wide range of such potential subject matter. Some of that knowledge may be held by the licensor as a 'trade secret', but know-how need not be a trade secret to be useful to

[3] There are international and national legal rules applicable to compulsory licensing, including government use licensing. Such rules allow such licensing subject to relevant conditions.

[4] For example, national rules may provide that a government may not be enjoined (or blocked) from using a patent, although it may be required to pay adequate remuneration for use of that patent (TRIPS Agreement, art. 44.2).

[5] For example, a precondition of prior negotiation with the patent owner for a voluntary licence may be waived (TRIPS Agreement, art. 31(b)).

[6] A trade secret may involve a unique and commercially valuable combination of information taken from the public domain. It is the valuable combination of information that may be held as a trade secret and protected against misappropriation, not the public domain information as such.

[7] This means that when a party engages in a particular practice or agreement it is unlawful without further demonstration of harm or effect, and it may not be defended by demonstrating potential or actual pro-competitive effects.

[8] For detailed information regarding the role of competition law in the health sector, including with respect to licensing, see United Nations Development Programme, 'Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries', UNDP, New York, 2014, https://www.undp.org/publications/using-competition-law-promote-access-medicine-0; United Nations Development Programme, 'Using Competition Law to Promote Access to Health Technologies: A Supplement to the Guidebook for Low- and Middle-Income Countries', UNDP, New York, 2022, https://www.undp.org/publications/using-competition-law-promote-access-health-technologies-supplement-guidebook-low-and-middle-income-countries.

the licensee. Provisions addressing the provision of technical know-how, including trade secrets, are often quite detailed. Acquiring rights to use patents in the absence of technical know-how may leave significant obstacles in the path of successful implementation of a technology transfer licence.

In some cases, the licensee of patented technology does not require supplemental know-how to make use of the technology (e.g. the licensee is already capable of reproducing the patented product). The licensee is mainly seeking permission to use the patent, to avoid a potential suit for patent infringement. In such cases, there is no need to include a know-how component in the licence that might entail expenses beyond those for the patent rights.

2. Geographical scope, exclusivity and limitations

Technology licensing agreements often contain provisions that define the potential manufacturing and distribution/sales[9] territory open to the licensee. A licence may be extended by the licensor for national (or subnational), regional or worldwide distribution/sales by the licensee. Such territorial restrictions are generally allowable under competition law.[10]

Geographical licensing limitations may significantly constrain the ability of licensees to achieve economies of scale in production, since there may be limited demand within one national territory. In addition, health products may be vitally needed among a substantial number of countries; therefore, a geographical limitation may deny products to markets where they are most needed.

In general, access-oriented licensees should seek the widest possible geographic scope for the exercise of licence rights. If limitations are necessary, restrictions on manufacturing in and sales to low- and middle-income countries should be avoided.

Consistent with access objectives, a patent licence should include a provision that the licensee is not restricted from selling into markets where the licensor does not hold patent rights, or where the government in the importing country has issued a compulsory patent licence or has otherwise lawfully authorized importation. This might require the licensee to use a different brand name (i.e. trademark) or a generic identifier (i.e. International Nonproprietary Name—INN) for exports to the foreign market if the licensor retains trademark rights there.

Unless a contract between the licensee and a third-party purchaser expressly limits resales, geographical limitations applicable to licensees do not extend to third-party resales. Absent a contractual limitation, third-party purchasers are free to resell and transfer products. In some circumstances, limitations on resales by third-party purchasers may be prohibited by competition law as likely to cause anti-competitive effects.

Patent licensees often seek to be the exclusive user of the patented technology for a geographic territory. Otherwise, the licensee potentially faces competition not only from other third-party licensees of the same technology but also from the patent owner itself. Because of the costs associated with introducing a patented pharmaceutical product onto the market, investors may not be willing to make a financial commitment without an assurance of at least temporary market exclusivity or other type of remuneration/incentives.

There may, however, be circumstances in which an access-oriented technology licensee does not require exclusivity. For example, when patent licences have been offered under low-royalty arrangements designed to permit low-price supply to low- and middle-income country markets, the producer under the patent licence may effectively be operating in a generic-type environment in which market exclusivity is not intended under a licensing programme. Thus, on the question of whether to accept a non-exclusive licence, the answer is 'it depends' on the specific circumstances.

A technology licence may limit the use of the technology by the licensee to certain areas or 'fields'. Such limitations are generally referred to as 'field of use' limitations, though different terminology may be used depending on the context. As an illustration, a technology licensee may be authorized to sell products to government or public purchasers but does not have authority to sell the same products to private sector

[9] Distribution of a product may involve transfers that do not involve compensation. When used in this document, 'sales' should be understood to incorporate such uncompensated transfers unless otherwise specified.

[10] This is to be distinguished from agreements between independent (or 'horizontal') enterprises to allocate exclusive territories among themselves. Such geographical allocation is *per se* illegal under competition law.

purchasers. Or a licensee may have authority to use technology to build a certain type of product (e.g. medical ventilators) but may not have authority to use it for building another type of product (e.g. aircraft ventilation systems). A field of use restriction may encourage a technology owner to make a transfer for beneficial public health purposes when it would otherwise be concerned about use of its technology to build products competitive with its commercial interests. While in principle it may be most desirable that technology be transferred without limitations, such as field of use restrictions, there are circumstances where the licensee may not have a significant interest in unrestricted access (e.g. it does not intend to build aircraft ventilation systems) and is better served by having limited access than no access. As with some other limitations on technology transfers, the answer as to whether such limitations are acceptable for public health purposes is 'it depends'.

3. Royalties, stage payments and other fees

Royalties, stage payments and other fees in patent and other technology licences are ultimately incorporated in the selling prices of products. Licensors seeking to promote the production and distribution of affordable and accessible health-related products should negotiate royalties or other licence payments or fees (such as fees that might be associated with providing technical support) that will minimize the financial burden on the users of those products. The royalty or other payment amount might vary depending on the economic and social characteristics of the country where the licence will be given effect. For example, different royalty percentages might apply depending on the level of economic development of the country where the technology is used (e.g. where the patented product is sold). For least developed country licensees, zero or very low royalty rates should be considered. Stage payments and other fees should be minimized or waived.

It is important to note that low royalty rates are only effective in reducing the burden on end users if they are reflected in the pricing of products. Therefore, a licence should include some form of pricing limitation (as in section 4 below) to ensure that a low royalty rate or fee benefits the purchasers/end users.

4. Pricing

Technology owners may attempt to require licensees to charge 'minimum prices' for products made with the licensed technology. This practice is used for a variety of purposes, such as to prevent multiple licensees within the same territory from competing with each other based on price. This practice may also be used as a means to prevent low-priced exported products from competing with higher-priced versions of the same product in the export market. From an access-oriented perspective, licensees should avoid accepting commitments regarding minimum selling prices.

Also, a technology licensor that is encouraging the provision of accessible and affordable products may in appropriate cases include a provision in the licensing agreement that establishes a maximum selling price for the covered products or that establishes an enforceable benchmark price that compares favourably to other low-cost suppliers (e.g. in other low- and middle-income country markets)—in essence, commercial 'reference pricing' control. However, if a licensee will sell into a price-competitive market, establishing a maximum selling price may be unnecessary or even counter-productive. The maximum price could mistakenly be interpreted by the licensee as a 'recommended' price, and this might discourage the licensee from lowering its prices.

5. Technology grant-backs

It is not uncommon for a licensee of technology to make improvements on the technology in the course of using it. This may include developing new techniques for manufacturing a product. Technology licensors often include requirements that the licensee 'grant back' to the licensor a right to use any improvements to the licensed technology. Usually these grant-back obligations are 'non-exclusive' so that the licensee may continue to use its own improvements without permission from, or additional payment to, the licensor. It is not uncommon for licensors to require that grant-back licences be royalty-free.

Although it might be preferable for licensees to refuse, or to demand royalties for, grant-back licences, it may be difficult to negotiate such conditions. It is not unreasonable from an access standpoint to accept a

non-exclusive grant-back condition. While not preferred, non-exclusive grant-backs are generally acceptable.

However, some licensors attempt to impose 'exclusive grant-back' obligations on licensees such that the licensees are not permitted to use their own improvements, at least without permission from the licensor and/or negotiating a new licence. Exclusive grant-backs are sufficiently oppressive to licensees that they may be prohibited under national or regional competition law. Access-oriented licensees should not accept exclusive grant-back obligations in their licence agreements. They should be allowed to use their own innovations.

6. Duties regarding regulatory approval

Some technology licences may relate to the production and distribution of health-related products that require approval by national, regional or other regulatory authorities before they are authorized to enter the market. Technology licences involving such products should address obligations of the licensor to provide materials and information in its possession that may be necessary or useful to the licensee in seeking required regulatory approval, as well as potential continuing obligations to provide materials and information as these are developed further by the licensor. In some cases, the licensor may itself pursue the required regulatory approval, or may participate with the licensee in the regulatory approval process.

Particularly if the licensor is granting an exclusive licence to the licensee, the licensor may want to ensure that the licensee will expeditiously pursue regulatory approval of a covered product. Failure of the licensee to pursue regulatory approval may deprive potential users of the opportunity to purchase and/or use the product; if the licence is exclusive, the licensor will not be able to appoint another licensee to alternatively seek approval and sell the product. The technology licence may therefore include commitments by the licensee to expeditiously seek regulatory approval (e.g. to submit an application within a certain number of days), cooperate with the regulatory authority (e.g. provide requested documents and respond to questions) and properly maintain any granted approvals. Failure by the licensee to fulfil these obligations may be grounds for termination of the licence. The licensee would not be responsible for delays outside its control, however.

7. Purchasing obligations

Licensors may attempt to include obligations on licensees to purchase supplies (raw materials, equipment, etc.) from the licensors as a condition of using the licensed technology. In some situations, this may be justified. A health product may be required to meet particular regulatory standards, and only the licensor produces (or has exclusive access to) a component necessary for the licensee's end product to meet those standards. However, in most cases, exclusive purchasing obligations merely act to prevent the licensee from securing the best available price for materials and equipment, and such obligations should be avoided. Bear in mind that the absence of a purchasing commitment in a licence agreement does not preclude the parties from otherwise doing business with each other.

Exclusive supply arrangements for so-called 'staple' inputs (e.g. paper for a printer) are typically prohibited under competition law because they unfairly increase the market power of the licensor/supplier.

8. Tie-in obligations

It is not uncommon for licensors to demand that prospective licensees accept licences for additional technologies and/or products as a means to secure additional revenue. Such obligations are commonly referred to as 'tie-ins' (the desired product known as the 'tying product', and the additional product known as the 'tied product'). Such arrangements may also be referred to as 'package licensing'.

Another type of tie-in involves ancillary services. There may well be situations in which a licensee wishes to purchase ancillary services from a licensor, such as technical consulting services to assist with implementing or maintaining the technology. However, licensors may also seek to require licensees to purchase services that the licensees do not need or want.

Access-oriented licensees should avoid accepting tie-in obligations that involve unwanted products or services.

9. Warranty, liability and indemnification

Licensors and licensees typically negotiate responsibility for injuries that may result from the use of a licensed

technology, including by the end user. The licensor typically has 'better information' regarding the safety of the licensed technology and generally should be responsible for ensuring its safety, except in those cases where there is an understanding among the parties that they are working with unproven/untested technology.

Licensees should be wary of releasing licensors of liability for injuries to consumers in circumstances where the licensors are aware of risks and have not disclosed them.

Producing and supplying products in the health sector inherently involves risk, as administering medicines to patients entails that some may suffer injury even when rigorous safety precautions are taken. National laws may mitigate these risks to product suppliers in the interests of overall public welfare. Nevertheless, the allocation of risk of loss in a licence may be very important for each party, and this aspect of licensing should not be treated lightly.

As a general matter, licensors of technology should be required to warranty or guarantee that they own and have the right to transfer the technology (such as patented technology) that is the subject matter of the licence. A licensor should agree to defend (or support the defence of) a licensee against claims that technology transferred under the licence violates the rights of a third-party right (such as by infringing a third-party patent), and to indemnify the licensee in the event an infringement award is made against it. There are various ways these warranty and indemnity provisions can be drafted. For example, the licensor may want to undertake the defence of an infringement claim on behalf of the licensee, or alternatively it may allow the licensee to undertake the defence and reimburse it for its efforts.

10. No-challenge clauses

A licensor may attempt to include a provision in the licence agreement providing that the agreement is automatically and immediately terminated if the licensee files suit to challenge the validity of licensed IP, such as a patent. This forces the licensee to choose between continuing to use the technology and challenging the validity of the licensed IP. Challenging IP validity may put the licensee in an economically untenable position. No-challenge clauses are sufficiently oppressive to licensees that they may be prohibited under competition law. They should not be included in access-oriented licences.

11. Disclosure of commissions and fees

To avoid impropriety, or the appearance of impropriety, any and all commissions or fees paid or payable to third parties in connection with securing a licence should be disclosed. A licence may include a representation that no fees or commissions have been paid (or are payable) in connection with securing the licence, other than those disclosed in an annex.

12. Transparency of terms and conditions/unjustifiable confidentiality constraints

It is preferable that access-oriented licences be made publicly available, or at least that the essential terms of the licences be made publicly available. While there may be specific elements—such as confidential technical information—that are not made public, access-oriented licences should otherwise avoid restrictions on making public the terms of the licence.

Technology licence agreement checklist

The checklist of terms and conditions listed below identifies provisions commonly found in technology licensing agreements. It is intended to provide a useful template for consideration of issues by negotiating parties. Licensing of specific technology subject matter may require that additional or different elements be included or excluded.

1. Basic introductory terms

- **a. Identity of parties, including formal entity names, and addresses**
  - i. Recitals: aid in the interpretation of the licensing agreement
    - A. Why the parties are entering into the agreement
    - B. Anticipated outcomes
- **b. Alternative structures include joint ventures, partnerships, etc.**
- **c. Definitions of commonly used terms**

2. Identify subject matter of technology transfer

- **a. Intellectual property (IP)**
  - i. Patents, as broadly defined, including applications, etc.
    - A. Product, process, method of use, etc.
    - B. Identify patents by number and place of grant
      - (a) Annex
      - (b) Application numbers
  - ii. Trademarks
  - iii. Copyrights
  - iv. Trade secrets and other information/data
    - A. Production processes and techniques
    - B. Lists of suppliers (materials and equipment)
    - C. Testing protocols
  - v. Designs
  - vi. Regulatory data (including regulatory dossiers)
- **b. Open source**
  - i. Technology identified: conditions on use and distribution defined
  - ii. Open source not the equivalent of ‘public domain’; IP may be attached to open-source technology
- **c. Public domain**
  - i. Available for use without restriction
  - ii. May form part of a technology transfer arrangement (e.g. in the context of training materials)
- **d. Materials**
  - i. Identify material to be furnished by or through the licensor, such as chemicals or biological substances, for use by the licensee in development and production
  - ii. Establish pricing terms or formula for determining price of materials, conditions of delivery, etc.

3. Grant of licence

a. **Identify rights conveyed**
   i. Depends on the form of IP
      A. For example, for a patent: to make, use, sell, offer for sale, import, export, have made, have sold
      B. For example, for a trademark: placement on goods and packaging, use in advertising and distribution, etc.

b. **Exclusive or non-exclusive**
   i. Exclusive licences should exclude the licensor, to avoid competition between the licensor and the licensee

c. **Geographic scope**
   i. Worldwide, region, country, etc.
   ii. Active and passive sales
      A. 'Passive' sales are initiated by an approach from a buyer (i.e. not solicited by the seller)

d. **Other potential scope limitations**
   i. Public or private procurement
   ii. For-profit or non-profit markets
   iii. Prescription/medical professional or over the counter
   iv. Field of use restrictions, such as limitation for use in the health care market

e. **Authority to sub-license**
   i. With or without consent of the licensor
   ii. Reasonableness

f. **IP owner's obligation to maintain IP in force**

g. **Duration: see 8 below**

4. Treatment of licensee (and licensor) improvements

a. **Define improvements**

b. **Grant-back obligations, if any**
   i. Non-exclusive
   ii. Exclusive
   iii. Royalty or royalty-free

c. **Party obliged and/or permitted to apply for/secure IP rights (e.g. patents)**
   i. Ownership of invention
      A. IP ownership is different from right to use
   ii. Patent maintenance

5. Other licence conditions

- **a. Obligations with respect to pricing**
  - i. Minimum and/or maximum resale prices
- **b. Obligations to purchase supplies**
- **c. Obligations to advertise and promote**
- **d. Obligations to license additional technologies**
- **e. Obligations to refuse designated purchasers**
- **f. Licensing conditions may raise competition law issues, including with respect to various terms mentioned above (e.g. resale price maintenance), depending on jurisdiction**
  - i. Addressed in a supplementary document

6. Royalties and other compensation obligations

- **a. Royalty, stage and other payment obligations for use of a licence**
  - i. Royalty options
    - A. Lump sum or fixed royalty amount
    - B. Percentage of gross sales
    - C. Percentage of net sales
      - (a) Define 'net'
        - (i) For example, net of commissions, returns, taxes, rebates, shipping, insurance, etc.
        - (ii) The royalty percentage may vary depending on the level of sales, typically decreasing as sales volume increases
  - ii. Licensor may seek minimum royalty payments as a condition for maintaining the licence in force
  - iii. Define applicable currency for payment, mechanism for establishing currency conversion rate (e.g. sales in local currency converted to royalty in foreign currency)
- **b. Stage payments**
  - i. Define contingencies or milestones that trigger a payment obligation (e.g. the grant of regulatory approval for the sale of the product in the territory)
    - A. There may be several stage payments, and the amount of each payment may be different
  - ii. Prescribe the amount of the stage payment(s)
- **c. Know-how and materials**
  - i. Licensor may require separate payments related to transfer of know-how, including obligations that can survive termination of the licensed patent(s)
  - ii. If licensor is providing materials, such as active pharmaceutical ingredients or biological substances (including, for example, cell lines), additional payments are customary
    - A. Material might be provided at licensor's cost or cost-plus
- **d. Payments for ancillary services**
  - i. Consulting on implementation of technologies
  - ii. Training services

7. Regulatory matters

a. **Regulated products (e.g. pharmaceuticals [including diagnostics], medical equipment) typically require registration and/or approval in the country where placed on market. Technology owner/licensor often previously obtained approval in some markets and maintains regulatory information (dossier) that may be useful or necessary in securing licensee approval in different jurisdictions. The licence should address access to regulatory information, right to use in regulatory submission, and potential cooperation by licensor in securing registration.**
   i. For certain products, the licence may require that the product meets internationally recognized stringent quality standard (e.g. World Health Organization pre-qualification)

b. **Define obligation to pay costs associated with registration**

c. **Obligation to update information as necessary/appropriate**

d. **Depending on subject matter, the licence may include provisions obliging the licensee to take measures necessary to secure regulatory approval (such as filing an application, providing relevant data, cooperating with requests from the regulatory authority, etc.)**
   i. May include time benchmarks, such as filing an application within a maximum number of days
   ii. Failure to adhere to benchmarks may constitute a default event, though provision may be made to excuse delay outside the licensee's control (e.g. delay within the regulatory authority)

8. Licence term

a. **The term of the licence should be defined—various options:**
   i. Term of years
   ii. Perpetual
   iii. Expiring when the technology enters the public domain (e.g. on expiration of relevant licensed patents)
      A. Because technologies or information other than patents may be involved, expiration of licence co-extensive with expiration of patent term is not always feasible
      B. IP may expire on different dates in different countries, and related obligations (e.g. royalties) adjusted accordingly
   iv. Expiring upon occurrence of a defined event

b. **Define rights and obligations upon expiration of the licence**
   i. Continued use of licensed technology
   ii. Obligations, if any, to return materials/data
   iii. Potential continuing obligation to maintain confidentiality

9. Taxes

a. **Define the party responsibility for payment of taxes**

b. **Address withholding requirements**

10. Representations and warranties, disclaimers, liability and indemnification

a. Knowledge of licensor
b. Express warranties or guarantees
c. Disclaimers of liability
d. Insurance requirements
e. Obligations with respect to consumer or patient injury
f. Responsibilities regarding infringement claims
    i. Claims brought against licensee based on licensor technology
    ii. Claims brought by licensee against alleged infringer
g. Indemnification
h. Obligations to defend and/or right to participate in defence

11. Breach of agreement

a. Define events constituting material default
b. Define requirements for notifying breaching party of a default event
c. Specify potential cure opportunity and relevant time-frame
d. Remedies in event of default
    i. Termination
    ii. Damages

12. Governing law

a. In the absence of agreement, local jurisprudence will determine appropriate governing law, such as by the location of the parties, where the agreement is negotiated and made, and where the licence is carried out
b. Licensors typically prefer to define governing law, either because of familiarity or because of a preference for a particular set of rules
c. Licensees typically prefer to define governing law by selecting local law with which they are familiar
d. Parties may compromise by selecting 'neutral' governing law (where neither party has perceived advantage)
e. Note that with respect to IP rights, parties cannot displace 'validity' rules where the IP rights are granted. The validity of a patent is governed by the law of the country where the patent is granted.

13. Dispute settlement

a. **Licensees typically have a preference for dispute settlement in local courts, or local arbitration (or mediation) if expeditious dispute settlement preferred**
b. **Licensors typically prefer courts or arbitration outside the licensee's home country**

14. Assignment

a. **Licence will typically address whether either or both parties may assign rights and obligations under the licence to third parties**
    i. Sub-licensing of rights to use technology may be addressed under licence grant terms

15. Reporting, audit and compliance

a. **Licensee may be obliged to provide periodic reports to licensor regarding compliance with licence terms, including, for example, territory limitations and regulatory adherence**
b. **Sales and related royalty calculations**
    i. If payment obligations are based on percentage of revenues (gross or net), provision is typically made for right of access to the licensee's books and records to confirm the accuracy of the reported revenue stream
c. **Access may be given to the licensor and/or to third-party accounting/auditing firm**
d. **Provision may be made for steps to be followed in case of dispute over audit results**

16. Transparency

a. **For access-oriented licensing agreements, parties should address whether the licence will be made public**
    i. May limit publication of technology information deemed confidential
b. **Any and all commissions or fees to third parties with respect to securing a licence should be disclosed**

17. Final terms

a. **Written agreement constituting entire agreement of parties**
b. **Amendment in writing signed by parties**
c. **Notice provisions**
    i. Contact information for parties
    ii. When notice is deemed given and received
    iii. Acceptability (or not) of electronic signature, execution in counterparts, notice, etc.
d. **Effective date of agreement**

World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland
www.who.int

United Nations Development Programme
304 East 45th Street, FF-10116A
New York, NY, 10017
United States
undp.org