



science & innovation

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NIPMO INTERPRETATION NOTE 2: INTELLECTUAL PROPERTY TRANSACTION APPROVALS

The National Intellectual Property Management Office (NIPMO) is mandated to promote the objects¹ of the Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 (Act 51 of 2008) (IPR Act). One of the functions of NIPMO, according to Section 9(4)(c)(iv)², is that NIPMO must provide assistance to institutions with any other matter provided for in the IPR Act.

This NIPMO Interpretation Note will provide clarity on which intellectual property (IP) transactions³ require NIPMO's approval, as well as indicate the associated sections and/or regulations in the IPR Act mandating such approval requirements.

Should you have any questions or comments, please do not hesitate to contact us.

Warm regards

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¹ Section 2(1) of the IPR Act: The object of this Act is to make provision that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic, whether it be for a social, economic, military or any other benefit.

² Section 9(4)(c)(iv) of the IPR Act: NIPMO must, furthermore provide assistance to institutions with any other matter provided for in this Act

³ Section 1 of the IPR Act: "intellectual property transaction" means any agreement in respect of intellectual property emanating from publicly financed research and development, and includes licensing, assignment and any arrangement in which the intellectual property rights governed by this Act are transferred to a third party

1. INTRODUCTION

1.1 Reference table

This interpretation note will discuss NIPMO approval process for local and offshore licenses and assignments. As a quick summary reference, the types of licences and associated paragraphs, where NIPMO approval is required and associated IP Forms are set out below.

	Reference paragraph	Approval required or not	IP Form
LOCAL IP TRANSACTIONS			
Exclusive, royalty/ revenue-bearing licence	2.1	No approval required	N/A
Exclusive, royalty-free licence	2.2	Approval required	IP8
Non-exclusive, royalty/ revenue-bearing licence	2.3	No approval required	N/A
Non-exclusive, royalty-free licence	2.4	Approval required	IP8
Non-exclusive, royalty-free licence for research, development and educational purposes (non-commercial licence)	2.5	No approval required	N/A
Assignment	2.6	Approval required	IP4
Partial assignment	2.7	Approval required	IP4
OFFSHORE IP TRANSACTIONS			
Exclusive, royalty/revenue-bearing licence	3.1	Approval required	IP6
Exclusive, royalty-free licence	3.2	Approval required	IP6
Non-exclusive, royalty/revenue-bearing licence	3.3	No approval required	N/A
Non-exclusive, royalty-free licence	3.4	Approval required	IP8
Non-exclusive, royalty-free licence for research, development and educational purposes (non-commercial licence)	3.5	No approval required	N/A
Assignment	3.6	Approval required	IP5
Partial assignment	3.7	Approval required	IP5
GENERAL			
Non-exclusive, royalty-free licence for Philanthropic funders	4.1	Approval required	IP8
Non-exclusive, royalty-free licence for IP created using open source licence	4.2	Approval required	IP8

1.2 Defining terms/concepts

Recipient: A recipient is a person or entity that receives public funds and undertake research and development (R&D). Typically, these are higher education institutions and science councils (collectively referred to as institutions).

Intellectual property (IP) transaction: Any agreement in respect of IP emanating from publicly financed R&D, and includes licensing, assignment and any arrangement in which the IP rights governed by the IPR Act are transferred to a third party.

Publicly financed research and development: R&D undertaken using any funds allocated by a funding agency but excludes funds allocated for scholarships and bursaries.

2. LOCAL TRANSACTIONS

2.1 Local exclusive, royalty/revenue-bearing licence

In terms of the IPR Act, a recipient is required to ensure that IP resulting from publicly financed R&D finds application and benefits⁴ the people of the Republic.

Before a recipient grants a local exclusive licence, it must be “*satisfied that the prospective licensee is capable of developing the intellectual property further where required and of undertaking the commercialisation thereof...*”⁵. The IPR Act further states that “*A private entity or organisation*” may become an exclusive licensee if it has the capacity to manage and commercialise the IP in a manner that benefits the Republic.⁶

NO NIPMO approval is required for this type of IP transaction. A local exclusive, royalty/revenue bearing licence may be granted if the recipient is satisfied that the licensee has the capacity to develop the IP further and/or has the capability to manage and commercialise the IP to the benefit of the Republic.

2.2 Local exclusive, royalty-free licence

In terms of Regulation 11(3)(b)⁷, **NIPMO approval is required** for any licence in terms of which a recipient grants a licensee rights to commercialise its IP on a royalty-free basis.

2.3 Local non-exclusive, royalty/revenue-bearing licence

Section 11(1)(a)⁸ of the IPR Act prescribes that the recipient determines the nature and conditions of its IP transactions and further prescribes that the recipient must give preference to non-exclusive licensing.

Regulation 11(1)⁹ further states that the recipient may determine the terms and conditions for any non-exclusive licence within South Africa to IP fully owned by the it and determined on an arms-length¹⁰ basis. **NO NIPMO approval** is therefore required for this type of IP transaction.

⁴ Regulation 1 of the IPR Act: “benefits” means contribution to the socio-economic needs of the Republic and includes capacity development, technology transfer, job creation, enterprise development, social upliftment and products, or processes or services that embody or use the intellectual property

⁵ Regulation 11(5) of the IPR Act

⁶ Section 15(1) of the IPR Act

⁷ Regulation 11(3)(b) of the IPR Act: NIPMO approval must be obtained for any licence in terms of which –(b) a recipient grants a licensee rights to commercialise its intellectual property on a royalty-free basis;

⁸ Section 11(1)(a) of the IPR Act: The recipient determines the nature and conditions of intellectual property transactions relating to any intellectual property held by it, but must take into account the following: (a) Preference must be given to non-exclusive licensing

⁹ Regulation 11(1) of the IPR Act: A recipient may, subject to section 11 of the Act and sub regulations (2), (3) and (4) determine the terms and conditions for any nonexclusive licence in the Republic to intellectual property fully owned by the recipient, on an arms-length basis.

¹⁰ Investopedia <https://www.investopedia.com>: **An arm's length transaction** refers to a business deal in which buyers and sellers act independently without one party influencing the other.

If the consideration payable (the royalty/revenue) is **not determined on an arms-length¹¹ basis** (for any licence; as per Regulation 11(3)(a)¹²) then **NIPMO approval** is required.

2.4 Local non-exclusive, royalty-free licence

In terms of Regulation 11(3)(b), **NIPMO approval is required** for **any** licence in terms of which a recipient grants a licensee rights to commercialise its IP on a royalty-free basis.

Instances where NIPMO is **prepared to grant** approval for a royalty-free licence include:

a) the R&D has been conducted by a recipient but at the end of the R&D agreement, further R&D is required to be carried out by a related third party (i.e. the co-funding party) before the IP can be commercialised or utilised. A royalty-free licence may be granted for the period in which further R&D is to be conducted. When the IP is reduced to a product or process, for example, which can be commercialised, the term for the royalty-free licence ends and a licence agreement for a reasonable royalty must be entered into;

or

b) where a party funds 70% or more of the direct costs of the R&D, the party may, at the discretion of the recipient, be granted a non-exclusive royalty-free licence. When such a licence is granted, the onus for compliance with the requirements of Sections 10 (Rights of IP creators) and 11 (Conditions of IP Transactions) of IPR Act, rests heavily on the recipient.

In instances where one of the two scenarios exist, a **Form IP8** must be submitted to NIPMO for prior approval on (Knowledge Information Management System) KIM.

2.5 Local non-exclusive, royalty-free licence for research, development and educational purposes (non-commercial licence)

In terms of Regulation 10(1)¹³, a recipient may transfer a right fully owned or co-owned by it to a third party for research, development and educational purposes.

NO NIPMO approval is required for this transaction. It should be noted that the term “*non-commercial license*” is limited to licenses for the use of the IP for research, development and/or educational purposes.

¹¹ Investopedia <https://www.investopedia.com>: A **non-arm's length transaction** refers to a business deal in which buyers and sellers have an identity of interest; in short, buyers and sellers have an existing relationship, whether business-related or personal.

¹² Regulation 11(3)(b) of the IPR Act: NIPMO approval must be obtained for any licence in terms of which – (a) the consideration payable by a licensee to a recipient is not determined on an arms-length basis

¹³ Regulation 10(1) of the IPR Act: Subject to any contractual arrangement to the contrary, a recipient is deemed to have reserved the right to use the intellectual property falling under the Act –

(a) owned fully by the recipient, for research, development and educational purposes and may at any time transfer that right, to a third party on such terms and conditions as the recipient may determine, for the same purpose; or

(b) co-owned by the recipient with co-owner(s), for research, development and educational purposes and subject to the consent of such co-owner(s) of the intellectual property, which may not be unreasonably withheld, may transfer that right, to a third party on such terms and conditions as agreed by the recipient and the co-owner(s) of the intellectual property, for the same purpose.

2.6 Local assignment

The recipient who is intending to transfer (assign) its IP within South Africa must submit¹⁴ a **Form IP4** for NIPMO approval on KIM. The recipient must motivate why the assignment is in the public interest or provide reasons as to why the IP cannot be commercialised¹⁵ through other means such as an exclusive licence.

Section 11(1)(c) of the IPR Act states that *"The recipient determines the nature and conditions of intellectual property transactions relating to any intellectual property held by it, but must take into account the following: **preference must be given to parties that seek to use the intellectual property in ways that provide optimal benefits to the economy and quality of life of the people of the Republic**".*

2.7 Partial Assignment

Regulation 15(4)(b) provides that *"In respect of intellectual property emanating from a collaborative research and development agreement involving one or more international funding or donor organisations, or research institutions or organisations, a recipient must, unless specifically provided for in section 15(2) of the Act - use reasonable endeavours to ensure commercialisation of intellectual property from the collaborative agreement, in accordance with sections 11 and 12 of the Act and regulations 11 and 12"*

If the parties entered into a collaborative agreement with the intention to co-own the resultant IP and they **have met three requirements of co-ownership in terms of section 15 (2) of the IPR Act**, however, could not meet **the co-creatorship** requirement, the recipient can apply to NIPMO for the assignment of the portion of its ownership to the other party, so that they can co-own the IP. It must be noted that this request will be dealt with on a case by case basis. It must be further noted that the parties must have also intended to jointly contribute to the protection and commercialisation of the IP.

NIPMO approval will be required and the recipient will apply for approval on KIM by submitting a **Form IP4** if the assignment is to the South African company or organisation.

¹⁴ In terms of Regulation 11(9) of the IPR Act: Any recipient wishing to assign the intellectual property governed by the Act, to an entity in the Republic must submit to NIPMO an application for approval of such assignment, in prescribed Form IP4, and in the case of co-owned intellectual property the recipient will do so in consultation with the co-owner(s)

¹⁵ Regulation 11(10) of the IPR Act: In the application referred to in sub-regulation (9) -

(a) the recipient must demonstrate that such assignment is in the public interest; or
(b) provide reasons as to why the intellectual property cannot be commercialised through other means such as an exclusive licence.

3. OFFSHORE IP TRANSACTIONS

3.1 Offshore exclusive, royalty-bearing licence

In terms of Section 12(1)¹⁶, **NIPMO approval is required** for an offshore exclusive licence. Regulation 12(7)¹⁷ further states that the recipient must lodge an application on a Form IP6. Furthermore, proof must be provided to satisfy NIPMO that there is (a) insufficient capacity in the Republic to develop or commercialise the IP locally, (b) that the Republic will benefit from such offshore transaction¹⁸ **and** further proof that the prospective licensee will ensure that the benefits of the IP are accessible to the Republic on reasonable terms¹⁹

3.2 Offshore exclusive, royalty-free licence

In terms of Regulation 12(3)(b)²⁰ **NIPMO approval** is required where the recipient grants a licensee rights on a royalty free basis. As set out in 3.1 above, the recipient must lodge an application on a **Form IP6**.

3.3 Offshore non-exclusive, royalty/revenue-bearing licence

Regulations 12(1)²¹ and 12(2)²² state that the recipient may determine the terms and conditions for any non-exclusive licence outside of South Africa to IP fully owned or co-owned by the recipient and determined on an arms-length basis.

In terms of the above; **NO NIPMO** approval is required for this transaction.

¹⁶ Section 12 of the IPR Act: (1) Offshore intellectual property transactions are subject to the following conditions:

a. A recipient must advise NIPMO of its intention to conclude an intellectual property transaction offshore;
b. subject to paragraph (c), offshore intellectual property transactions may occur only in accordance with prescribed regulations and any guidelines contemplated in section 9(4)(e); and
c. any intellectual property transaction which does not comply with the regulations and guidelines requires prior approval of NIPMO. (2) A recipient wishing to undertake an intellectual property transaction offshore in the form of an assignment or exclusive licence must satisfy NIPMO that: a. there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and b. the Republic will benefit from such offshore transaction.

¹⁷ Regulation 12(7) of the IPR Act: A recipient must lodge an application in prescribed Form IP5 or IP6 with NIPMO for approval of an assignment of intellectual property offshore or grant of an exclusive licence, respectively, in terms of section 12(2) of the Act in compliance with the following conditions - (a) the application must detail compliance with section 12(2) of the Act and this sub-regulation (6); and (b) the recipient clearly articulates the benefits of the intellectual property to the Republic.

¹⁸ Section 12(2) of the IPR Act: A recipient wishing to undertake an intellectual property transaction offshore in the form of an assignment or exclusive licence must satisfy NIPMO that— (a) there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and (b) the Republic will benefit from such offshore transaction.

¹⁹ Regulation 12(6) of the IPR Act: An exclusive licence agreement must in addition to the statement in sub-regulation (4) include appropriate terms and conditions, in particular - (a) require that commercialisation of the intellectual property by a prospective licensee must ensure that the benefits of the intellectual property are accessible to the Republic on reasonable terms; (b) an irrevocable and royalty-free right of the State to use or have the intellectual property used on behalf of the Republic, for the health, security and emergency needs of the Republic in terms of the Act; and (c) NIPMO's rights in terms of section 14(4) of the Act, if the intellectual property is not commercialised within the reasonable period set out in the exclusive licence agreement.

²⁰ Regulation 12(3)(b) of the IPR Act: NIPMO approval must be obtained for any licence in terms of which - (b) a recipient grants a licensee rights to commercialise of its intellectual property on a royalty free basis;

²¹ Regulation 12(1) of the IPR Act: A recipient may, subject to section 11 of the Act, and sub regulations (2), (3) and (4) determine the terms and conditions for any nonexclusive licence to intellectual property governed by the Act that is fully owned by the recipient, outside the Republic or with an off-shore entity or person, or on an arms-length basis or for the purposes of promoting or facilitating the recipient's research and development activities.

²² Regulation 12(2) of the IPR Act: Subject to the written consent of co-owner(s) of intellectual property co-owned by a recipient with co-owner(s), which may not be unreasonably withheld, a recipient may determine the terms and conditions for any non-exclusive licence outside the Republic or with an off-shore entity or person, to such co-owned intellectual property, on an arms-length basis.

Section 12(1)(c) of the IPR Act further states that “*any intellectual property transaction which does not comply with the regulations and guidelines requires prior approval of NIPMO.*”

3.4 Offshore non-exclusive, royalty-free licence

In terms of Section 12(1)(a) a recipient must advise NIPMO of its intention to conclude an offshore IP transaction. Regulation 12(3)(b) further states that **NIPMO approval is required** for any licence in terms of which a recipient grants a licensee rights to commercialise its IP on a royalty-free basis.

Similar to what was stated previously, NIPMO is prepared to grant approval for an offshore non-exclusive royalty-free licence in instances where:

- a) the R&D has been conducted by a recipient but at the end of the R&D agreement, further R&D is required to be carried out by a related third party (i.e. the co-funding party) before the IP can be commercialised or utilised. A royalty-free licence may be granted for the period in which further R&D is to be conducted. When the IP is reduced to a product or process, for example, which can be commercialised, the term for the royalty-free licence ends and a licence agreement for a reasonable royalty must be entered into.
- or**
- b) where a party funds 70% or more of the direct costs of R&D, the party may, at the discretion of the recipient, be granted a non-exclusive royalty-free licence. When such a licence is granted, the onus for compliance with the requirements of Sections 10 (Rights of IP creators) and 11 (Conditions of IP Transactions) of the IPR Act, rests heavily on the recipient.

In instances where one of the two scenarios exist, a Form IP8 must be submitted to NIPMO for prior approval on KIM. **NIPMO approval is required** for this transaction.

3.5 Offshore non-exclusive, royalty-free licence for research, development and educational purposes (non-commercial licence)

In terms of Regulation 10(1)²³, a recipient may transfer a right fully owned or co-owned by it to a third party for research, development and educational purposes.

NO NIPMO approval is required for this transaction. It should be noted that the term “**non-commercial licence**” is limited to license issues for the use of the IP for research, development and/or educational purposes.

²³ Regulation 10(1) of the IPR Act: Subject to any contractual arrangement to the contrary, a recipient is deemed to have reserved the right to use the intellectual property falling under the Act -

a. owned fully by the recipient, for research, development and educational purposes and may at any time transfer that right, to a third party on such terms and conditions as the recipient may determine, for the same purpose; or

b. co-owned by the recipient with co-owner(s), for research, development and educational purposes and subject to the consent of such co-owner(s) of the intellectual property, which may not be unreasonably withheld, may transfer that right, to a third party on such terms and conditions as agreed by the recipient and the co-owner(s) of the intellectual property, for the same purpose.

3.6 Offshore assignment

A recipient wishing to assign IP offshore or outside South Africa must submit²⁴ a Form IP5 on KIM for NIPMO approval. The recipient must satisfy²⁵ NIPMO that there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and that the Republic will benefit from such offshore transaction.

3.7 Partial Assignment

Regulation 15(4)(b) provides that *“In respect of intellectual property emanating from a collaborative research and development agreement involving one or more international funding or donor organisations, or research institutions or organisations, a recipient must, unless specifically provided for in section 15(2) of the Act - use reasonable endeavours to ensure commercialisation of intellectual property from the collaborative agreement, in accordance with sections 11 and 12 of the Act and regulations 11 and 12”*

If the parties entered into a collaborative agreement with the intention to co-own the resultant IP and they **have met three requirements of co-ownership in terms of section 15 (2) of the IPR Act**, however, could not meet **the co-creatorship** requirement, the recipient can apply to NIPMO for the assignment of the portion of its ownership to the other party, so that they can co-own the IP. It must be noted that this request will be dealt with on a case by case basis. It must be further noted that the parties must have also intended to jointly contribute to the protection and commercialisation of the IP.

NIPMO approval will be required and the recipient will apply for approval on KIM by submitting a Form IP5 if the assignment is to the foreign company or organisation.

4. GENERAL GUIDANCE

4.1 Non-exclusive, royalty free license for IP developed using open source license

According to the open source website, *“[o]pen source software is software with source code that anyone can inspect, modify, and enhance”*²⁶, meaning that open source software allows the software **source code** (i.e. IP) to be publicly used, analysed and/or modified subject to risks and certain conditions stated in the specific open source license agreements. Examples of risks is that most open source agreements offer no warranty protection on the functioning of the software or possible harm of the software (e.g. affecting the user’s device memory).

²⁴ Regulation 12 (7) of the IPR Act: A recipient must lodge an application in prescribed Form IP5 or Form IP6 with NIPMO for approval of an assignment of intellectual property offshore or grant of an exclusive licence, respectively, in terms of section 12(2) of the Act in compliance with the following conditions -

(a) the application must detail compliance with section 12(2) of the Act and this sub-regulation (6); and
(b) the recipient clearly articulates the benefits of the intellectual property to the Republic.

²⁵ Section 12(2) of the IPR Act “A recipient wishing to undertake an intellectual property transaction offshore in the form of an assignment or exclusive licence must satisfy NIPMO that-

(a) there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and
(b) the Republic will benefit from such offshore transaction”.

²⁶ <https://opensource.com/resources/what-open-source>

What is important to note is that while the IP, i.e. the software source code, can be widely used and/or modified, open source software has IP protection through the various open source licenses that have different provisions with resultant consequences. For example, some license conditions forbid commercialisation of the source code while others may permit it. Of particular concern are ‘**open source infection**’ clauses in some open source licenses which state that the open source code may be freely used, but that once incorporated into other software, all the software must become open source and licensed as per the open source licensing contract. This point can be illustrated as follows: *“if a developer at a large corporation unwittingly incorporates a small open source software module governed by an infectious open source software license into his company’s software, his company’s software will consequently become open source and free to users – a prospect that has resulted in many nights of lost sleep to house IP managers”*²⁷.

If the recipient is intending to use open source license to create IP and the terms of the license require the recipient to license the IP on a non-exclusive royalty-free license basis, **NIPMO approval is required** through the submission a Form IP 8 before the use of such software license commence.

4.2 Non-exclusive, royalty-free license for philanthropic funders

Regulation 12(3)(b) and 11(3)(b) states that **NIPMO approval is required** for any license in terms of which a recipient grants a licensee rights to commercialise its IP on a royalty-free basis.

Some philanthropic funders of R&D insist on the research contract having a humanitarian clause so that the resultant IP may be available wherever it is needed to promote human welfare.

The humanitarian clause does not always meet all the requirements stated above in paragraphs 2.4 and 3.4 as the funding may be less than 70% of the direct costs of R&D and the license is not to conduct further R&D before commercialisation of the IP.

Regulation 15 (4) (d)²⁸ of the IPR Act provides that if the collaborative agreement requires that IP resulting from the collaborative research and development will be licensed to the collaborators or other parties for commercialisation on a royalty-free basis, or should not be commercialised, the recipient must submit Form IP8 and such agreement to NIPMO for approval, prior to commencement of work under such agreement.

NIPMO is prepared to approve a non-exclusive royalty-free license for humanitarian purposes if:

- a) the license is in the public's best interest and
- b) the funder funded 50% or more of direct cost for R&D.

²⁷ WIPO/OMPI: DL450. Open Source and Development

²⁸ Regulation 15 (4) (d) of the IPR Act: In respect of intellectual property emanating from a collaborative research and development agreement involving one or more international funding or donor organisations, or research institutions or organisations, a recipient must, unless specifically provided for in section 15(2) of the Act - where the collaborative agreement requires that intellectual property emanating from the collaborative research and development be made available to the collaborators or other parties for commercialisation on a royalty-free basis, or should not be commercialised, the recipient must to refer in Form IP8 such agreement to NIPMO for approval, prior to commencement of work under such agreement.

4.3 Clauses to be included in all IP transactions/agreements

- a) Section 11(2) of the IPR Act: *"Each intellectual property transaction must contain a condition to the effect that, should a party fail to commercialise the intellectual property to the benefit of the people of the Republic, the State is entitled to exercise the rights contemplated in section 14 (Acquisition of intellectual property rights by State)."*
- b) Regulation 11(4) of the IPR Act: *"The intellectual property under this transaction was created with support from the South African Government; (under the contract number where applicable) awarded by (identify the Funding Agency or relevant government department) where applicable) and is subject to the requirements of the South African Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 and its regulations ('Act 51 of 2008"). The South African Government has certain rights to the intellectual property in terms of sections 11 (1)(e), 11(2) and 14 of Act 51 of 2008"*
- c) Section 11 (1) (e) of the IPR Act: *"each intellectual property transaction must provide the State with an irrevocable and royalty-free licence authorising the State to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic"*

5. FORM SPECIFICATIONS

In the table below is a summary of the requirements for each specific form:

Form	Documents	NIPMO action
Form IP8	Completed by the recipient and submitted to NIPMO for approval on KIM. To submit draft (or final) license agreement, indicate clauses and provide motivation why the clause/s need/s approval	NIPMO to respond within 30 days of receiving application. If NIPMO does not respond within 30 days, the application will be deemed granted. ²⁹
Form IP6	Completed by the recipient and submitted to NIPMO for approval on KIM. To submit draft (or final) license agreement and provide motivation on lack of capacity to commercialise the IP in South Africa and how the license will benefit South Africa.	
Form IP5	Completed by the recipient and submitted to NIPMO for approval on KIM. To submit cover letter and the draft (or final) assignment agreement.	
Form IP4	Completed by the recipient and submitted to NIPMO for approval on KIM. To submit cover letter and the draft (or final) assignment agreement.	

²⁹ Regulation 15(6) of the IPR Act: Within 30 days of receiving a referral made in terms of sub-regulation (4)(d), NIPMO must notify the recipient of the outcome of the referral, failing which approval will be deemed to have been granted.