### INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

SECTION ON MEDICINAL CHEMISTRY

## GENERAL FEATURES OF CONTRACTS FOR NATURAL PRODUCT COLLABORATIONS

(Technical Report)

Prepared for publication by

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# General features of contracts for natural product collaborations (Technical Report)

Abstract: Many scientists in developing countries are interested in orderly development on an equitable basis of economically useful discoveries based upon research on indigenous natural products. Availability of funds and technical expertise in the country of origin is often a limiting factor. Cooperation with individuals and organizations possessing these is frequently a practical necessity for the work to go forward. Inexperience in patent and legal matters as well as perceived differences in comparative power are often found to be inhibitory. The discussion by IUPAC is intended to be helpful in such cases by setting forth the elements which are commonly present in collaborative contracts. This material was developed by considering a dozen such contracts in present effect between persons from several different countries of origin and firms based in Europe and USA. This paper is not a contract, but indicates the elements usually present and the negotiable items which need to be settled amicably. Some explanatory comments by IUPAC are appended in appropriate places as well. This information is for background purposes only and is not intended to substitute for legal expertise. All parties entering into such negotiations should avail themselves of experienced legal advice.

#### INTRODUCTION

Many scientists in developing countries are interested in the orderly development on an equitable basis of economically valuable natural resources and products stemming from or available to their research efforts but often lack the elements of the necessary expertise and the funds to bring this about. Companies in developed countries possess these funds and expertises but lack access to the necessary biota. Thus the natural basis exists for fruitful collaborations providing that certain inhibitory factors can be resolved to everyone's reasonable satisfaction.

It is our experience that one significant inhibitory factor stems from the comparative inexperience in negotiating with confidence suitable agreements which would protect the interests of both parties. The individual scientist often feels at a disadvantage lacking the experience of such negotiations and often possessing perceived lesser power. After many conversations on the subject, we believe that IUPAC can allay many of these concerns by publication of the elements that are often present in such agreements so that proffered contracts can be judged with greater confidence that most important features have been settled. Many firms wishing to enter into such agreements have readily submitted sample contracts in current force in order to accomplish this goal.

The following synopsis has been developed by considering a dozen contracts from Switzerland, England, Germany, and the United States and should not be regarded by the reader as exhaustive or restrictive or representing the specifics of any particular contract. The following is not a sample contract but rather an indication of the items which are often contained in such contracts and, as such, can serve as the basis for a productive negotiation. Individuals entering into such negotiations should have the benefit of legal council before executing a final agreement. Those working in formal organizational settings, firms, universities, institutes, and the like, have access to such expertise and should employ it.

If this brief exposition allays fear that negotiation would lead to exploitation and enhances the comfort level of both parties then it will have served its purpose.

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#### AGREEMENT FEATURES

#### Title:

Agreement Between --- Company and --- [Names and addresses: date]

#### Recitals:

Whereas [---] Company desires to obtain selected plants/extracts/pure natural products in order to screen, assay and develop novel therapeutic agents and whereas [---] is interested in providing same under the following terms and conditions, the parties agree as follows:

#### Agreements:

- [---] will arrange for the provision to [---] Company of up to [#] of different plants/extracts/pure natural products in [#] quantity each at a rate of [#] samples per [#]. It is common that the means of purification or preparation of such substances is described here or in an exhibit. It is also common that the Company involved wishes to receive in advance a list of the materials potentially available so that they can make selections of those it wishes to receive and exclude those it has already or has no interest in having. It is also common that the labeling of the sample is also described here.
- [---] will also arrange for resupply of those items found to be of continuing interest by [---] Company. The cost of such resupply is usually significantly greater than that indicated in the previous paragraph and is usually spelled out (\$/Kg, for example). This can, alternately, be negotiated in a subsequent agreement. It is sometimes specified that [---] Company will make every reasonable effort to obtain additional supplies from [---] before going to a third party. It is usual also to require information about the location of collection, time, and the deposit of a voucher specimen in a recognized herbarium. It is also common to specify that payment will take place from a suitable invoice within [#] days of receipt of the sample in the premises of [---] Company. In some cases, money is advanced to defray reasonable out-of-pocket collection costs in advance of receipt of invoice and receipts.
- [---] warrants that he/she has the authority, licences and ability to perform these duties and to export the products and that [---] Company will not be subject to claims or liabilities by other parties in connection with the work covered by this agreement.
- [---] Company has the right to perform such biological tests as it deems appropriate. Such tests will be performed with reasonable promptness (within [#] weeks/months) following receipt of the sample. [---] Company will inform [---] whether it has any further or continuing interest in the materials provided or has obtained positive results and wishes to continue working on the material. A time limit for this information is also specified. Six months or a year following receipt of the sample is common.
- [---] Company has the exclusive right to decide which leads it will pursue.
- [---] will indicate whether [---] has previously investigated or provided samples of these materials previously to a third party. It is common that it is specified that no third party not under obligative control on either party may receive a sample of the material unless [---] Company informs [---] that it has permission to do so or that it has no further interest in the material. This restriction may have a time limit associated with it.
- [---] will not collaborate with a third party on these materials unless permitted in writing or released from obligation by [---] Company.
- [---] will not patent these materials independently of [---] Company unless released to do so in writing.

#### Product development and royalties:

Discoveries made by [---] Company with these samples are the property of [---] Company although they may be jointly or individually be patented depending upon negotiation, with legal assistance if necessary, of inventorship.

The Company owns the materials generated as a result of the contract. Inventorship represents intellectual property and does not relate directly to material ownership.

[---] Company will use its legal resources and funds to patent the fruits of this collaboration in all economically significant countries, including the country of origin of the samples, if it decides to do so.

[---] will provide all reasonable assistance (records, signing documents, etc.) to [---] Company to support the effort to obtain patent protection.

The patent will belong to [---] Company. Several articles dealing with various aspects of patenting have been published lately. The reader is referred to Mitscher *et al.* (1994) and Pidgeon (1993) and the references contained in them.

[---] Company will notify [---] if it decides to isolate the active principle or a plant or extract. The sponsoring company sometimes makes provision for the collector to do the isolation if the two parties agree to this. The length of the agreement may be extended when continuous work of this type is undertaken.

[---] Company agrees to pay a royalty of [#] [typically 2%] of Gross or Net Sales [which is specified] if a product results from a sample provide by [---] under this agreement, provided that [---] Company was not previously in possession of this material from a third party, or not isolated previously independently from a different source in their own laboratories from a sample not provided by [---]. Sometimes an upper limit is placed upon the total magnitude of the royalties to be paid (#\$M) or payments to cease when the patent expires. The royalties are commonly adjusted downward by reasonable charges against the Gross or Net Sales (discounts given to purchasers, credits for unsold remanents, transfer charges, customs costs, excise taxes, and the like). The actual magnitude of the royalty which may be proffered by a firm is commonly a function of the intellectual content and state of the material actually provided to them. For example, a pure and novel substance is more valuable than a crude extract because of the defined nature of the material and the previous labor expended upon it. Crude extracts provided on the basis of a specific criterion are generally more valuable than samples which have been collected randomly.

It is becoming increasingly common for the sponsoring company to specify that a percentage (commonly 50%) will be paid directly to the collector and the remainder to a foundation jointly chosen by the collector and the company. Such foundation is to use the funds to promote conservation of biomass and biological diversity in the country of origin of the materials, to ensure an equitable economic benefit to the country of origin of the materials, and to develop long term strategies for sustainable cultivation of targeted biota in the country of origin.

Transfer among subsidiaries of the sponsoring company are not normally considered sales nor is distribution of free samples to clinicians or promotional samples provided to physicians.

If the product sold contains other active ingredients, the value for royalty purposes will be arrived at proportionally.

Royalties are normally calculated either biannually or annually and are paid according to an agreed upon schedule ([#] months after the end of the accounting period).

Royalties are normally paid in the currency of the country in which the sponsoring company has its principal business location.

Appropriate books will be maintained by [---] Company specifying quantity sold, total billings, sales to governments, royalties due, and the like.

These books will be reasonably available for inspection by a Certified Public Accountant selected by [---] should [---] wish to verify the royalties. In this case, the costs of this will be borne by [---].

#### Confidentiality:

Each party can freely disclose relevant information of a proprietary or confidential nature to each other and to those subordinates bound to them who agree to maintain confidentiality. Confidential written material should be so marked.

Neither party will disclose to third parties such confidential and proprietary information without written permission. The duration of this restriction is usually negotiated.

These disclosure restrictions do not apply to information already known to the receiving party. This should be in the form of documentary evidence. Also excluded is information already known to the public or which becomes known to the public through no fault of the parties in this agreement. Also excluded is information revealed by third parties with the legal right to make such disclosures. Disclosure to

appropriate third parties for the purpose of cooperating in getting a patent is allowed.

Either party will inform the other promptly if an invention is believed to have been made.

#### Miscellaneous:

Termination of the agreement can be made by either party on [#] days notice in writing to the official address to the other party. Prior obligations survive the termination.

This is the entire agreement. It can be amended by [---] and [---] Company only in writing.

[---] and [---] Company remain independent of each other. They do not become partners, agents, etc., of the other party by virtue of this agreement. Neither can independently obligate or bind the other party without permission.

Notices required or permitted are to be sent to specified parties at specified addresses by verifiable means of receipt (registered letters, etc.).

Neither party may use the name of the other party in advertising, brochures or other literature without written permission.

The terms of the agreement are confidential to the parties executing it.

The agreement is governed by the laws of the country or state of [---] Company.

If any part of the agreement is subsequently discovered to be invalid or illegal, the remaining parts remain in force.

Unresolved disputes are settled in court, usually in the country of [---] Company.

The agreement begins with the last dated signature executed below.

#### Signatures, titles and dates: