

de-sized companies that offer custom synthesis, the chemical production divisions of the big agrochemical and pharmaceutical companies are entering this arena. They are looking for contract synthesis in their specialised fields, while at the same time, branching into new fields where they may have only minor technological strengths. Overall, this development means lower production costs for all final products. Some commodity chemical producers are also entering the fine chemicals market, but only few have been successful. Many of these companies often have difficulties assimilating the culture of the fine chemicals market.

### What is the Outlook for Custom Synthesis in the Future?

The outlook for chemical intermediates in life science is favourable. Worldwide sales for drugs grew in the range of 7% in 1997. More than one third of the industry's growth has come from products less than two years old. Also the world market for agrochemicals has an average growth of 2%. It is believed that this trend will not change in the near future. This means that outsourcing in form of custom synthesis and toll manufacture will see strong sales and profit growth during the next few years.

### Key Factors for Successful Custom Synthesis

- Technical know-how
- Professional competence for quick response to customers' inquiries
- Quick development in laboratory, pilot plant and production
- Reliability (dead lines, quality, etc.)
- Mutual trust (partnership)

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## Intellectual Property Right Issues in Custom Manufacture

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**Abstract.** In recent years, intellectual property rights have become more and more a key issue in negotiations with pharmaceutical and agrochemical companies relating to *Lonza's* development and manufacturing of active ingredients or advanced intermediates. Whilst *Lonza's* customers are interested in ownership and use rights to such intellectual property rights developed by *Lonza* in order to obtain maximum protection for their end product, *Lonza* is interested in being able to use such intellectual property rights for other projects in order to broaden its technology offering to its customers. This article outlines how *Lonza* has been approaching this issue with its customers in order to find a solution covering both parties' interests.

### 1. *Lonza's* Customer Synthesis Business

Over the last 25 years *Lonza*, developed considerable research and development capabilities and is continuing to heavily invest into these capabilities. *Lonza* has thus been successful in developing new manufacturing technologies, and cus-

tomers approaching *Lonza* with a project or only a project idea have today access to an ever growing technology and know-how pool.

*Lonza's* investments into research and development are ultimately geared to manufacturing intermediates and active ingredients for its customers under long-term supply agreements. *Lonza* is bearing, however, a high risk that a customer project is being stopped at any time, in particular with *Lonza* being asked more and more to participate in early development efforts. Therefore, it is of vital importance that *Lonza* remains in a position to add intellectual property rights developed in one customer project to its technology and know-how pool and to prevent that the

technology developed by *Lonza* is making its way to other fine chemicals manufacturers without adequate compensation for the value created by *Lonza*. Where *Lonza* is finally manufacturing an intermediate or active ingredient for a customer under a long-term supply agreement, exclusive rights are offered to the customers, as will be further described below.

### 2. Customer Project Sequence

After receiving a technical package from a customer, *Lonza* starts a first desk evaluation of the project. As no laboratory work is carried out during this phase, intellectual property rights will not be developed by *Lonza* and need not to be addressed in the secrecy agreement under which *Lonza* received such technical package. If the customer is interested to pursue the project according to *Lonza's* project proposal submitted following receipt of the technical package, a research and development agreement is proposed, with intellectual property rights being addressed. Such agreement defines the work program with description of objectives, activities to be carried out by *Lonza*, timing and price.

If upon conclusion of the research and development phase a long-term supply agreement is concluded, the terms regarding intellectual property rights from the research and development agreement will be incorporated into the supply agreement. Additional specific development work (e.g., second-generation process development) could be carried out under amendments to the research and development services agreement, whilst the long-term supply agreement is in effect.

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### 3. Scope of Intellectual Property Rights – *Lonza's* Interest Therein

Intellectual property rights will thus be primarily developed in the research and development phase of a project, before a manufacturing process is established and validated. Intellectual property rights may consist of inventions, discoveries, improvements or know-how developed in a customer project, whether patentable or not. It goes without saying that all proprietary information disclosed by the customer under the secrecy agreement or the research and development agreement will remain the exclusive property of the customer. Likewise, *Lonza's* preexisting technology which *Lonza* is offering to the project remains the exclusive property of *Lonza*.

*Lonza* has identified two major cases of intellectual property developments:

#### 3.1. Sequence Selection

The customer discloses the chemical structure of a compound. *Lonza* then develops a process for the manufacture of such compound; or the customer discloses not only the chemical structure, but also the manufacturing process. *Lonza* then proposes to change the process sequence:

Customer sequence: A ⇒ B ⇒ C ⇒ D

Proposed *Lonza* sequence: E ⇒ F ⇒ D

#### 3.2. Route Selection

The customer discloses the compound structure and the manufacturing process. *Lonza* then proposes process optimisation to certain process steps without changing the process sequence.

As a fine chemicals manufacturer, *Lonza* is interested in ownership of and use rights to such intellectual property rights as they relate to chemical processes and intermediates. *Lonza* is, however, not interested in ownership and use rights as they relate to the customer's active ingredient or final product.

### 4. Ownership and Rights to Use the Intellectual Property Developed

Whilst it seems appropriate that the party developing an intellectual property right should also be entitled to exclusively own such right, *Lonza* is also proposing joint ownership under long-term collaboration agreements.

Regarding the use of intellectual property rights, it is then proposed that the customer shall have exclusive rights thereto

insofar as they relate to a specified customer compound.

Where a customer wishes to use such intellectual property rights for own manufacture of such compound, *Lonza* would only expect a separate, reasonable compensation for the value created, should *Lonza* not become at least a comanufacturer of the compound under a long-term supply agreement.

Should the customer wish to have the compound manufactured at a third party applying the intellectual property rights developed by *Lonza*, such use would need *Lonza's* consent, and *Lonza* would expect a reasonable compensation.

This proposal is addressing *Lonza's* prime goal to become a long-term manufacturer of a proposed active ingredient or intermediate. On the other hand, *Lonza* is interested to adequately protect its customers' intellectual property rights position as it relates to a specific compound during the development or manufacturing of which the intellectual property was developed. The customer shall also be free to have the compound manufactured with the intellectual property rights developed by *Lonza* elsewhere, but then only against an adequate compensation.

### 5. Summary

Intellectual property rights developed in a custom synthesis project are generally viewed today as being much more valuable than in the past, in particular as the fine chemical manufacturer becomes more and more involved in the early development phases of a compound.

For the fine chemical manufacturer, investing heavily in its research and development capabilities in order to manufacture compounds for its customers applying the best possible processes, protection of the intellectual property rights position has become of great importance. Three main interests have been shown:

- Firstly, the ability to use intellectual property-rights developed in one project for other customer projects (subject to certain restrictions relating to customer compounds), which in the end should be beneficial for all customers.
- Secondly, adequate compensation if the customer is not considering *Lonza* as a long-term supplier of the relevant compound, but wishes to benefit from the value created through *Lonza's* research and development efforts through continuous use of intellectual property rights developed by *Lonza*.

- Thirdly, the prevention of intellectual property rights developed by *Lonza* being made available to competitors of *Lonza*, unless this is made with *Lonza's* consent and against an adequate compensation.

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