

Intellectual Property and Pharmaceutical Innovation:

a model for managing the creation of knowledge
under proprietary conditions

Rik van Reekum

*Dedicated to my mother and
in memory of my father*

Rijksuniversiteit Groningen

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Pharmaceutical Innovation:**

a model for managing the creation of knowledge
under proprietary conditions

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PREFACE

Before viewing the contents of this thesis, I would like to draw your attention to those people who somehow contributed to its conception.

First of all, I would like to thank my 'academic godfather' Jos van der Werf, who made it possible for me, a little more than 10 years ago, to acquire some preliminary experience in academic research. Later on, Liesbeth Kneppers-Heynert enabled me to build on this experience as a research trainee on the project that culminated in this book. Thanks to both of you, Jos and Liesbeth, for your supervision and support in this troublesome period of my life!

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family, my late father Ton and my mother Gerda for raising, always supporting and believing in both me and my sisters Judith, Janine, and Carien.

As a remark on reading, notation is applied as following:
Both footnotes and endnotes have been used. Footnotes are indicated with a superscript letter and contain cross-references, definitions and short explanations. Endnotes are indicated with a superscript number and contain secondary explanations and digressions.

Finally, all comments are welcome (r.vanreecum@bw.kun.nl).

Rik van Reekum

Nijmegen, April 1999.

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ABBREVIATIONS

AHP	Analytical hierarchy process
CRF	Concept record form
DMU	Decision-making unit
EIRMA	European industrial research management association
EPO	European patent office
FDA	Federal drug administration
GST	General systems theory
HRM	Human resource management
IO	Industrial organization
IMR	Institute for medicine research
IMS	Institute for medical statistics
IP	Intellectual property
IPR	Intellectual property right
MNC	Multinational corporation
NCE	New chemical entity
NIH	Not-invented-here
O&M	Organization and management
PLC	Product life cycle
PMC	Product-market combination
PMS	Post marketing surveillance
R&D	Research and development
RBV	Resource-based view
ROI	Return on investment
S&T	Science and technology
SCP	Structure conduct performance
SM	Strategic management
SPC	Supplementary protection certificate
SSM	Soft systems methodology
TCA	Technology competitor analysis
TLC	Technology life cycle
UNIDO	United Nations industrial development organization
USPTO	United States patent treaty organization
WIPO	World intellectual property organization

GLOSSARY

Appreciation	the on-going process of perceiving, judging, and acting (Vickers 1965, 1983, Checkland & Casar 1986).
Appreciative system	a pattern of concerns and their simulated relevant situations (Vickers 1983: 55).
Appropriability	the ability of private originators of ideas to obtain for themselves the values that society attributes to a new idea (Magee 1977).
Appropriation	the (trans)actions of an agent aimed at the accumulation of and organizational control over new ideas.
Control	<ul style="list-style-type: none">● the achievement and maintenance of a preselected perceptual state of affairs in the controlling system, through actions on the environment that also cancel the effects of disturbances (Powers 1973).● any manner of directed influence (De Leeuw 1986).
Data	transmittable representations of attributes of entities (e.g. creatures, things, events, or concepts) (Sebus 1991).
Epistemology	the theory of knowledge, the major questions concerning the nature of our knowledge of the external world, the sources of knowledge and how claims to knowledge can be substantiated (Barry 1981).
Exploitation	the development and use of a patented idea for commercial purposes, by marketing the idea or the resulting product (i.e. licensing or selling).
Feedback	a closed unidirectional causal chain relating a system and its environment (Powers 1973).
Information	interrelated and interpreted data (Bemelmans 1987).

Infringement	intellectual property law gives rights to the owner of the property permitting him to do certain acts with the thing to which the right applies. Any person who does one of these acts without the permission of the right's owner is said to infringe the right, unless the act concerned is permitted by law or another defence applies (Bainbridge 1994).
Innovation	(the process of creating) a new product or service which is successfully introduced in the market.
Intellectual property rights	legal rights associated with intangible assets arising from rights creative effort, commercial reputation and goodwill (Bainbridge 1994).
Invention	(the act of making) a patentable discovery.
Knowledge	<ul style="list-style-type: none">● the sum total of information incorporated by an individual (Sebus 1991).● the way information is organized to be productive and the degree to which it can be organized (Boulding 1956).● the final and always unfinished stage of heuristic action, rooted in the biological human functions and the free life of society (Polanyi 1958).
Lead	a piece of information or an idea which may help people to discover the facts in a situation where many facts are not known (COBUILD 1995).
Licence	a permission given by the owner of a right (licensor) to another person (licensee) allowing the licensee to do certain specified things in respect to the subject matter of the right. Intellectual property licences are usually contractual in nature and the licensor will usually receive royalties by way of consideration for the permission (Bainbridge 1994).

Patent	an arrangement between the state and an inventor whereby the inventor is granted a legal monopoly for the exploitation of the invention over a limited period of time in return for full disclosure of his new machinery, industrial process or product. It is the right to stop others from exploiting an invention belonging to a patentee (Cole, Shears & Tiley 1990).
Perception	a signal emitted by the input function of the system that is a continuous analogue of some aspect in the state of affairs outside the system (Powers 1973).
Property rights	the sanctioned behavioral relations among men that arise from the existence of goods and pertain to their use (Furubotn & Pejovich 1974).
Proprietary knowledge	the knowledge of inventors and the intellectual activity and resources of their organizational environment which are assumed to have contributed to inventors' conceptions of patented ideas.
Proprietary positions	the demarcation of a firm's interest with respect to certain private goods indicating its relative strength and competitive relations in terms of property rights.
Proto-information	the result of data processing through defined systems before validation by the user (Sebus 1991).
Public domain	the publically available information that may be freely used and exploited without infringing on anyone's intellectual property rights. It may be available because: <ul style="list-style-type: none">● the information is commonplace;● IPRs have expired;● it has been put there deliberately by the originator (Bainbridge 1994).
Role	the position an entity has in a particular situation and which determines how much the entity is involved in the situation or how much responsibility it has; its function (COBUILD 1987).

Royalty	a payment mechanism, normally calculated on a percentage of the income derived from sales of works or articles subject to an IPR (Bainbridge 1994).
Specialties	drugs that are protected by both brand and patent rights.
Technology	technical knowledge and its materialized applications.
Teleology	the doctrine that explains the nature of things in terms of the ends or purposes they are supposed to bring about (Barry 1981).