JENNIFER A. TEGFELDT, ESQ.

Jennifer holds a degree in Biological Sciences from the University of California, Davis. Following a several year career as an analytical chemist, Jennifer graduated from Pierce Law in 1985 with the goal of practicing intellectual property law. The IP program, back then, was substantially different than now – Jennifer was the only woman in a class of eight men. She served as an editor to "Idea, the Journal of Law and Technology" almost from the beginning of her legal education. She counts among her most important mentors and guides (as do a number of IP students of Pierce Law), the irreplaceable Professor Bob Shaw, who never saw obstacles, only opportunities.

Jennifer was the first alumnus to be appointed law clerk to a judge of the Court of Appeals for the Federal Circuit. Jennifer served as law clerk to Judge Pauline Newman from 1985-1987, and assisted in such proceedings as <u>Pennwalt</u>, <u>Texas Instruments</u>, <u>In re Thorpe</u>, and the FAA air controller cases.

When her clerkship ended in 1987, Jennifer entered private practice with a small boutique patent law practice and was later recruited to join Fitzpatrick, Cella, Harper and Scinto in the firm's Washington D.C. offices. Her practice focused on patent prosecution and enforcement, appeals, trademarks, copyrights, licensing, and opinion work of all types. Jennifer was very active in the Federal Circuit Bar Association, AIPLA, ITC Trial Lawyers Association, American Bar Association, including gaining Delegate status in the ABA's House of Delegates for the Federal Circuit Bar Association, and the American Inns of Court, Giles S. Rich Inn.

In 1994, Jennifer left private practice to join Genzyme Corporation as one of four attorneys supporting the company. Since that time, the legal team has grown to over twenty patent and corporate lawyers. Jennifer maintains a patent practice, while working closely with the corporate legal team in transactional matters, and in leading legal efforts to develop and put in place collaborations. Within the last year, Jennifer has expanded her "Transactional IP" role in taking on a strategic position in the Business Development team for the Therapeutics business unit of Genzyme General, a division and tracking stock of Genzyme Corporation. As Director, Business Initiatives and IP Legal Affairs, she continues to pursue her business knowledge as a logical and necessary component of intellectual property management and corporate growth.

Jennifer lives in the Boston area, and her friends know that when the winter weather breaks, she'll most likely be out on the water exploring the coast in her sailboat.

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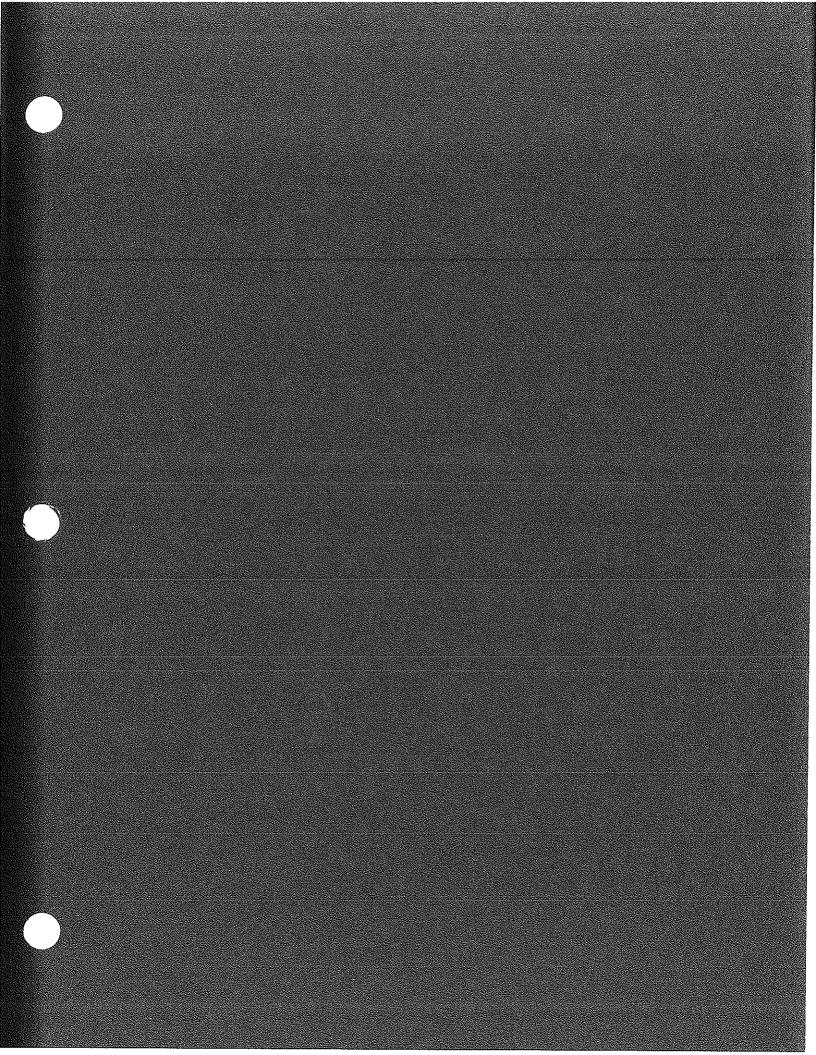
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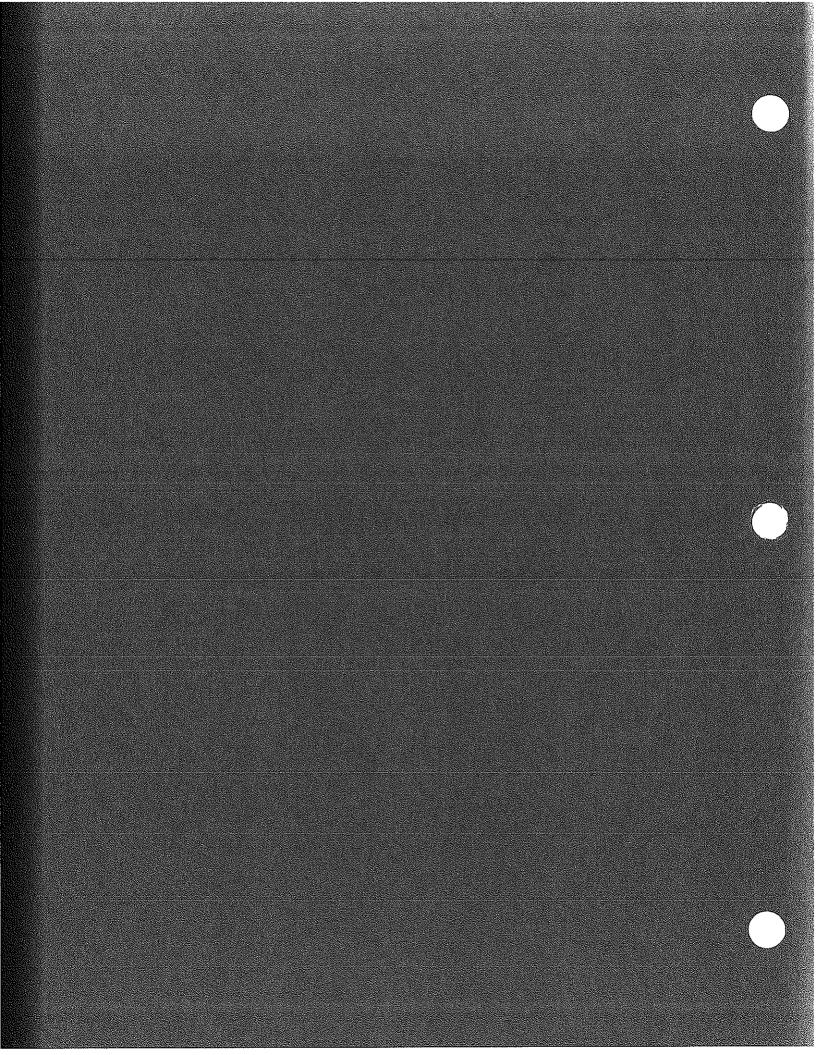
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BIOTECHNOLOGY LICENSING

A VIEW FROM THE INSIDE

ELEVENTH ANNUAL ADVANCED LICENSING INSTITUTE PIERCE LAW CONCORD, NEW HAMPSHIRE JULY 15-19, 2002

Jennifer A. Tegfeldt, Esq. Director, Business Initiatives and IP Legal Affairs Genzyme Corporation Cambridge, Massachusetts

DISCUSSION POINTS

- THE BUSINESS OF BIOTECHNOLOGY
 - FORMS OF COLLABORATION
 - DEVELOPING THE PROCESS
 - CONTRACTUAL CONSIDERATIONS
- ADDITIONAL THOUGHTS IN CRAFTING A SUCCESSFUL COLLABORATION

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I. THE BUSINESS OF LIFE -- BIOTECHNOLOGY

An Historical Perspective

Source : 2002 Biotechnology Industry Association, www.bio.org, Time Line of Biotechnology

800 B.C.	Humans domesticate crops and livestock	
4000-2000 B.C.	Production of cheese and fermentation of wine (Sumeria, China and Egypt) Babylonians control date palm breeding by selectively pollinati	
	female trees with pollen from certain male trees	
500 B.C. and states	First antibiotic made of moldy soybean curds to treat boils (Chi	ina)
A.D. 100	First insecticide made of powdered chrysanthemums (China)	
1590-1675	1590 – Janssen invents the microscope 1663 – Hooke discovers the cell	
and Baragan Baran Lawa (Maragan Araba)	1675 – Leeuwenhoek discovers bacteria	11. ¹⁹ .2
1797	Jenner inoculates a child with a viral vaccine against smallpox	
1830-1855	1830 – Proteins discovered	÷
	1833 – First enzyme discovered and isolated	
	Scheiden and Schwann propose that all organisms are made of cells	
	Virchow announces "Every cell arises from a cell"	
1859	Darwin publishes the theory of evolution by natural selection	*
1865	Genetics begins with Austrian monk Gregor Mendel studying	· .
	garden peas and discovering that genetic traits are pass from parents to offspring in a predictable way – the laws of heredity	2.45 -
1877-1879	1877 – Koch develops a technique for staining and identifying	
North Constants	bacteria 1878 – The first centrifuge is developed by Laval	
na an Meitaraga. Sa	1879 – Fleming discovers chromatin, the rodlike structures in the nucleus that became known as chromosomes	he .
	1902 The term "immunology" first appears 1906 The term "genetics" is introduced 1915 Phages, or bacterial viruses, are discovered	
-	1715 I habes, or bacterial thrapes, are apporting	· .

1920	Human growth hormone discovered by Evans and Long
1928	Penicillin discovered as an antibiotic by Alexander Fleming
1944	Avery et al. prove DNA carries genetic information
1946	Discovery that genetic material from different viruses can be combined to form a new type of virus, an example of genetic recombination
1949 And Frank (1977) No.	Pauling shows that sickle cell anemia is a "molecular disease" resulting from a mutation in the protein molecule hemoglobin
1953 (1993) (1995) (1995) 1953 (1997) (1997) (1997) 1953 (1997) (1997) (1997) (1997) (1997) (1997) (1997) (1997) (1997) (1997) (1997) (19	"Nature" publishes James Watson and Francis Crick's manuscript describing the double helical structure of DNA
1956 1956	Kornberg discovers the enzyme DNA polymerase I, leading to an understanding of how DNA is replicated
1966	The genetic code is cracked, demonstrating that a sequence of three nucleotide basis (a codon) determines each of 20 amino acids
1969	An enzyme is synthesized in vitro for the first time
1971	First complete synthesis of a gene
1973 ₎ trafficare dal 10 195	Stanley Cohen and Herbert Boyer perfect genetic engineering techniques to cut and past DNA (using restriction enzymes and ligases) and reproduce the new DNA in bacteria
1976 (110 Marshold Mar A	First time the sequence of base pairs for a specific gene is determined (A, C, T, G)
	First expression of a human gene in bacteria Recombinant human insulin first produced Human growth hormone first synthesized
1980	U.S. Supreme Court, in Diamond v. Chakrabarty, approves the patenting of genetically engineered life forms
1981	Scientists at Ohio University produce the first transgenic mice
1983	Conception of polymerase chain reaction (PCR), in which heat and enzymes are used to make unlimited copies of genes and gene fragments

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1985	1985Genetic markers found for kidney disease and cystic fibrosis1986First genetically engineered vaccine for humans: hepatitis B First anticancer drug through biotechnology: interferon	
1986		
1988	Harvard molecular geneticists receive first U.S. patent for genetically altered animal – a transgenic mouse ("the onco-mouse")	
1990	Human Genome Project – an international effort to map all the genes in the human body – is launched First transgenic dairy cow used to produce human milk proteins for infant formula	
1994	First breast cancer gene discovered	
1997	First animal cloned from an adult cell: a sheep named Dolly	
1998	Embryonic stem cells used to regenerate tissue and create disorders mimicking diseases	
2000	Rough draft of the human genome sequence is announced	
2001	Scientific journals publish complete human genome sequence	

"anything under the sun that is made by man." Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)	n an
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The Possibilities of Biotechnology	
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o Higher producing and drought and insect resistant plants	and the second
o Better tasting and longer lasting vegetables and fruits	$= - \sum_{i=1}^{n-1} \frac{1}{i} \sum_{i=1}^{n-1} $
• Higher productivity animals	
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Therapeutics	
on o Gene Therapy an arrange and record to be build shall	
o Protein Therapies	
o Diagnostics, including genetic testing	
o Improved patient therapy monitoring	
al subjective server of Cell Therapies in the server is th	
o Combination Therapies	
• Synergies with "chemical" therapies	
Discovery	
o Models for disease, cell and animal	
o Screening techniques	· · · · ·
■ Manufacture	
• Plant (such as picchia)	
o Insect	• • • • •
• Mammalian cells (human and CHO)	
o Transgenic animals	
Environmental uses	
o Hozordous waste clean un	

o Hazardous waste clean-up

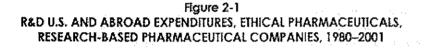
DRUG DEVELOPMENT IN THE PHARMACEUTICALS INDUSTRY

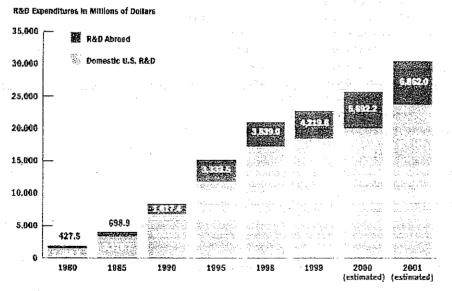
Pharmaceutical Industry Profile 2001 Pharmaceutical Researchers and Manufacturers of America, <u>www.phrma.org</u>

RESEARCH AND DEVELOPMENT INVESTMENT

- In 2001, R&D investment, worldwide, reached \$30.5 billion
 - 18.7% increase in expenditures from 2000, and triple the R&D expenditure in 1990

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Source: PHRMA Annual Survey, 2001,

Source: Pharmaceutical Industry Profile 2001, Chapter 2, Research and Development – The Key to Innovation, page 12; www.phrma.org

RELATIONSHIP OF R&D TO SALES

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• Greater than three times level of R&D investment in drugs and medicine

Figure 2-3

R&D AS A PERCENT OF SALES, RESEARCH-BASED PHARMACEUTICAL COMPANIES AND U.S. INDUSTRIAL SECTORS, 2000

Research-Based Pharmaceutical Companies

Domestic 8&D 17.65 Globel R&D 15.6% industrial Sector Comparison;¹ Drugs & Medicine" Computer Software & Services 10.5% Electrical & Electronics 8.4% Office Equipment & Services 7.6% Telecommunications 5.3% Leisure Time Products 4.7% Automothe 1986 3.9% Aerospace & Defense 3.8% Metals & Mining 1.2% Paper & Forest Products 0.73% All Industries, Excluding "Drugs and Medicine" 3.9%

1 Researched-Based Pharmaceutical Companies' based on ethical pharmaceuticals sales and ethical pharmaceuticals R&D only as tabulated by PhRMA.

2"Standard and Poor's Compustat - 4 digit SiC codes.

3 "Drugs and Medicine" category based on ford R&D and soles for companies classified within The "Drugs and Medicine" sector as republiced by Standard & Poor's Compustal, a division of McCraw-Hilt (includes research- and non-research-based companies).

Source: PhRMA, 2001, based on data from PhRMA Annual Survey and Standard & Poor's Compusited, a division of McCraw-Hill,

Source: Pharmaceutical Industry Profile 2001, Chapter 2, Research and Development – The Key to Innovation, pages 13, 15; www.phrma.org

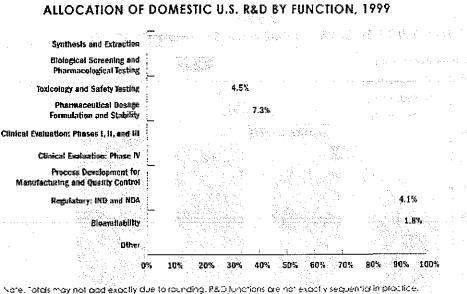
WHERE THE FUNDING GOES

• 36% spent on preclinical studies

29.1% spent on Phase I, II and III studies

Figure 2-4

11.7% spent on Phase IV studies, post approval by the FDA



None, Totas may not bad exocity due to rounding, R&D Junchons are not exactly sequentia in province. Source, PhRMA, Annual Survey 2001.

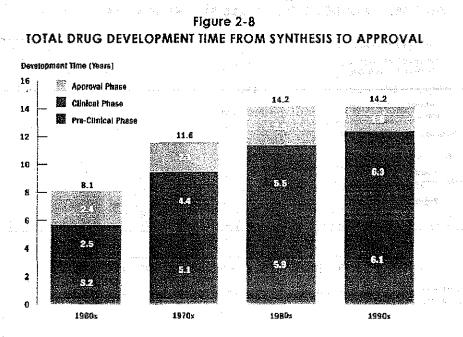
Source: Pharmaceutical Industry Profile 2001, Chapter 2, Research and Development – The Key to Innovation, page 14; www.phrma.org

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OTHER ISSUES BEARING ON COST:

TIMELINE FOR R&D

- The Developmental Timeline has increased
 - 8 years to approval in the 1960's
 - 14.2 years to approval in the 1990's



Soulde: DiMasi, J.A., "New Drug Development in U.S. 1963-1999." Clinical Pharmacology & Therapeutics 2001, May, 69(h).

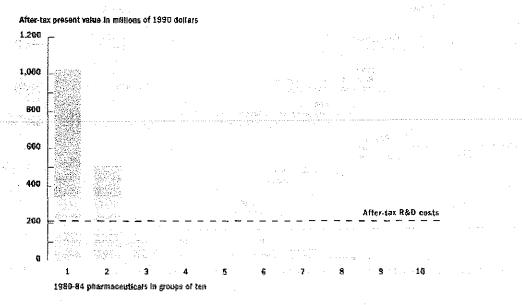
Source: Pharmaceutical Industry Profile 2001, Chapter 2, Research and Development – The Key to Innovation, pages 17, 19; www.phrma.org

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SUCCESS FACTOR FOR DRUG CANDIDATES AND FUNDING OF DEVELOPMENT EFFORTS

- Only three out of ten new drug products or new drug entities (introduced 1980-1984) had returns higher than average after tax R&D costs
 - Duke University study also showed that the revenues of 20% of the products provided 70% of the returns
 - Companies rely on the success of a few products to support their product development pipeline

Figure 2-9 ONLY THREE OF TEN MARKETED DRUGS PRODUCE REVENUES THAT MATCH OR EXCEED AVERAGE R&D COSTS



Note. The arug development cost cited in this chart is after-tax in 1999 abiliars for drugs introduced. 1980-1984, Based on a separate analysis by the Boston Consulting Group, the pre-tax %&D cost for drugs introduced in 1990 is \$500 million.

Source: Pharmaceutical Industry Profile 2001, Chapter 2, Research and Development – The Key to Innovation, pages 18, 20; www.phrma.org

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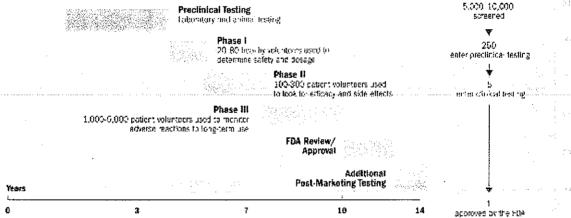
LIKELIHOOD OF SUCCESS IN DEVELOPMENT

One in up to 10,000 compounds ultimately becomes a marketed drug

Rigorous science at the early stages of development is critical to improving the odds of success



Figure 3-1



Source: PhRMA, based on data from Center for the Study of Drug Development, Tufts University, 1995.

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Source: Pharmaceutical Industry Profile 2001, Chapter 3, Regulatory and Legal Aspects of Drug Development, page 24; www.phrma.org

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FDA REVIEW PROCESS – TIMELINE

FDA review period reduced by almost half since 1987 due to increased pre-clinical efforts and clinical trials supporting more comprehensive regulatory filings, and FDA efficiency

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Safety is a paramount concern throughout

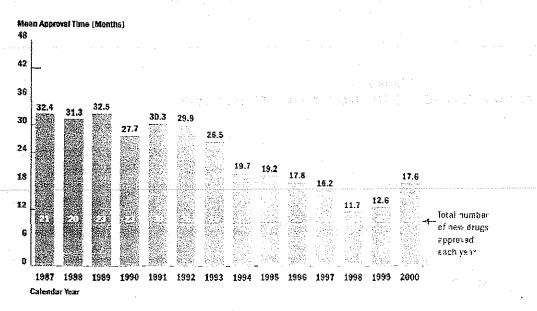


Figure 3-2 MEAN APPROVAL TIMES FOR NEW DRUGS, 1987-2000

Source: U.S. Food and Drug Administration, 2001.

Source: Pharmaceutical Industry Profile 2001, Chapter 3, Regulatory and Legal Aspects of Drug Development, page 25; www.phrma.org

OPTIONS FOR MEETING THE FINANCIAL CHALLENGE

- Opportunities of success optimized through collaboration
 - o Development expertise
 - Regulatory support, national and international 0
 - Marketing expertise, national and international 0
 - Capital 0
 - The impetus to form strategic alliances has built nearly seven fold in the twelve year period from the mid 1980's to the late 1990's

The frequency of mergers and acquisitions (shown in Figure 5-8) have grown annually, and have included larger transactions

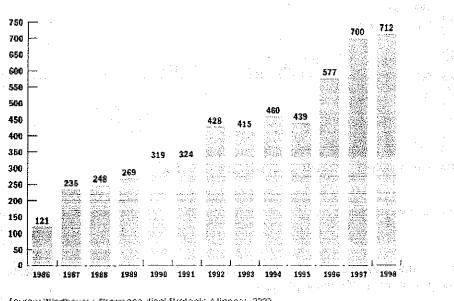


Figure 5-7 **INCREASING FREQUENCY OF STRATEGIC ALLIANCES, 1986–1998**

Source: Windhover's Pharmaceutical Strategic Aliances, 2000.

Source: Pharmaceutical Industry Profile 2001, Chapter 5, pages 62-63; www.phrma.org

Figure 5-8 MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL INDUSTRY

2000	G.D. Searle and Pharmacia & Upjohn > Pharmacia Corporation Warner-Lambert and Pfizer Inc. > Pfizer Inc.	n 1995 - Alexandre Angelei an star an		· ·
2000	Rhone-Poulenc and Hoechst Marion Roussel > Aventis AG	·		
2000	SmithKline Beecham and Glaxo Wellcome > GlaxoSmithKlin			
2000	Centecor and Johnson & Johnson + Centecor acquired			•
2000	Knoll Pharmaceuticals acquired by Abboll Laboratories			
2000	Alza Corporation anticipated to be acquired by Johnson &		1 6. g	
2000 2000 2000	Johnson (subject to Board approval) The Liposome Company acquired by Elan Pharmaceuticals Pasteur Merieux Connaught > Aventis Pasteur Pathogenesis Corporation acquired by Chiron Corporation	e Maria Maria Maria (1997) La Mitra de Compositoria de Persona de Person	e u V	
	(non-member)			
1999 1999	Monsanto and Pharmacia & Upjohn AHP/Warner-Lambert and Pfizer/Warner Lambert (pending)		38 	
1999	Roche and Genentech		* *	•
1999 1998	Warner-Lambert and Agouron Hoechst AG and Rhone-Poulenc Rorer			
1998 1998				
1997	Hoffmann-La Roche and Boehringer Mannheim			
1997	Nycomed and Amersham	en statistie approximation Availatie on an engening		
1996 1996 -	CibaGeigy and Sandoz Elan and Athena Neurosciences			
1995	Knoll and Boots	n 19 mart an 19 mart an Tha an 19 mart an 19 mar		
1995 1995	Giaxo and Burroughs Wellcome			
1995	Gynopharma and Orlho-McNeil			
1995	Hoschst-Roussel and Marion Merrell Dow			
1995	Pharmacia and Upjohn			
1995 1995	Rhone-Poulenc Rorer and Fisons Schwarz Pharma and Reed & Carnrick			
1994 1994	American Home and American Cyanamid Hoffmann-La Roche and Svntex			
1994	Pharmacia and Erbamont	Angle of the end by		4
1994 19 94	Sanofi and Sterling (prescription drug operation) SmithKline Beecham and Sterling (over-like-counter	an a		
	phamaceutical unit)	nan ha shina a sa sa sa sa sa sa sa sa		
1991	SmithKline and Beecham	a na aga a gunada guna.		•
1990	Bools and Flint			
1990 1990		ana ao amin'ny faritr'o dia 1944. No amin'ny faritr'o Manaza		
1989	American Home and A.H. Robins	an an traight ann an Arthreanna an tarainn an Tarainn an tarainn an ta		
1989 1989	Bristol-Myers and Squibb Dow and Marion	n di na sha ka sha bi s		
1988				
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1986 1985 1985	Schering-Plough and Key Monsanio and Searle Rorer and USV/Armour	e Marenaeta Antonio de la contrata antonio de la contrata antonio de la contrata antonio de la contrata antonio de la contra		•
Source: V	Vindhover's Health Care Strategist, 2000.			•

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	II. FORMS OF COLLABORAT	ION	λ
THE RELAT	IONSHIP BEGINS	land an an an an an ann an Anna an an Anna an an Anna Anna	
• • • • • • • • • • • • • • • • • • •	INTENTIONS AND OBJECTIVES ARE	PARAMOUNT	
	ENSURE THE AGREEMENT MATCHE BOTH SIDES – ASK QUESTIONS!	가지, 이번 방법 사람과 위험 것 같은 것 같은 것 같은 것 같아요. ㅠ ㅠ ㅠ	
an a	and a strategy of the second secon I a second sec	an a tha a' an	n an Anna an A Anna an Anna an Anna an Anna an
•	CONFIDENTIAL DISCLOSURE AGREEM		
	 Purpose: To exchange Proprietary inform confidentiality 	nation under obligations of	
and an an An an an an an an an an An an	o Limited term (often five years)	a the second second second second second	skand Andrea Britech
	• Use of the exchanged information only for the contemplated collaboration		
	o "Industry standard" format and terms	and a second strategy of the second secon Second second	
	n and der	(a) Construction of the sugar of the distribution of the construction of the sugar of the sugar of the distribution of the sugar of	- 1997) 1993 - Mariana Mariana, ang katalong ang katalong ang katalong ang katalong ang katalong ang katalong ang kata 1995 - Ang katalong a
•]	MATERIALS TRANSFER AGREEMENTS	Sandrik un en enzek deter en en 48 ulderen 1. Die ∦eur er en une en eren ausgeste	an Dh
•	• Purpose: To exchange of materials to conexperimentation	nduct specified	lige Solo
	o Use limited to specified uses	के भी सही भारत के भी के देखें है। हैं भी के स्वराद्ध के सही देखें है। हैं दिया के स्वराद्ध स्वराद	al An ann an Aonaichtean An Anna Anna Anna Aonaichtean
ананананананананананананананананананан	o Typically requires exchange of resulting	data je se se se sector de la serie de la sector de la sec	
	 May include a provision permitting publi confidentiality provisions 	cation of results, subject to	
· · · · · · · · · · · · · · · · · · ·	• Materials cannot be transferred to third parameterials must be returned or destroyed	and the second second	
C	o "Industry standard" format and terms	(Addition of the state of t	
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CONSULTING AGREEMENTS

- Purpose: To engage a collaborator, often an individual, in the provision of services of mutual interest
- Term can be one or multiple years, depending on the objectives for the services

- Should clearly define:
 - The services to be provided by the consultant
 - The time commitment required
 - Payment terms
 - Ownership and use of the consultancy results, and any
 - er a inventions of the second processing where
- o Typically includes confidentiality provisions
- Can be used as an adjunct to other forms of agreement, such as licenses or sponsored research agreements
 - ntree name de la constant de la
- If an academic collaborator, be aware of institutional restrictions on scope, time commitment, and rights in intellectual property
- nag isang ang kanang ang kanang ka
 - If the consultant is an employee of an institution, seek institutional approval and sign off

MORE COMPREHENSIVE FORMS OF AGREEMENT:

SPONSORED RESEARCH AGREEMENTS

- Performed under a Research Protocol and Budget
- Provides for exchange of results obtained
- Typically includes provisions of confidentiality, and rights to intellectual property developed
- Often includes publication provisions, if an academic collaborator, subject to obligations of confidentiality and the subject to a su

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- Be sure to include a scientific contact within the company to work with the research collaborator and the science between the science of th
- Can be developed concurrent with a license or other strategic
- leuropeilleur agreement de quive la respectate de destationer en la generation

AGREEMENTS WITH INCREASING STRATEGIC IMPORTANCE:

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LICENSE AGREEMENTS

COLLABORATION AGREEMENTS

• Marketing, manufacture, product development, delivery and formulation

JOINT VENTURE AGREEMENTS

o Focus on a field defined by product or service

MERGERS AND ACQUISITIONS

- o Can involve companies of greater/lesser or approximately same size
 - general and set of the set of the

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o Asset Acquisitions

o Formation of a new business entity

- Spin-outs of some or all technology
- Second Strategy provides and the second s
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 - a en la Militaria (1986). A la seconda de Estador de Casterre esta esta esta esta esta en la comunicación de c

III. DEVELOPING THE PROCESS

A SUCCESSFUL COLLABORATION CANNOT BE BUILT WITHOUT:

♦ ◆ DETERMINING THE INTENTIONS OF THE PARTIES IN WORKING TOGETHER, <u>AND</u>

CLEARLY DEFINING THEIR OBJECTIVES

CONSIDER:

Relationship defined by Industry

- o Synergistic technologies
- o Service provider becoming collaborator
- Advantage of broader collaboration to provide guidance for relationship in the future (such as Master Agreements)

2 Martin Artes

o Customer/Supplier

Relationship defined by Technology

- o Value of Intellectual Property held, and improvements
- o Anticipated future development of the technology field
- o What other technologies will offer alternatives
- Is the value in Patents, or driven by trade secrets, copyrights or trademarks
- **Relationship** between the Parties
 - o On-going participation of seller
 - Allocation of responsibilities, such as R&D and manufacture, marketing
 - Is the collaboration an entry into a broader future collaboration/acquisition
 - o Is "relationship building" a purpose for the collaboration
 - o Alliance Management

ASK:

What does the client want at the end of the day?

What is important to the deal, and what is not?

What makes a good deal a great deal (and when does it go in the other direction)?

CLIENT AND COUNSELOR SHOULD UNDERSTAND:

How is the collaboration going to move forward, after execution?

What is the effect of not thinking through all aspects of the collaboration?

- Lengthy and difficult negotiations
- Poor future relationships in the future
- **Project abandoned**

IV. CONTRACTUAL CONSIDERATIONS

The agreement must clearly reflect the obligations and rights of the parties and what is important to each

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0	Research funding	
0	Services funding	
· · O	Option fees for improvements	
ο	Patent expenses	
0	Royalties on earned sales	
o	Minimum annual royalties	٠.
0	Milestones	
0	Patent enforcement expenses	
0	Options for fully paid up rights	
Gr	rant clause	
0	Exclusive or non-exclusive	
0	When can one shift to another	
	Ruy upe or Ruy-downe	

- Term and Termination
 - o Term and patents, pending applications, and trade secrets
 - o Termination
 - Unwind provisions
 - Financial considerations
 - Disposition of results
 - Disposition of intellectual property (solely or jointly owned)
 - On-going obligations (such as confidentiality, participation in Intellectual Property Litigation)
 - Termination for cause
 - Termination for convenience
 - Due Diligence
 - o Development and Milestone Timelines
 - o What happens if technical events interrupt the timeline
 - Confidentiality and Publications
 - Publications not often issue with companies, but a key issue for academic collaborators
 - Period allowed for removal of the disclosing party's confidential information and patent application filings
- Definitions
 - o Test the definitions with a "lay person" reading of the agreement
 - o Layering

DRAFTING THOUGHTS

♦♦ DON'T WRITE AN AGREEMENT YOU WOULDN'T SIGN

♦ IF THE AGREEMENT REQUIRES A LAWYER TO UNDERSTAND IT ...

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V. ADDITIONAL THOUGHTS

- **Reevaluate the collaboration positioning through the negotiation process**
 - o Have the goals or the objectives of the parties changed?
 - As discussions proceed, are there new opportunities for tailoring the collaboration (broadening or narrowing)?
 - o Have outside events changed the needs/wants of the parties?
 - o Have internal events changed what parties want/need or can afford?
 - Coordinate stacking provisions for royalties

Consider tax implications

o Joint ventures, spin-outs, wind-ups

- o International collaborations
 - Manufacture on one shore, fill-finish on another
 - Customs duties and COGS
- The real cost to the collaborator
 - In management time
 - In consumption of R&D resources
 - In consumption of manufacture resources
 - o In \$\$ outlay

WORK TOWARD A WIN-WIN COLLABORATION

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