

Hashemite Kingdom of Jordan

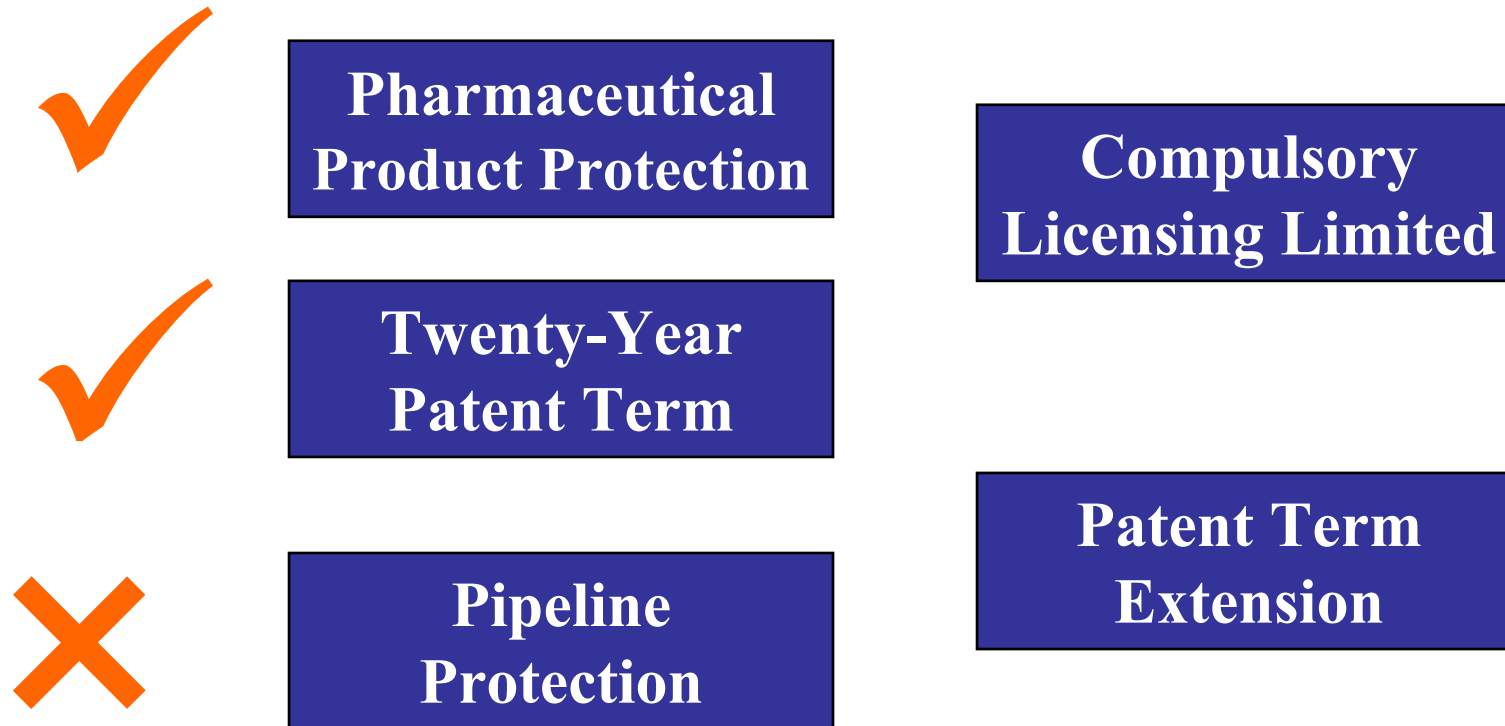
**Beyond TRIPs:
Pharmaceuticals Industry
Strategy**

**Ministry of Planning
The National Competitiveness Team**

Agenda

- ✓ Trade liberalization/Patent Laws under TRIPs.
- Jordanian action plan regarding TRIPs.
- Possible strategies for dealing with Patent Laws under TRIPs.
 - Current strategies of international companies
 - Future strategies for the Jordanian Pharmaceutical Industry

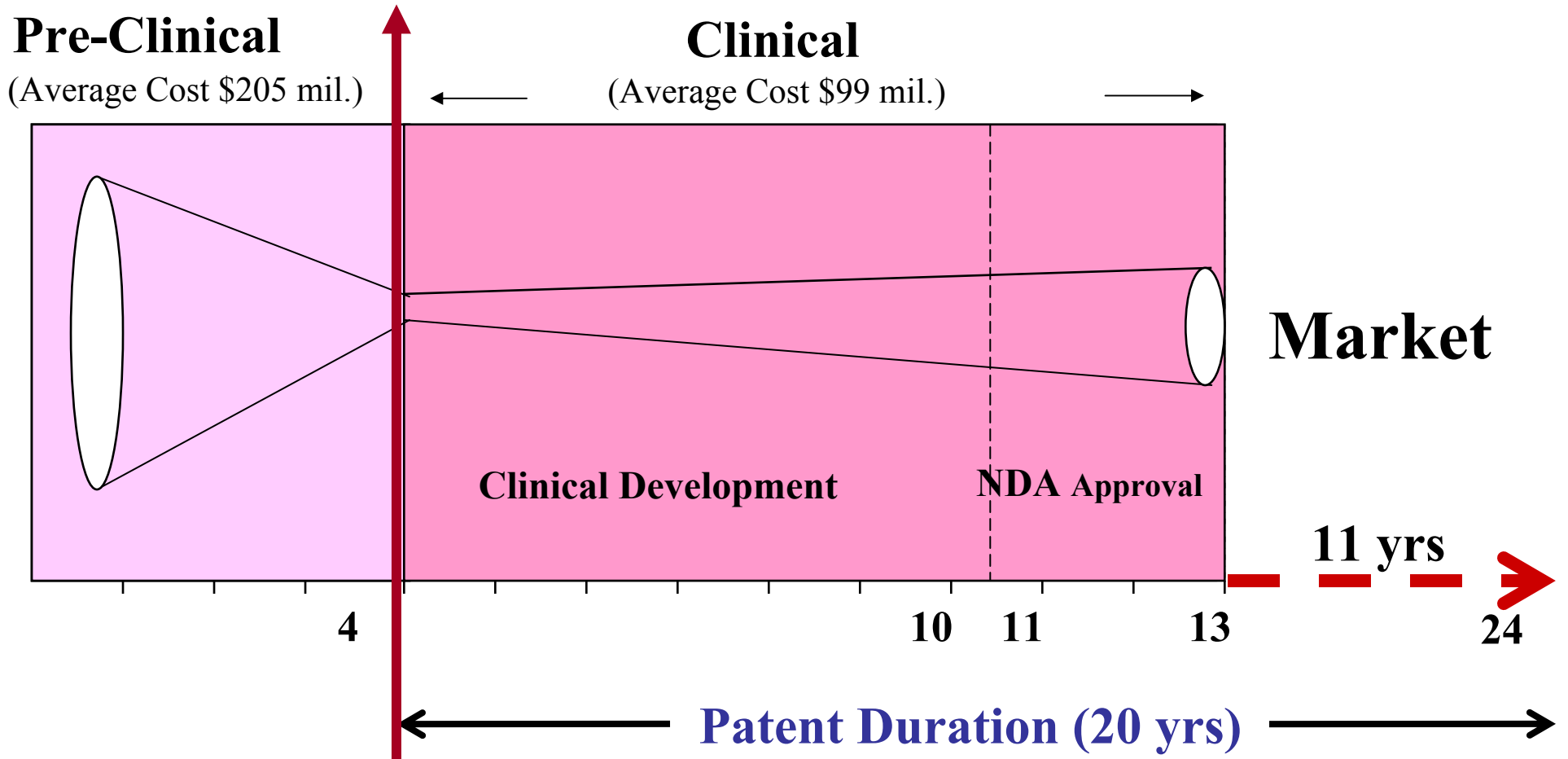
Criteria to Measure the Progress in Intellectual Property Rights Protection



Source: Phrma Publications Industry Profile 1998






The 1995 TRIPs agreement includes all of the above provisions except the existence of a pipeline for drugs

Drug Development Pipeline



Patent protection starts, lasting until year 24

Criteria to Measure the Progress in Intellectual Property Protection

| | | | |
|---|--|-------------------------------------|---|
|  | Pharmaceutical Product Protection | Compulsory Licensing Limited |  |
|  | Twenty-Year Patent Term | Patent Term Extension |  |
|  | Pipeline Protection | | |

Differing Perspectives on Patent Laws under TRIPs

Multinationals

Non-abiding countries are suffering from:

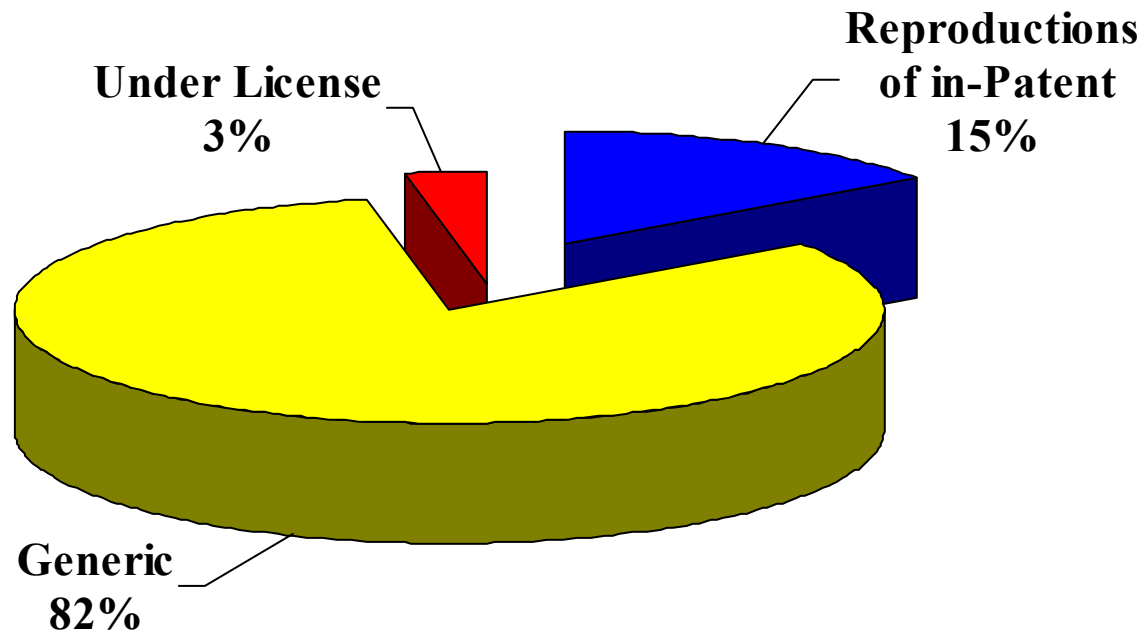
- Minimum foreign direct investment in the pharmaceutical sector
- Low quality technology transfer
- Inclusion in the US “priority watch list”
- Exclusion from the list of beneficiaries from the GSP
- Delays in obtaining newly invented foreign drugs
- Limited R&D in local pharmaceutical companies
- Reputation as imitators

Local Producers

**Jordan will witness,
by abiding,**

- Minimum foreign direct investment, a result of Jordan’s unattractive small local market valued at \$127 million only
- 30% average increase in the prices of patented drugs
- Significantly reduced profit margins or increased bankruptcies of some pharmaceutical companies

Effect of Patent Laws under TRIPs on the Local Industry



International Patent Laws will force firms to restructure and invest in specific fields of R&D. It will also push them to attract multinationals to produce under-license.

Effect of the Patent Laws under TRIPs on the Local Industry

**Companies established
before 1985**

5 Co.

89.4% of Production

92.2% of Exports

**Companies established
after 1990**

9 Co.

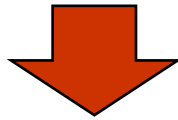
**3 Co.
Start-ups**

10.6% of Production

7.8% of Exports

Companies established after 1990 rely mainly on patented products. The percentage of patented products sold in the local market to the total sales is greater than that of the old companies.

However, TRIPs is not the only obstacle facing pharmaceutical industry, standards and technical barriers are obstacles as well.





Yet, TRIPs is not a real obstacle since accessing the WTO offers significant potential benefits to Jordan, including:

- Access to new markets
- Increase of attractiveness to strategic partners
- Creating incentives to upgrade quality and standards
- Supplying the means for challenging the USA and Germany to open their markets for Jordanian products

Current situation of TRIPs Protection

| Country | Level of Protection | Barriers to entry | Market lost |
|---------|--|--|--|
| Egypt | Lack of meaningful protection : duration of patents too short. Legislation emerging with effective patent protection, but not passed | Rigid price Control System | One of largest markets in the Middle East/North Africa but exact size still undetermined |
| Bahrain | Some legal protection. Registration of patents in UK necessary | Rigid price Control System | Piracy not significant, thus not much room for increased exports |
| Lebanon | At crossroads, not much piracy now, but also not safeguards | Rigid price Control System | Market of tens of million of dollars |
| Oman | No legal protection. Few gov. efforts | Rigid price Control System | US\$10 million to US\$15 million |
| Qatar | No legal protection Gov. buys pirated copies | Govt. denied tender offer to US bidder | US\$ 5 million to US\$10 million |
| Kuwait | No legal protection. piracy increasing | Rigid price Control System | Large market (\$110 million) |

 : priority watch list

 : watch list

| Country | Level of Protection | Barriers to Entry | Market Lost |
|---------|---|--|---|
| Israel | Considering amendment to patent law that would allow Israeli companies to export patented products before their patents expires | None | Undetermined but could be significant as regional supplier of pharmaceuticals |
| Turkey | New patent laws will not offer effective protection. Falls well short of TRIPS standards in numerous areas | Regional allow copied products to pass using tests from original product | Approximately \$70 million annually |
| India | Indian patent Act of 1970 only provide seven years for process patents, which is so short that the patent "protection" will expire even before the relevant product is ready for market launch. | Drug prices fixed by the Govt. using outdated cost data, High import tariffs, Difficult for companies to open 100% owned subsidiaries. | Loss of about \$500 million, including copies domestically and their export. |
| Jordan | Jordanian government has been considering new legislations to provide adequate pharmaceutical patent protection. | Rigid price Control System | Loss of about US\$ 5-25 million |



: priority watch list



: watch list

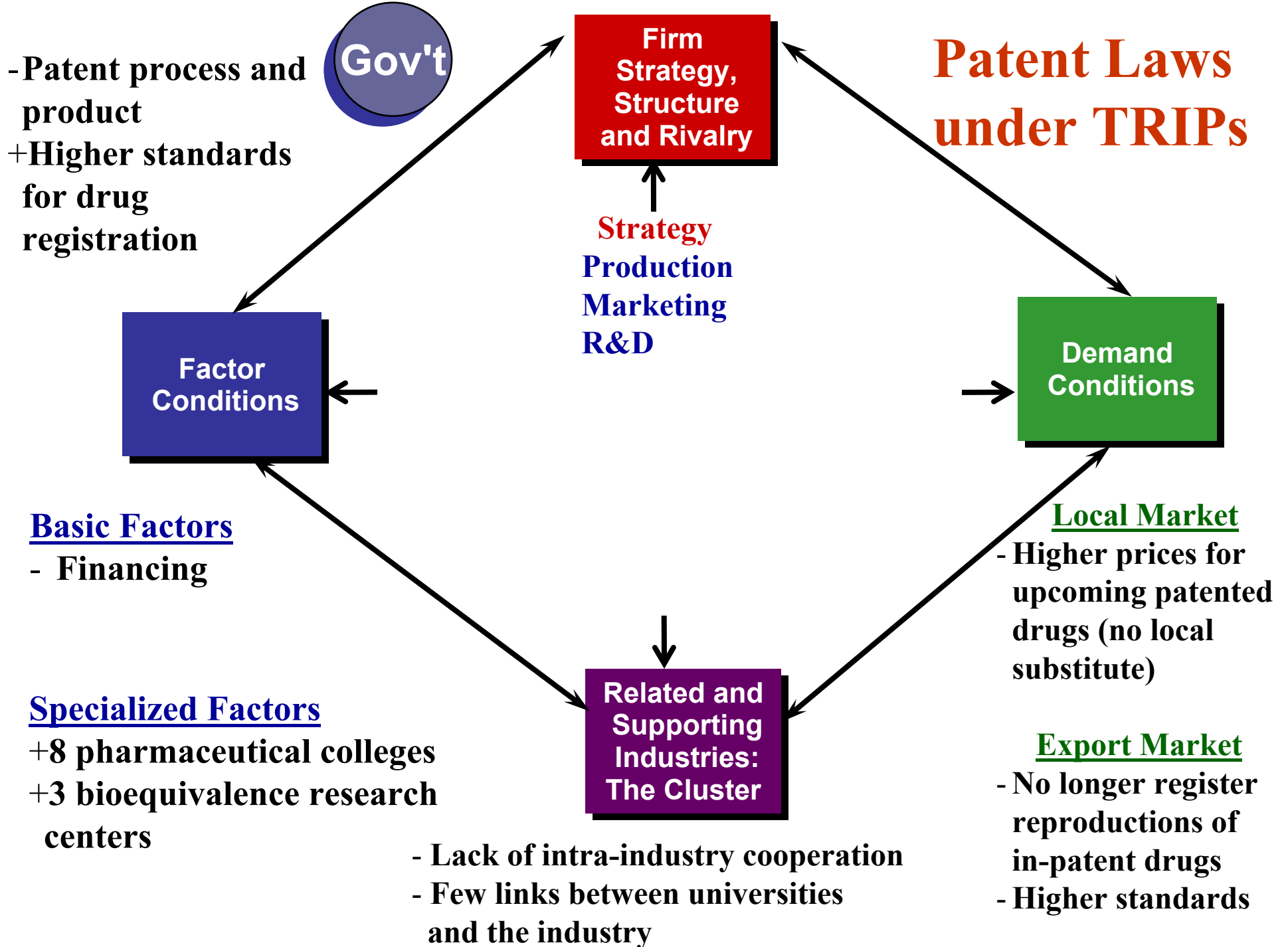
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Action Plan for TRIPs Agreement

- The government conducted a timetable for IPR compliance, starting from the year 1998 and is expected to last until the year 2000. However, the timetable may be subject to change and/or extension depending on legislative procedures.
- The relevance of such a timetable shows that the government is in the process of implementing the action plan regarding IPR laws.
- USAID will provide funds for conducting seminars in which GOJ officials and other institutions will be trained on IPR law enforcement techniques and database management.



Firm Strategy, Structure and Rivalry

Current Strategies:

Production

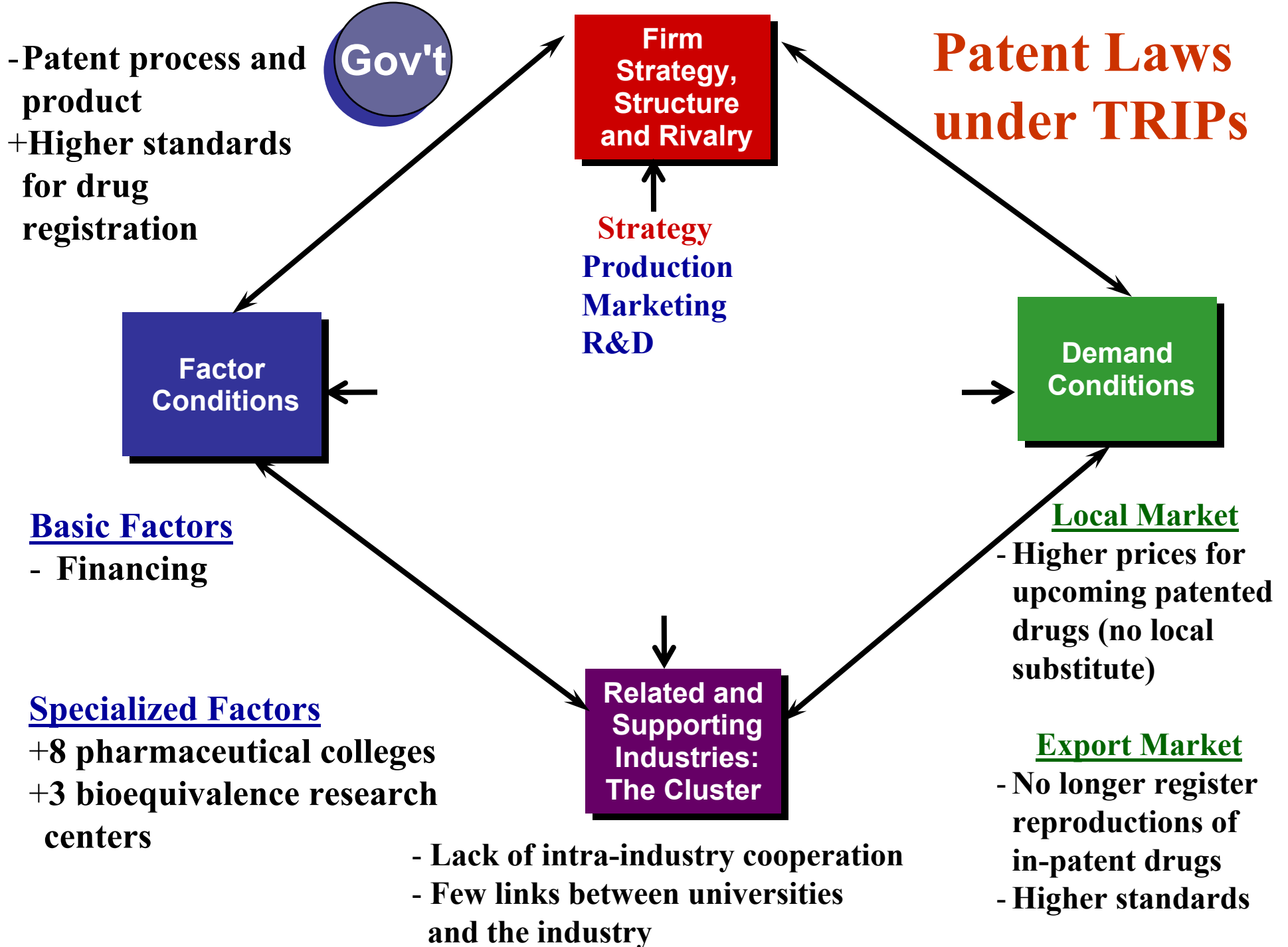
- +Fulfill new international production standards
- +Strategic partnerships for production under license

Marketing

- +Building factories in large regional export markets
- +Entrance into new markets
- +Generic products registration in the US

R&D

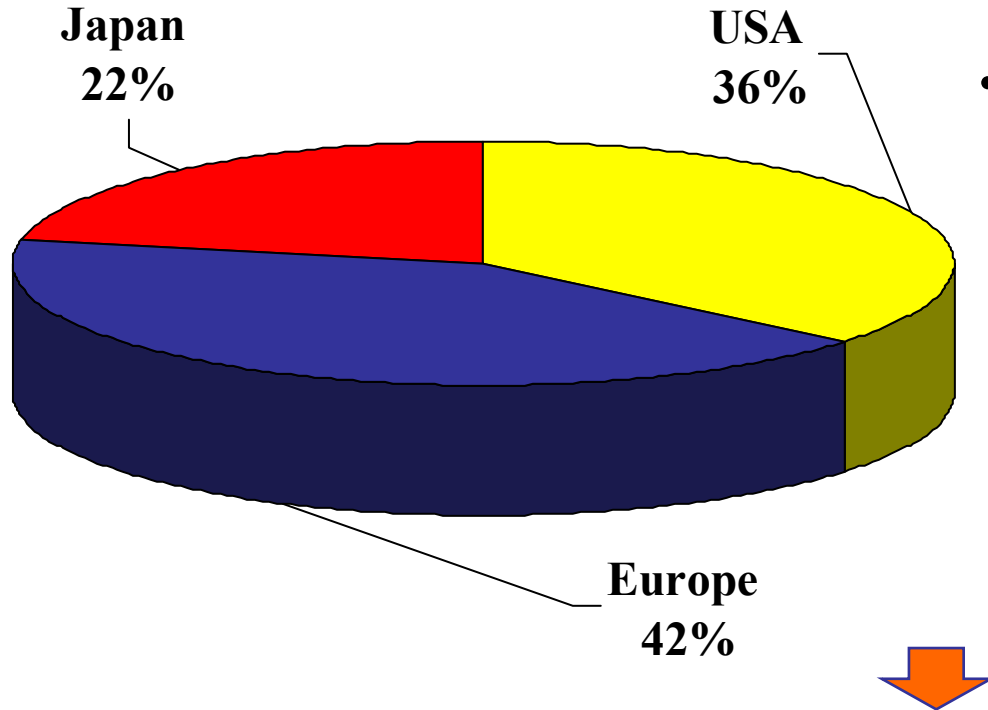
- +New product lines (herbal, dermatotherapy)
- +Entrance into biotechnology



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Distribution of Top 50 Pharmaceutical Companies



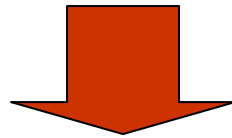
- **Benefiting from what leaders are doing to:**
 - Stay in business
 - Get partnerships with foreign firms
 - Identify mutual benefits regarding expertise



The availability of state-of-the-art technology, flexible work force, stable political environment and a strong economy have made the USA a thriving ground for most global pharmaceutical companies.

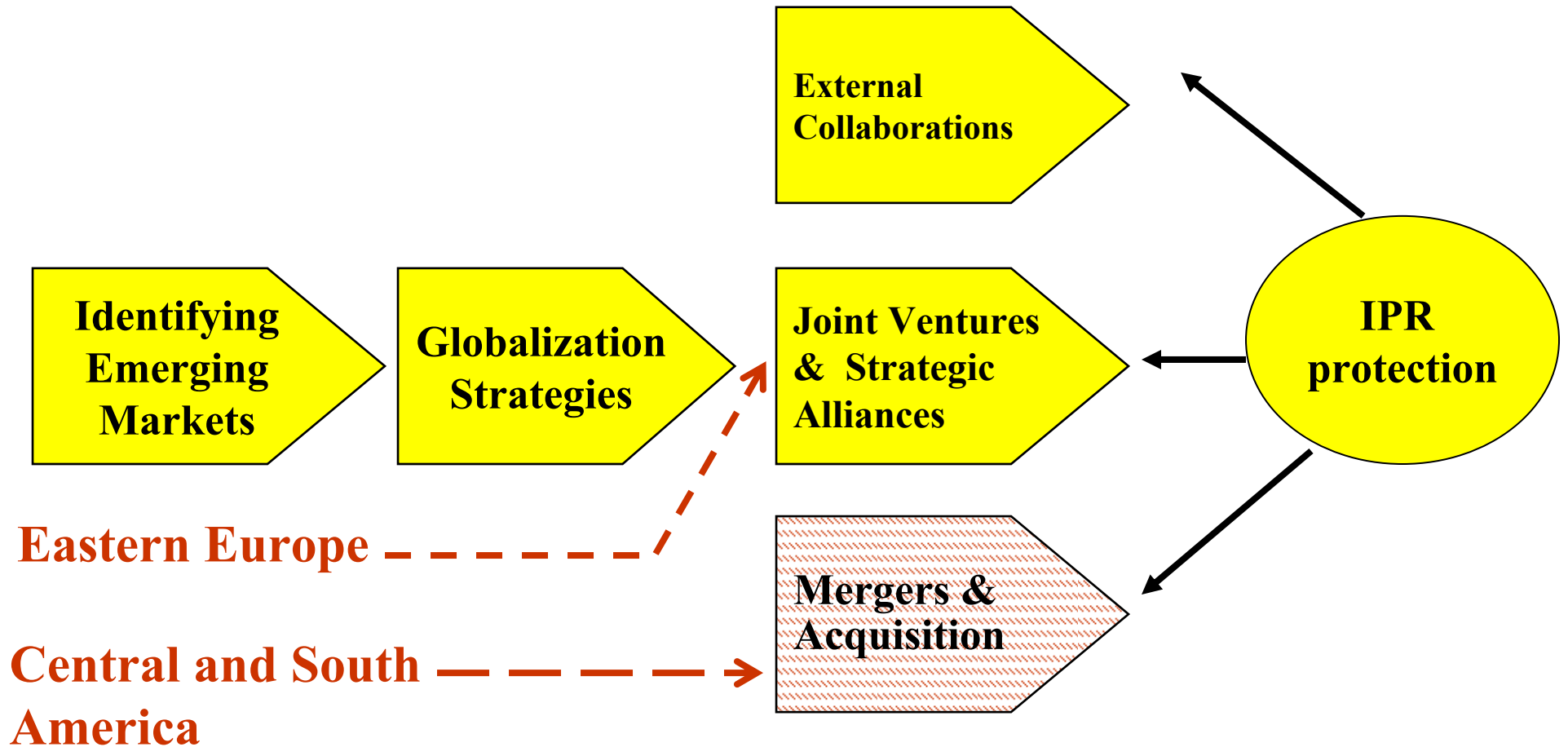
What leaders are Doing?

- Global expansion
- Portfolio optimization
- Supply chain integration
- Value creation



Critical Success Factors for Increasing
Competitiveness

How they Go about Global Expansion



Globalization Strategies

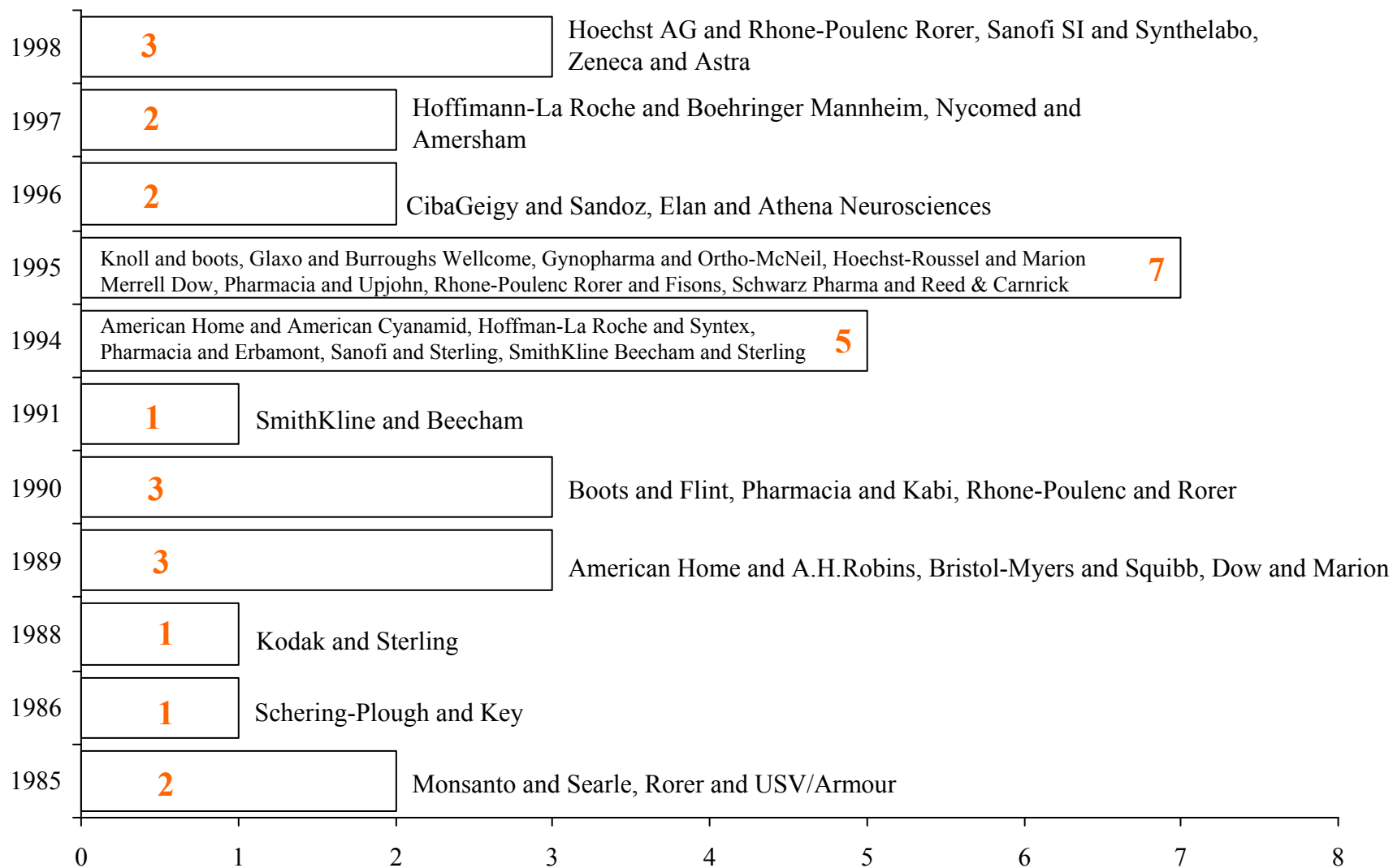
Strategic Alliances and Joint Ventures

- Provide companies with access to advanced technologies and local distribution channels
- Provide knowledge of local regulations and consumer preferences
- Enhance the credibility of global companies

Mergers and Acquisitions(M&A)

- Reduce cost and generate economies of scale in R&D and marketing. Hence, companies will use M&A primarily for expansion in existing markets and for penetrating new markets.
- The pharmaceutical industry faces a record number of patent expirations. Few companies have been able to survive such assaults on their earnings.
- The need for more marketing muscle.

Mergers and Acquisitions in the Pharmaceutical industry



Portfolio Optimization

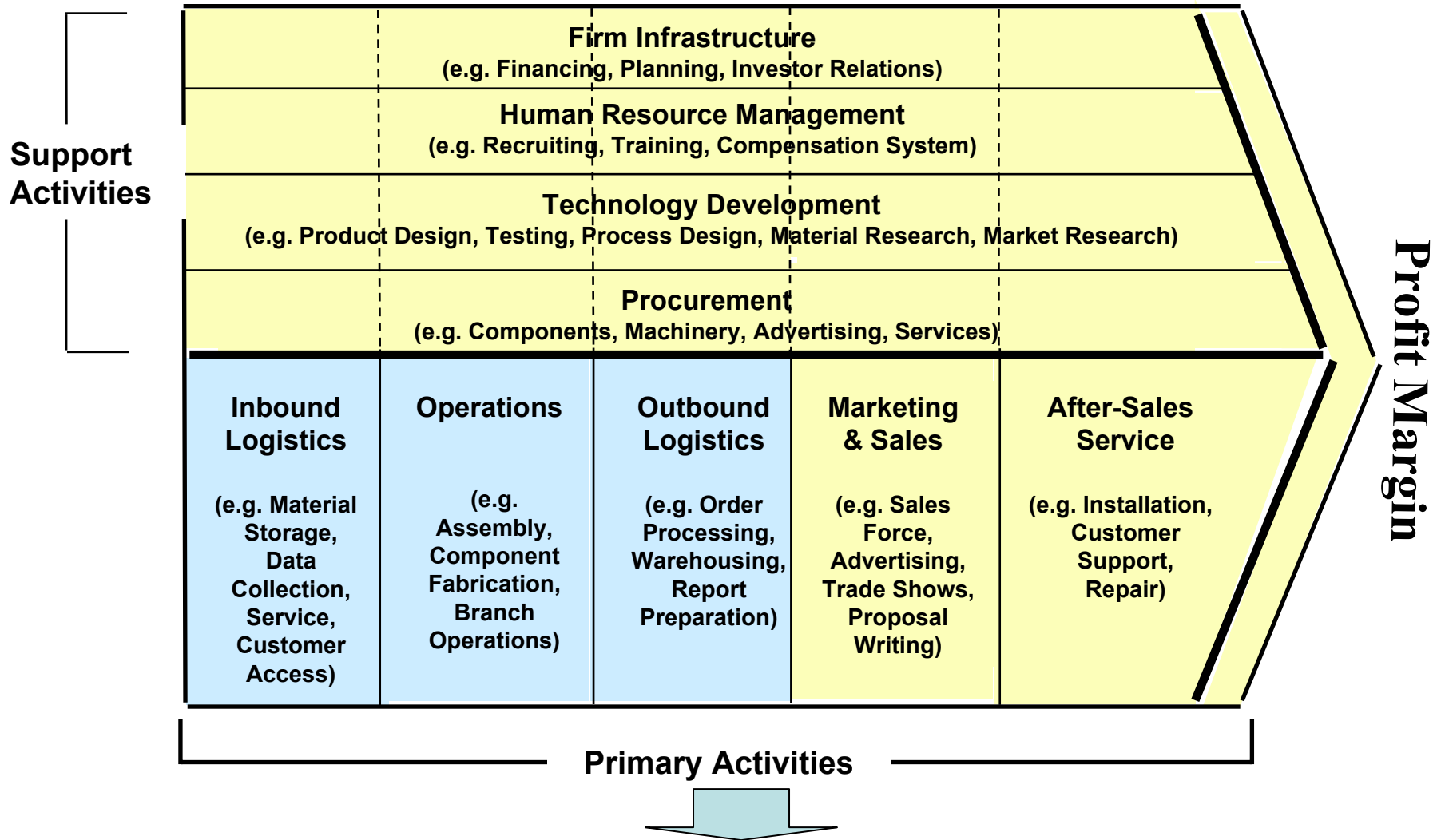
Maximizing portfolios require:

- Developing new drugs while managing existing products.
- Focusing on ways to extend the life cycle of existing products.
- Buy into health service areas.
- Focus on R&D, marketing and sales, and coordination of function.

Supply Chain Integration

- **Components of the supply chain:**
 - Generated products
 - Delivery time and pre-and postsales support services demanded by the customers
 - Integration with raw material suppliers
- **Strategies for improving supply chain integration:**
 - Alliances and joint ventures with foreign companies
 - Using information technology
 - Mergers and acquisitions
 - Contracting and subcontracting
 - Outsourcing

Value Creation



To create a more value-oriented chain, companies should focus on improving their efficiencies in distribution, marketing, and sales.

Beyond the Millennium

- ✓ The financial resources required in the new diagnostic and therapeutic technologies, is only available in fewer major companies.
- ✓ Large company will no longer account for just 5% of the global market, there are still significant economies of scale to be achieved.
- ✓ No company or small group of companies will be capable of monopolizing the enormous growth of scientific knowledge and understanding that will have occurred over the decade.
- ✓ Alongside the pharmaceutical leaders, a sector of niche companies will continue to thrive, based on specialized knowledge and a narrow technological focus. **The networks that will link these smaller, specialized companies with the unique competencies of the global “big pharma ” businesses will guarantee a dynamic and competitive sector.**
- ✓ Today, around 80% of the pharmaceutical industry is based on the needs of the developed markets. **By 2010, today’s developed and developing regions will be seen as equal components in the global pharmaceutical market.**

Agenda

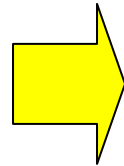
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Future Strategy Options

Jordan's Situation

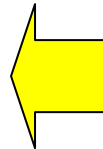
Option I

**Do it
Ourselves: To
be innovative
leaders in terms
of inventions,
creativity and
value added.**

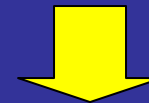


**We can do minor R&D
to:**

- **Improve delivery mode**
- **Reduce development and manufacturing time of generics products**



- Little capital is available for investment in R&D.
- Weak enforcement of intellectual property rights (i.e. patents) in Jordan which may be a disincentive to drug development.
- “Doing it ourselves” will take time and with the imminence of the WTO and EU regulations, Jordan does not have very much time.
- Weak local research institutions and capabilities.
- **It is almost impossible** for the pharmaceutical industry, given the present inadequacies and established habits, to become an innovative world leader in the short run.



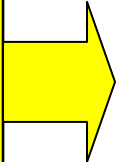
- + Jordan can capitalize on local diseases and herbal products for which it has knowledge.
- + Jordan has some good drug development expertise due to the production of generic drugs.
- + Some Jordanian companies were able to develop their own original products. They were patented in Jordan and registered in foreign countries.

Future Strategy Options

Jordan's Situation

Option II

Strategic Partnership:

- Joint Ventures/ under License
 - Subcontracting production of patented and generic drugs
 - Co-marketing and distribution agreement
- 

- The only partnership that currently exist is under license agreements.
 - Jordanian companies have limited under license agreements due to small local market size compared to other regional markets such as Egypt and Saudi Arabia.
 - Currently, there are no partnerships or joint ventures aiming at strengthening the capabilities of Jordan's R&D.
- 

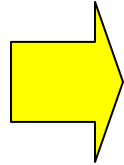
This option might be visible due to:

- No longer small markets.
- Jordan's action plan regarding TRIPs.
- Good reputation of Jordanian pharmaceuticals industry.

Future Strategy Options

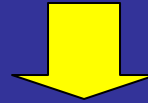
Option III

**Buying the
Know-How**



Jordan's Situation

- Know-How is expensive.
- Jordanian companies are under-capitalized.



- However, it might be easier to buy the know-how than 'do it ourselves'.

Future Strategy Options


Option IV

**Cost
Leadership
Strategy**



Jordan's Situation

Jordanian industry should review the value chain (all the stages of the good or service) of its products and focus on increasing efficiency in any or all the stages of production. And, thus become a low-cost producer.



It is probably the more feasible competitive strategy

Future Strategy Options


Option V

Early
Adoption of
International
Patent Law



Jordan's Situation

Jordanian industries might negotiate with foreign companies for the early adoption of international patent law in exchange for specific concessions.

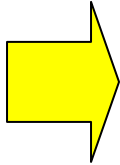


JUSBP, BST, and USAID may help and facilitate such initiative.

Future Strategy Options

Jordan's Situation

Other Options

- Shifting from Hardware to Software mentality
 - Collaboration between industry and academia.
 - Intra-industry cooperation
- 

- Stop building factories and invest in technology and marketing.
- Establish an advisory committee for pharmaceutical colleges and focus on more specialization in pharmacology departments.
- Enhance intra-industry cooperation through....

Through....

- Formulating a shared strategy, to upgrade the industry as a whole including supporting industries.
- Encouraging specialization in existing pharmaceutical companies to reduce product overlap and meet local demands on new product lines.

Product Concentration

