

Impact of nutrition and health claims regulation (1924/2006) on innovation and the economy in the European Union

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Summary

Articles of concern to the food industry:

- Article 14 (disease reduction and children's health claims)
- Article 13 (generic nutrition and health claims)
- Due to negative publicity of failed health claims, companies are withdrawing health claims from EFSA (European Food Safety Authority) assessment. 10 major multinationals have withdrawn health claims. The withdrawal of three health claims by Danone is a recent example.
- Many of the products carrying health claims that have been withdrawn from EFSA assessment are already marketed or labeled with the claims included therefore change would be hard to implement and costly.

The nutritional profiling approach of the legislation requires that the food is proven to be beneficial in its complete form ingested by the consumer if a health claim of an ingredient is to be permitted

Threats

(learning through the experience of the pharmaceutical industry)

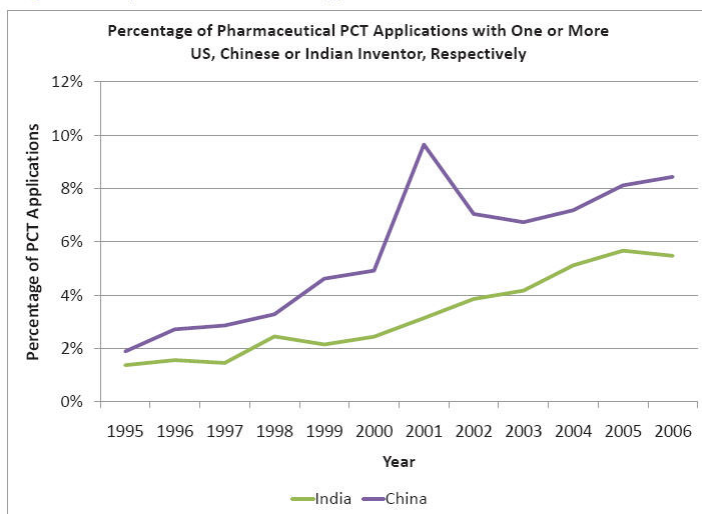
A restrictive regulatory environment (good examples in the pharmaceutical sector are provided by stem cell research and research involving non-human primates) has been shown to result in:

- Relocation of Research and Development (R&D) to less restrictive global sites (e.g. from Europe to Asia or the US).
- Loss of leading researchers (e.g. 'brain drain') as they follow the R&D.
- Reduction of innovation due to brain drain.
- Economic downturn from reduced innovation.

Furthermore, a restrictive regulatory environment may result in certain important foods to be withdrawn from the European market

Is Europe losing ground in innovation?

Figure 3: Global pharmaceutical WIPO PCT applications with one or more Indian or Chinese inventor



ANIMAL RESEARCH NEWS FEATURE

NATURE | Vol 444 | 14 December 2006

Primates in the frame

Primate researchers have long faced violent protests over their work. But in some countries, regulatory obstacles are taking a greater toll. **David Cyranoski** meets European scientists who feel that bureaucratic pressures are closing their labs.



US stem cell research lagging Without aid, work moving overseas

The Boston Globe

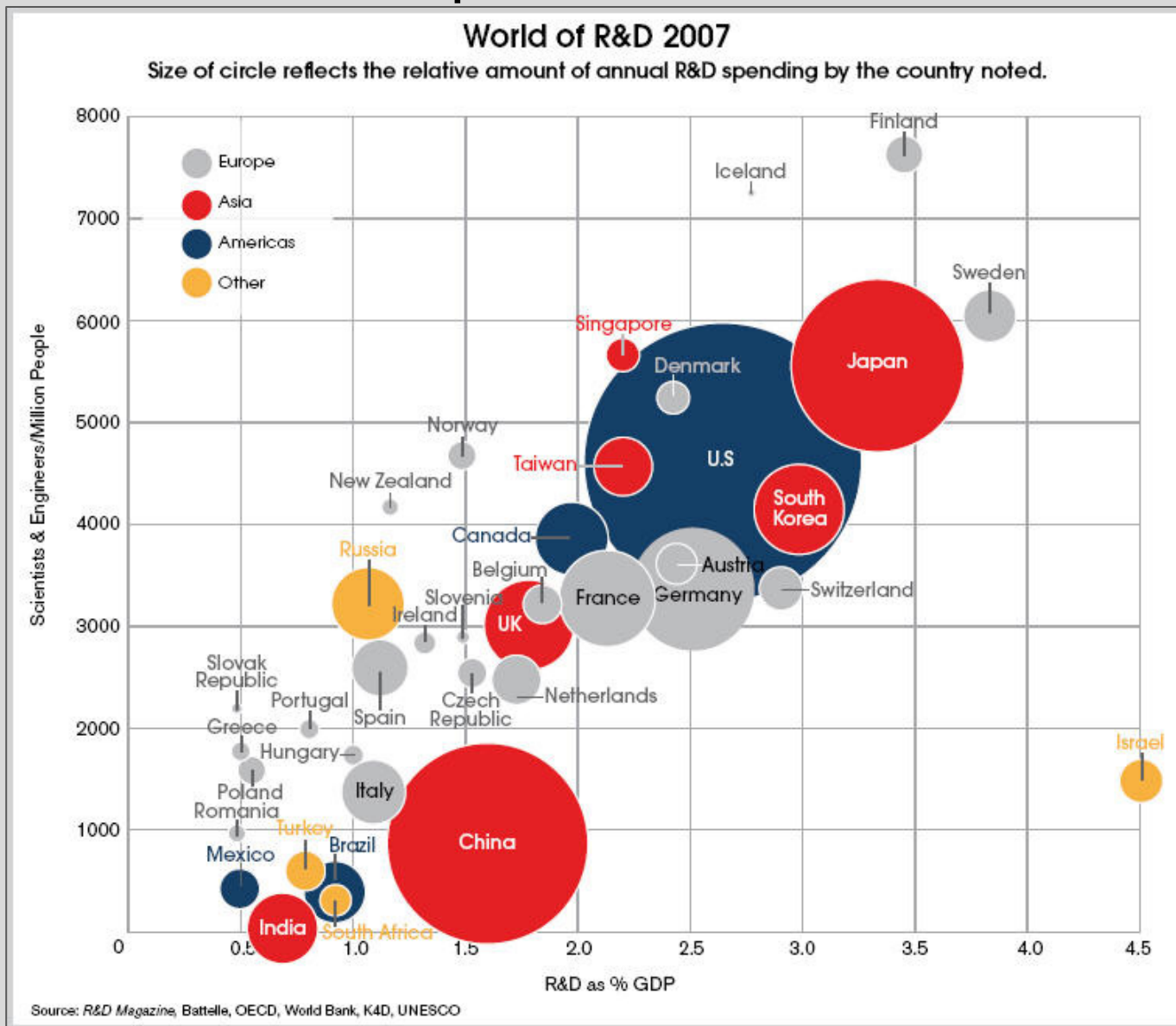
By Gareth Cook, Globe Staff | May 23, 2004

| Patent Office | Number of applications filed* |
|-----------------------|-------------------------------|
| United States (USPTO) | 456,154 |
| Europe (EPO) | 140,725 |
| Japan (JPO) | 396,291 |
| China (SIPO) | 782,000 |

In 2007, US inventors / companies filed 27,000 patents in the EPO while Chinese inventors / companies filed significantly less (5,000). However, this number is the most rapidly growing.

*data are from 2007

Highly skilled technical labour versus R&D expenditures



Where are multinationals investing in R&D?

Changes in R&D Offshore Outsourcing

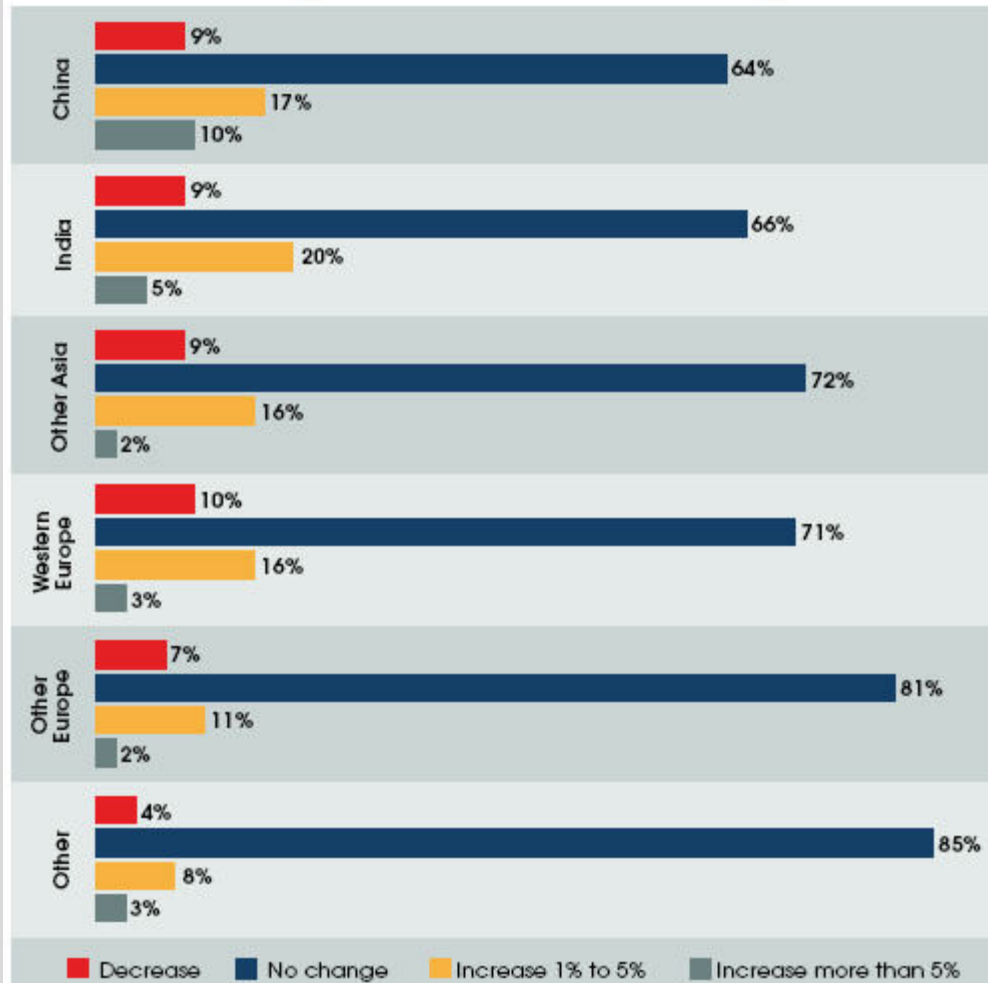


Table 1: Top ten global pharmaceutical firms — 2007 global sales

| Rank | Company | Global sales | Global Market-share percentage |
|------|-------------------------|--------------|--------------------------------|
| 1 | Pfizer (USA) | USD 45.1 bn | 6.3% |
| 2 | GlaxoSmithKline (UK) | USD 39.2 bn | 5.5% |
| 3 | Sanofi–Aventis (France) | USD 37.4 bn | 5.3% |
| 4 | Novartis (Switzerland) | USD 29.5 bn | 4.1% |
| 5 | AstraZeneca (UK) | USD 25.7 bn | 3.6% |
| 6 | Johnson & Johnson (USA) | USD 23.3 bn | 3.3% |
| 7 | Merck (USA) | USD 22.6 bn | 3.2% |
| 8 | Roche (Switzerland) | USD 16.9 bn | 2.4% |
| 9 | Wyeth (USA) | USD 15.7 bn | 2.2% |
| 10 | Eli Lilly (USA) | USD 14.8 bn | 2.1% |

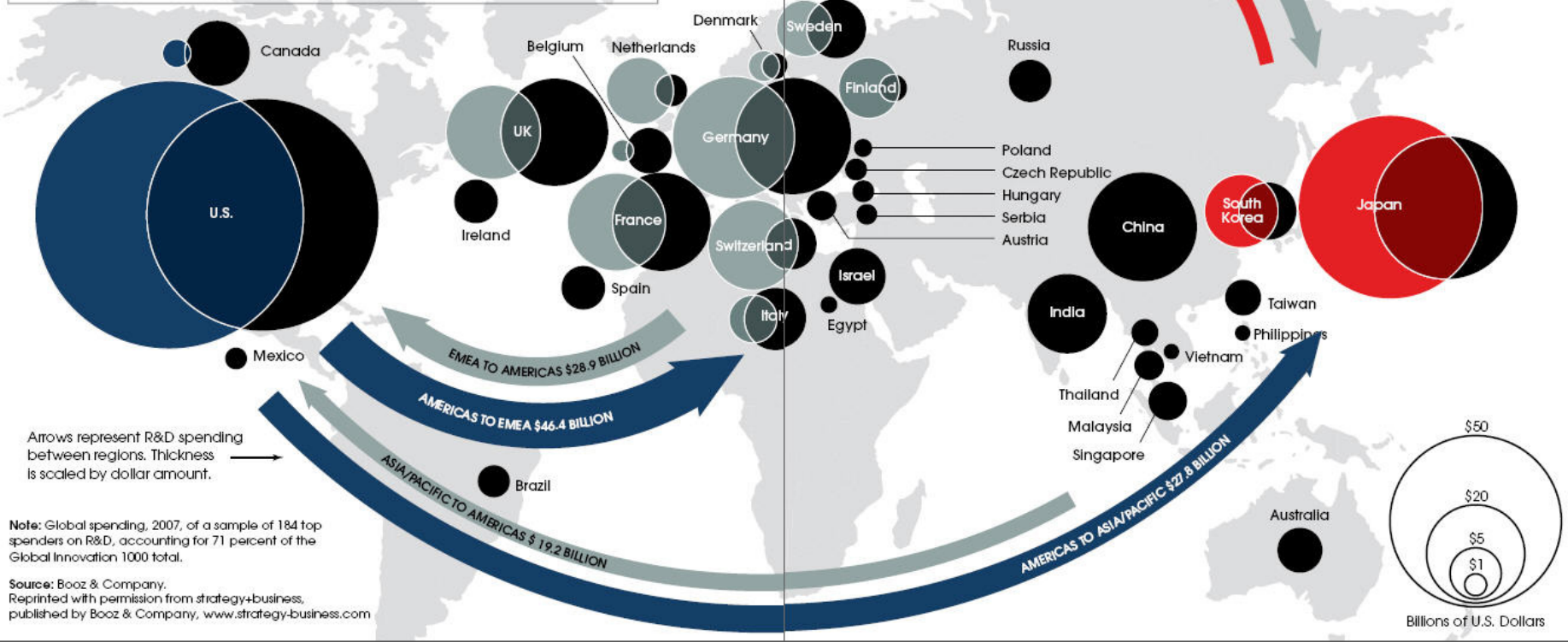
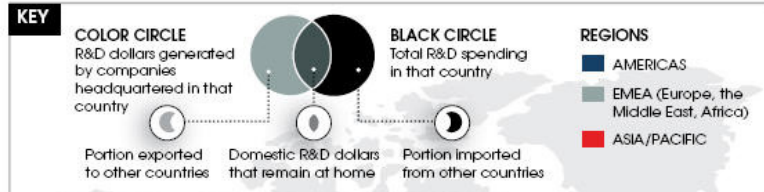
Despite 5/10 of the top 10 pharmaceutical companies being headquartered in Europe, Europe lags behind particularly China and India as a location for outsourcing R&D from US corporations

Balance between R&D expenditure at home versus abroad

Importers and Exporters of Technology

The World of R&D

As business has become increasingly global, so too has corporate spending on R&D. Here is a look at the 2007 flows of the top R&D spenders between the Americas, EMEA (Europe, the Middle East, and Africa), and the Asia/Pacific region.



Multinational companies are spending a significant portion of their R&D monies outside the countries in which they're headquartered. This might appear to be a loss of jobs, intellectual property, and influence for the home countries. But innovation spending appears to flow in both directions simultaneously. According to a Booz study, about 40% of the monies spent on R&D in the U.S. is spent by companies headquartered in offshore locations. Companies that invest wisely in a multinational innovation footprint are gaining better returns on their R&D investments than companies that keep their laboratories exclusively at home.

Science

- Nutraceuticals, nutrigenomics and personalized nutrition are considered key drivers of public health for the coming period.
- Population genomic studies are defining risk factors for disease and poor health.
- Certain individuals are at risk of developing disease through eating particular food ingredients while others are not depending on their genetic background
- Risk of developing many diseases depends on an interaction between the environment (e.g. food ingestion) and the genetic constitution of the individual.
- If individuals with a genetic precondition that puts them at risk if they eat certain food ingredients instead avoided such ingredients, they may avoid the risk of developing the disease.

Personalized nutrition has the potential to have a major impact on public health

Personalized nutrition

- Personalized nutrition has been ongoing from the beginnings of society... without confounding pressures that prejudice choice, people largely avoid foods that make them feel bad and are more likely to eat foods that make them feel good.
- The same food ingredient may be good for some and bad for others depending on the overall physiological state of the individuals concerned (which is also dependent on their genetic background).
- Technologies of the post genomic era permits profiling of individuals to identify risk factors that will define a healthy diet on an individual basis.
- Innovation in the personalized nutrition and nutraceutical sector will define Europe's competitiveness in the growing health and wellness global market (which grew over 60% from 2002-2007).

Precautionary measures?

EFSA Approach: Though it is hard to judge the opinions in detail as the precise content and quality of the applications is not published, the opinions show clearly that only a 'gold standard' is acceptable to EFSA to gain a positive opinion:

- Only convincing evidence from several RCT's with flawless design seems acceptable and only if this evidence supports exactly the population addressed by the claim and the conditions described by the applicant.
- Any human intervention study submitted not matching the conditions or target group of the claim is not pertinent for EFSA and is not even accepted as supporting evidence.
- Inconsistencies between data and studies are given too much weight over the consistencies of presented data and studies.
- Epidemiological evidence and other supporting data from animal or mechanistic studies seem not to be given due consideration.

Precautionary measures ctd

- Alternative claim wording offered to best formulate a claim reflecting the level of scientific evidence is not considered in a consistent and transparent manner.
- All favourable opinions are either based on long-established nutritional science or seem to require a considerable number of RTC's performed with the claimed ingredient or product.
- Is such the best scientific basis for precautionary measures in health and wellness? If the food is safe, what are we being precautionary of?
- Good and innovative science is being done by health and wellness companies. Will this stop when instead the companies have to target regulatory approval?

Conclusions

- Information of a product's likelihood of beneficially impacting an individual's health should be accurately communicated.
- The regulatory requirements to support a health claim should be based on the current scientific state-of-the-art, should not be excessively burdensome, and should recognize the complexity and heterogeneity of genetic backgrounds that impact responses to food ingredients or the risk of developing disease.
- General nutritional guidelines should be adopted with caution and should be based on exceeding population thresholds (e.g. it should be known that at least 1/3 of the community is affected) before implementation.
- The regulation in its current form is acting as a deterrent of food R&D in Europe. This may pre-empt the development of important nutraceuticals as well as closing the door on European competitiveness in nutrition, wellness and health.

Conclusions ctd.

- A balance must be found between protecting consumers from unfounded health claims and creating an environment that stimulates innovation in food products for health.
- A particular level of regulatory involvement protects the consumer while also stimulating industry innovation (e.g. there is a market reward for companies that succeed in fulfilling the regulatory requirements). Excessive regulation stops the development of preventative measures (e.g. treatments and cures) through the implementation of a set of too excessive precautionary measures.
- Too much precaution by regulatory measures will pre-empt the development of innovative preventative measures that may actually have a greater and further reaching and profound impact on the health of a greater cross-section of the community.