

THE CRITICALITY OF NON-MARKET STRATEGIES: THE EUROPEAN BIOTECHNOLOGY PATENTS DIRECTIVE

By Shail Thaker

BACKGROUND TO THE DIRECTIVE

The European Commission (EC) Directorate General III (DGIII), Services for Industry, originally proposed the concept of legal protection of biotechnological inventions in the European Union (EU) on 12th Oct. 1988. The DGIII had publicly stated that the European Biotechnology industry should be supported and encouraged in order to increase employment in such a key industry as well as to develop the technology for the benefit of the European economy. At that time, approximately twice as many biotechnology inventions originated in the United States as in the whole of the EU, and biotech research by small and medium sized companies in the United States vastly exceeded the development done by such companies in Europe¹. This disparity had been increasing, and a trend had been for European companies to move their biotechnology research from the EU to the United States because they regarded the commercial and legal climate there as more encouraging. European firms did this despite the expense involved; it moved their research base away from their "rent chain" (especially university relationships, traditional pools for recruitment etc) and forced them into a geography where they had less lobbying influence on the approval process relative to their strong US competitors. American and Japanese rivals had also been using their vast, profitable home markets to generate R&D funding for development. Leading American and Japanese life sciences companies made 56% and 94% of their sales in their respective home markets, versus only 43% for their European counterparts².

A Directive supporting the legal protection of biotechnological inventions reached its final reading in the European Parliament (EP) seven years later, in March 1995, having received significant support from industry. The European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents many of the largest pharmaceutical companies operating in Europe, European trade associations and smaller biotech firms [see Appendix 1], had publicly stated that their members were suffering a "systematic disadvantage" as a result of the U.S. and Japanese edge and the absence of consistency in European biotechnology patent rules. Brian Agar, director general of EFPIA said, "Harmonization will provide the confidence necessary to embrace new technologies, and encourage innovation in health care. We need effective European policies in the race with America. Intellectual property protection is vital if we are to build on previous research. No protection means no innovation."

E.U. PATENT LAW AND THE DIRECTIVE

The European patent system is mostly based on the European Patent Convention (EPC). The EPC does not create a single European patent but provides a centralized route to apply for protection in as many of the signatory states as the applicant wishes. Hence, patent applicants may either apply to individual national patent offices for national patents or apply for a European patent to the European Patent Office (EPO). Once granted by the EPO, these European patents form a bundle of national patents whose validity and effects are determined by the national laws. Consequently, any infringement or revocation actions have to be brought before the national courts of each country for which the European patent has been granted. Two serious factors increased the uncertainty for life sciences companies in Europe in 1995:

- Firstly, several countries (notably Netherlands and France) had national legislation heavily restricting biotechnology, and especially gene, patenting. This was a much stricter position than the EPO's case law³ indicated
- Secondly, since there were no clear guidelines for the EPO to operate within, in terms of what biotechnology inventions were patentable and what weren't, there was significant inconsistency in EPO judgments as they were based on interpretation of case law. In

¹ Nott, Robert. 1995. "The Biotech Directive: Does Europe Need a New Draft?" *European Intellectual Property Review* 17 (12): 563-567.

² EFPIA 1999-2002

³ EPO case law had precedent for biological process, organism and gene sequence patenting

particular, the "Morality Clause"⁴ of the EPC introduced significant uncertainty for applicants and examiners alike. Hence, even the EPO was in support of the draft Directive. Consider a biotechnology company that manages to win a European patent from the EPO. It must then undergo the significant expense to have the patent translated and notarized in all languages of the EU. Then assume that a competitor infringes the patent in France. There is a significant risk that the French court could interpret case law differently, or even dispute that the patent is valid if contradictory to French national law, and therefore refuse to enforce the patent. The company's only recourse under "Direct Effect" is to undergo a tortuous and often prohibitively expensive legal action in the European Court of Justice (ECJ) against the national government, which still does not restrict the infringer's behavior.

CONTENT OF THE DRAFT DIRECTIVE

While the Directive could lead to some harmonization of the member states' patent laws, it would not necessarily ensure a uniform and harmonized patent granting policy of the national patent offices on the one hand, and the EPO, on the other. The draft Directive did however, for the first time in the history of patent law, establish a set of rules specifically addressing the scope of biotechnology patents. These rules were, in fact, the core of the Directive, since neither the member states' patent laws nor the European Patent Convention specifically addressed this issue. In general the draft Directive allowed for a broad scope of biotechnology patents:

- Biological material: Patents on biological material possessing specific characteristics shall extend to any biological material derived from the patented material, provided the patented material still possesses those same characteristics.
- Biotechnological processes: Likewise, patents on processes that enable a biological material to be produced possessing specific characteristics shall extend to all material directly and indirectly obtained through that process. Patent protection shall also cover all biological material directly derived from that material provided that the derived material still possesses those same characteristics.
- Products containing or consisting of genetic information: Finally, patents on products containing or consisting of genetic information shall extend to all material (except human beings) in which the product is incorporated and in which the genetic information is contained and performs its function.

Whether living material, such as plants or animals, or naturally-occurring substances may have constituted the subject of a patent application was still controversial. The Directive took a clear position by stating explicitly that inventions which are new, involve an inventive step and are applicable for industrial purposes shall be patentable "even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." By stating this, the Directive did not depart from the case law of most patent offices, including those of Japan, U.S. and the EPO itself. Already in 1984, the EPO had stated "that no general exclusion of inventions in the sphere of animated nature can be inferred from the European Patent Convention." Also for the patentability of naturally-occurring genes, the Directive only reaffirmed the long-standing practice of the EPO and most European national patent offices: naturally-occurring substances are considered to be patentable inventions provided they first have to be isolated from their surroundings, and are new, inventive and have industrial applicability⁵.

THE LEGISLATIVE ARENA

The Maastricht Treaty on European Union (Nov. 1993) introduced the procedure of co-decision into the EU law-making process. Co-decision, which greatly enhances the EP's legislative power with respect to national governments (represented in the Council of Ministers), is a process whereby the EP and the Council of Ministers jointly agree legislation. Up to three readings of legislative proposals are permitted, however if agreement is not reached during the first two, a process of direct dialogue and negotiation known as conciliation, occurs between the

⁴ Article 53(a) in the EPC (and correspondingly of Article 6 of the Directive), states "if the exploitation of the invention would be contrary to morality, a patent shall not be granted.

⁵ EPC, with precedent in Howard Florey Institute versus the Green Party of European Parliament for "Relaxin" (EP-B-0112149)

two institutions in order to agree a joint text. Ultimately, Council and EP are required to approve legislation jointly and hence, to bargain over draft EU legislation. Moreover, to enable the full Parliament to more easily accept the compromises reached in conciliation, a simple majority vote is required to pass such motions. The corollary of this is that a simple majority can also reject the proposal. The implication of the EP-Council dialogue at the heart of co-decision is an increasingly bipartite bargaining process, with the Commission more an onlooker, especially at later stages.

Since its conception the draft Biotechnology Patents Directive had survived two plenary readings and several amendment petitions in the EP, reaching the conciliation committee stage at the end of 1994. Agreement on the draft, a painful process within such a committee, was completed and a finalized text was presented to the EP on 1st March, 1995.

NON-MARKET ACTION AND ITS EFFECT

The pro-legislation lobby, which consisted mainly of industrial entities and trade associations, under the banner of the Forum for European Bio-industry Coordination (FEBC) [See Appendix 2], not only included European companies, who stood to gain the most, but also Japanese and US firms, who would benefit in general from any greater level of patent protection. They had expended significant effort and expense from 1988 to 1995 lobbying the EP as well as national representatives to the Council of Ministers. The focus of their message had been that intellectual property protection was crucial for innovation in scientific research within the EU, a message that tallied well with the objectives of the legislation. The result had been that the draft Directive proceeded through the conciliation stage. It should be noted that at this time no motion that had been approved in the conciliation stage had ever been then rejected in the EP plenary.

In opposition were various activist groups with diverse motivations. These included groups that believe that patenting organisms is unethical (e.g. GRAIN, RAFI), that the modification of either animal or human genomes is immoral (e.g. European Ecumenical Commission for Church and Society, German Protestant Church), that patenting would unfairly penalize developing world farmers and indigenous peoples (e.g. ActionAid) and that farmers would be obliged to pay royalties on every generation of plants and livestock they buy and reproduce for production purposes and that breeders will no longer have free access to germ-lines for developing new varieties of plants and animals⁶ (e.g. Coordination Paysanne Européenne/European Farmers' Coordination). Led by Greenpeace, this coalition opposed the legislation and had strong support from (mostly German) Members of the European Parliament (MEPs) for the Green Party. Anti-legislation measures they undertook included:

- **Focusing message on the "No-patents-on-life" campaign:** They "...played on the fears and lack of knowledge of the wider public and parliamentarians by spreading alarmist information...it was claimed that patents granted ownership rights leading to the complete commercialization of nature, to bio-piracy...that medical treatment would become immensely expensive because of license fees that would need to be paid every time a certain treatment was applied."⁷ Arguably one of the greatest achievements of the opposition lobby was to "rebrand" the legislation in the media and public eye, as the "Life Patents Directive."
- **Recruiting a broad coalition:** The interest groups recruited into the opposing coalition included a wide range of groups, from farmer's representatives to various religious organizations which together could exert significant constituency pressure.
- **High profile direct action:** During the week of the vote, Greenpeace mounted an intensive campaign outside Parliament's Brussels premises, picketing every entrance and handing out leaflets and brochures to everyone trying to enter or leave the buildings. On the morning of the vote, a huge banner ("No life patenting!") and two protesters in hammocks were suspended above the busiest five-lane traffic artery in Brussels, which also happens to separate two of Parliament's main buildings.
- **Targeted lobbying of pivotal MEPs:** Vocal lobbying exploited the reluctance of newly elected MEPs (over half the membership of the EP was replaced in the June 1994 elections) to support unquestioningly what had transpired in the previous parliament

The media strategy employed by the protesters won significant support in terms of public sentiment, and MEPs felt constituency pressure increase daily. "All these last minute efforts led to

⁶ Phil Bereano (University of Washington), Seattle Times Op Ed, August 20, 1995

⁷ Armin Machmer, Biotechnology unit of the European Commission's DG III, Press Conference Transcript on www.fedesa.be

a lot of confusion and insecurity on the side of the members, especially those who already had their doubts...the debates in plenary were highly emotionalized and sometimes even personal accusations were made. The vote on the patenting directive obviously was a vote on biotechnology in general.”² All these factors led to the conciliation committee’s joint text being rejected by the EP by 240 votes against to 188 in favor, with 23 abstentions. The EP was unable to secure a majority for the joint text despite the fact that, in the words of one industry commentator, “[The] Council had met many of Parliament’s demands, even on amendments that failed to secure the required majority”⁸. The draft Directive retains the distinction of being the only EU legislative measure to have fallen following agreement in conciliation.

KEY CHALLENGE

Assuming the role of the Board of Directors of a large pharmaceutical, biotech and life-sciences corporation, (Company X), given that the EC has stated its intention to retable the Directive, what non-market strategy should be adopted to ensure maximize the probability of success on the second attempt?

DISCUSSION AND ANALYSIS:

Issue: In the face of an EP rejection of the 1995 Draft Directive, Company X needs to regroup for a second attempt at passing EU-wide biotech patent legislation. This is the key to creating an environment conducive to biotechnology research in Europe and keeping Europe and Company X competitive in such a rapidly developing industry.

Interests: The 1995 Draft Directive triggered an “Interest group” politics-based stand-off with both sides organized: a pro-legislation group consisting of European, US and Japanese pharmaceutical/biotech companies and their rent chains (including researchers and members of the chemical industry) with proposing arguments based on technical and economic information. The opposition, an anti-legislation coalition made up of animal and human rights, pro-life, environmental and religious groups as well as farmers’ associations, based its arguments largely on ethical and moral grounds.

A comprehensive distributive politics analysis [See Appendix 4] reveals that some of the interest groups could have been mobilized to join Company X’s coalition in 1995. These groups can be identified based on two criteria: positioning and expected influence. On “positioning”, Company X could broaden its coalition to include those interest groups that were pro-legislation, convince “on-the-fence” interest groups to support its cause and neutralize certain anti-legislation interest groups. The “expected influence” criteria allow Company X to prioritize and focus efforts on interest groups that stand to have the greatest effect on the outcome. As seen in the summary Table 1 below, the patient groups, European Commission and agricultural associations emerge as particularly interesting points of action for Company X.

Table 1: Summary of interest groups, their position, view and likely relevance to SB

| Interest Groups | Positioning | Expected Influence ⁹ | Is this Interest Group An Enabler To SmithKline Beecham’s Cause? |
|---|-------------|---------------------------------|---|
| Active interest groups in the 1995 Draft Directive | | | |
| Company X & its rent chain | Pro | Med | Already in FEBC coalition |
| EFPIA members | Pro | High | Already in FEBC coalition |
| US and Japan Pharma firms | Pro | Low | Already in FEBC coalition |
| Biotech start-ups | Pro | Low | Already in FEBC coalition |
| Chemical and derivative companies and associations | Pro | High | Already in FEBC coalition |
| Environmental Activists | Anti | High | No – irreconcilable ideology and positioning |
| Human Rights Activists | Anti | High | No – irreconcilable ideology and positioning |
| Animal Rights Activists | Anti | High | No – irreconcilable ideology and positioning |
| Religious Groups | Anti | High | No – irreconcilable ideology and positioning |
| Agricultural and Livestock Farmers | Anti | High | Anti-legislation stance based on economic interests, which can be neutralized thro’ |

⁸ Mario Monti, European Commissioner, Verbatim transcript, Biotechnology Conference, 11th January, 1996, p.26

| | | | |
|--|--------------|------|--|
| | | | targeted concessions. Effect is disruption of the anti-legislation coalition |
| Non-active interest groups in the 1995 Draft Directive | | | |
| Pharma firm investors | Pro | Low | N/a |
| Academics (Biotech researchers) | Pro | Med | Provide technical information on available cures and usage of genetic research and have "expert" role in advising the EC |
| Governmental Health Care Institutions | Anti | Low | N/a |
| Insurance Companies | Anti | Low | N/a |
| Patient Groups | On the Fence | High | Provides a strong human interest element to the pro-legislation lobby group's message |
| European Commission | Pro | High | A "channel" for the pro-legislation lobby to feed information to MEPs |
| European Patent Office | Pro | Med | Source for expert advise to MEP and the European Patent Commission |
| Likely compliant National Patent Offices (UK, Germany, Denmark, Rep. of Ireland) | Pro | Low | Key to successful implementation of the Draft Directive once it is passed by the EP |
| Likely non-compliant National Patent Office (France, Netherlands) | Anti | Low | Potentially can slow down the implementation process |
| Other National Patent Offices (Other countries) | On the Fence | Low | Key to successful implementation of the Draft Directive once it is passed by the EP |

Institutions: EP, EC, European Council of Ministers. Given past support in the first proposal attempt from both the EC and the Council, the EP remains the key pivot institution.

Key characteristics of the political arena:

- European Commissioners, as authors of the proposal, have interest in the Directive's success
- The EP is different from parliaments of individual countries. Where typical European parliamentary governments are characterized by strong party voting discipline, MEPs do not exhibit such strong party-based voting alignment for several reasons:
 - **EP formal policy for non-partisan representation.** According to EP Rules of Procedure rule 2: "Members of the EP shall exercise their mandate independently. They shall not be bound by any binding instructions and shall not receive a mandate."
 - **Existence of non-party members in the EP.** Not all MEPs are attached to specific political parties. They are relatively free from party influences that drive voting behavior.
 - **Weakness of trans-national coalition positions.** EP party coalitions are weaker due to heterogeneity in national interests.

Information: As biotechnology is an evolving industry, external lobby groups are used by the Commission in formulating draft proposals and are heavily relied on for informing decisions within the EP. Simply put, the proponents failed in their communication due to two reasons: an un-compelling message and lack of credibility. The message, based largely on economic interests and technical arguments, was high on societal significance but lacked audience interest. This gave the opponents room to escalate the issue and occupy audience interest with messages focusing on ethical and moral concerns. Secondly, due to the profit paradox (i.e. the proposers of the legislation were those most likely to benefit from it), the pro coalition lacked the credibility to fully convey their message.

In addition to reiterating the economic message, the proponents need to bring in new, favorable information that will place the issue high on audience interest and societal significance.

⁹ Expected influence is determined by 2 criteria: (a) Incentives of each incentive group such as the availability of substitute opportunities, magnitude of benefits overall and per capita; (b) Capabilities of each incentive group such as numbers, coverage, resources and cost to organize

The most relevant way to do this would mean emphasizing the potential role of biotechnology in saving lives from incurable diseases and in providing hope to patients.

Depending on its strategic choices and audiences, Company X and its coalition could play on any of the following three messages: saving lives (emotive), saving jobs (economic) or encouraging scientific innovation (technical).

ANALYSIS OF STRATEGIC ALTERNATIVES

The drawn-out legislative phase of the issue life-cycle for the Directive came to a halt in 1995. By not having a comprehensive grasp on three of the four “I”s (interest groups, institutions and information), what could have remained a low-profile client politics lobbying dialogue between the FEBC and the EC and EP had been allowed to escalate into the interest group politics arena. Company X and its coalition were now faced with two alternatives:

- **“Broaden coalition/Extend issues”** – This strategy seeks to broaden the coalition by directly lobbying of all MEPs with the economic as well as other new messages, addressing the issues of agriculture, healthcare, religion, ethics and scientific research. **Pros:** Development of new, consistent and simple message broadens reach and therefore increases likelihood of new members joining coalition; **Cons:** Costs of developing new messages and costs of a “carpet-bombing”-approach, rolling-out message across broad scale of MEPs.
- **“Pivotal Lobbying”** – This strategy alternative involves direct lobbying using informational strategies of identified pivots such as interest groups, political group leaders and the Commission. **Pros:** Efficient in terms of informational and lobbying efforts; **Cons:** Might invoke some of the more negative connotations of client politics. Weaker party discipline in EP means higher risk of individuals deviating, hence some scale would be required to allow for “cushion”.

STRATEGY AND IMPLEMENTATION FOR COMPANY X AND THE PRO-LEGISLATION COALITION

Objective: The objective is to lobby the EP to pass the biotechnology patenting directive. The Directive must also be implemented across all EU member states and should be positioned such that candidate countries must effectively meet intellectual property protection requirements before acceding to the EU. Company X also has an objective to improve both its extra and intra-EU competitive position.

Institutional Arenas: The European Parliament and the European Commission.

Strategy Formulation: Company X’s immediate priority is to win the larger legislative battle in order to provide it with a long term strategic parity with its US and Japanese rivals. Its integrated non-market strategy should also account for the preservation and protection of their brand.

An analysis of the failed 1995 draft Directive highlights a need for Company X to strengthen its strategic position. Specifically it should look to: (1) Broaden its coalition and extend the issues. (2) Lobby MEPs through an informational strategy with simpler messages. (3) Ally with the commission as proposer. (4) Position for Implementation.

Key Lobby Message: Biotechnology patenting saves lives¹⁰. The Directive offers European Governments a chance to unshackle the restraints on innovation placed on European firms, and allow them to develop therapies for the hundreds of thousands all over Europe, suffering from debilitating and currently incurable conditions, including cancer, cystic fibrosis and Alzheimer’s disease, while simultaneously creating jobs and stimulating innovation.

Implementation:

(1) Broaden coalition and extend the issues. In addition to relying upon existing FEBC coalition members and their rent chains, Company X needs to prioritize and recruit new allies

¹⁰ Companies develop products in countries where i) they have research bases to support the regulatory process and ii) where they have the greatest chance of succeeding in winning enforceable IP protection. This had traditionally been the US and Japan. Due to the expense and uncertainty of the drug approval and patent process, firms would rarely initiate parallel approval processes in Europe until after US/Japanese approval and patents had been secured. The European drug approval process, like that of the FDA, takes several years, during which time the drug is not available to European patients, many of whom may be in acute stage. Moreover, uncertainty on enforceability of biotech patents in Europe may mean firms will dedicate less resources to the approval process in Europe (due to the inevitable competition) further delaying drug availability for European patients.

such as patient groups¹¹, and academics. Furthermore it has to disrupt the opposition coalition by neutralizing the farmers in view of their influential position within the EU.

The new allies can be activated through a new message that addresses their concerns and by providing financial support by the coalition. By switching from an economical and technology-based discussion to one of “saving lives” the coalition can firmly align itself with the patient groups. Financial support in the form of donations, grants and sponsored research could further solidify this relationship.

Unlike the rest of the anti-legislation lobby group whose arguments are firmly rooted on ideals and beliefs, the farmers’ contention is economy-based. Thus, they can be neutralized by modifications of the Directive that would eliminate their obligation to pay royalties and secure their free access to germ-lines. The proposing coalition should lobby the EC to ensure these exemptions are included in the next draft of the Directive, potentially jointly with the very farmers’ associations who opposed the first draft.

(2) Lobby the MEPs and support the effort using an informational strategy. This strategy involves direct lobbying of all MEPs using informational strategies delivered by interest groups, political group leaders and the European Commission. The coalition should communicate a consistent, simple and emotive message that focuses on the potential medical benefits of biotechnology as well as the new jobs that the legislation would provide for the European economy. This information should be made available broadly to all of the MEPs, since members do not follow a strong party-based voting pattern. This information strategy should employ grassroots letter-writing and rally campaigns around the “No patents, no cure” message by patient groups, as well as theses on the “Jobs and competitiveness” message by economists, financial analysts and third party intellectuals.

(3) Ally with the commission as proposer. Recognizing that the co-decision process relegates the European Commission to the role of interest group, it is necessary for the FEBC to provide the EC, the proposer, sufficient technical information to allow it to act as internal lobbyists within the European Parliament. In particular, Willi Rothley, a socialist and the Rapporteur of the Directive, as well as head of the DG III¹² committee is a potentially credible ally to lobby MEPs on behalf of the FEBC, since, after 10 years of work on the Directive, DG III’s interests to pass the directive are aligned with that of the FEBC.

(4) Positioning for Implementation. It is critical that the FEBC members position themselves to ensure the rapid and strict implementation of the Directive. This would require lobbying of national patent offices as well as the EPO. National patent offices vary as to likelihood of implementation. Some are very likely to implement (e.g. the UK), while others have legal impediments (e.g. Netherlands and France) to do so. The coalition must focus on potential “switcher” governments which have no legal obstacles, but which may have opposing public sentiment (e.g. Germany). Most importantly, the coalition must focus on ensuring that the EPO adopts the directive as quickly as possible, since the legislation then applies to all applications for European patents, and exerts pressure on the national offices to follow suit.

Long Term Company X Strategic Outlook – Turning Issue into Opportunity

The patent Directive issue also presents a longer-term opportunity for Company X to differentiate its brand, both internally and externally. The lobbying campaign conducted to pass the Directive is likely to generate significant public attention among key constituencies for Company X such as patient groups, academics, politicians and employees. Company X should build on the necessarily “non-corporate” positive lobby message by aligning its corporate messages to the lobby message, and by positioning itself as socially responsible company at the heart of therapy development and innovation in the industry. This will ultimately improve Company X’s ability to attract the brightest people, improve profitability, and boost credibility for future lobbying campaigns.

In addition, Company X should support its communication with highly visible actions; working to actively improve access to medicine in developing countries, to research and develop new life-saving medicines in less profitable areas (incl. tropical/neglected disease), and to offer donations

¹¹ Ignored in the pre-1995 coalition, Company X should realize that patient groups are a powerful ally as: they have wide reach across all EU countries, they are easily organized and most importantly, they can provide a crucial “human interest” element to the coalition’s message, countering the “profit paradox” issue

¹² Directorate General III

to well publicized causes e.g. discount drug pricing to less financially strong countries, funding academic institutions etc .

OUTCOME

Phoenix from the ashes - The Directive relaunched: Just a few months later, in December 1995, the Commission submitted a new proposal, officially launched by Mario Monti, EU Internal Market Commissioner, at a public hearing in Brussels in January 1996, in the presence of national officials, MEPs, industry representatives and non-governmental organizations (NGOs). According to Monti the new text explicitly took into account factors that had led MEPs to reject the earlier text, especially concerns on ethical issues. Indeed, the Commission acknowledged the inadequacy of its forerunner proposal, as being 'largely technical in character', and claimed that 'the new proposal fully reconciles the ethical concerns of the European Parliament'. To assuage the EP's ethical fears, the proposal now stipulated that "the human body and its components in their natural state are not considered patentable inventions." It also banned patents for "germ-line therapy", which involves modifying genes that will be passed on to the genetic make-up of offspring. Further, transgenic animals may only be patented if the suffering of the animal is proportionate to the benefit to the human race¹³. Finally, the new text included "farmer's privilege", which allowed farmers to have access to feedstock and bloodstock for farming purposes without royalty, and breeders to access patented animals for their own purposes under compulsory cross-licensing.

While the bulk of the Directive's text, and indeed sentiment, remained unchanged, the Commission had incorporated all but one of the sixty-six amendments suggested by the Parliament. The omitted Amendment 76, stated that when an application is made to patent plant or animal material, the application must provide evidence of compliance with legislation of the country of origin governing access to and export of such material and when an application is made to patent human material, the application must contain evidence of the consent of the source. The Directive furthermore required the EC's Group on Ethics in Science and New Technologies to evaluate "all ethical aspects of biotechnology." This group, however, may be consulted only where biotechnology was to be evaluated at the level of basic ethical principles, including where it was consulted on patent law. Moreover, it was very clear that any common positions taken by this group were without legal effect for the actual granting of patents.

The Opposition mobilizes: As in 1994-5, the opposing coalition again deployed similar non-market strategies, with heavy lobbying. The farming lobby was present, however to a much less vocal degree, following the addition of the derogation to the Directive. In response Greenpeace broadened its coalition to include more representation of developing countries. The message remained unchanged and the levels of activism remained high-profile. The opponents of the Directive explicitly and frequently sought to enhance their credibility by claiming to represent European 'civil society'. On opening the first reading debate in July 1997, the EP's rapporteur, Willi Rothley, observed that the "European Parliament had been under considerable pressure over the last few days, not only here in the House. The Protestant Church in Germany, my own church, allowed Greenpeace to stage a children's crusade against the Directive at its General Assembly".

A New Message and a Stronger Coalition: From 1995-8, the credibility of potential gene therapy treatments and the use of genetics in diagnosis, resulting from advances in the US, changed the perception of biotechnology for European citizens. The European biotechnology industry promoted potential therapies [see Appendix 3], such as the discovery of the *Her-2* gene¹⁴, with the claim that patents were essential for the availability of such treatments in Europe. The key to the credibility in this message was the recruitment of vocal patient support groups to the proposing coalition¹⁵. Activists stated that "...Industry [was] striking at the hearts of ...MEPs

¹³ The case of Oncomouse: EPO vs Harvard University

¹⁴ Bazell, R., "Her-2: the making of Herceptin". Her-2 is a proto-oncogene linked to breast cancer. Its discovery led to the development by Genentech of Herceptin, the first humanized antibody, approved by the US FDA in September 1998, for the treatment of metastatic breast cancer.

¹⁵ European Biomedical Research Association (EBRA)- Bulletin, August 1997: "Patients and the European Parliament, lobbying and the Biotechnology Directive"

with the slogan 'No patent No cure', borne on the yellow T-shirts of an army of disabled people on wheelchairs, recruited from patient groups and highly visible in the parliament"

While industry also maintained its argument that the Directive was essential for the development of a job-creating biotechnology industry within Europe, using media such as EFPIA adverts signed by pharmaceutical industry CEOs in the *European Voice*, it also pushed the 'No patent, No cure' message at every opportunity. Irish Liberal MEP, Pat Cox, for example, remarked that "Again today my mailbox is full of letters, not least from groups in my own country representing those who suffer from genetic and other medical disorders currently without a cure, requesting support for this measure because it offers them some hope. In conscience I will not vote against offering that hope."

This message proved compelling and in concluding the first reading in July 1997, the EP supported the Commission's proposal, as amended, by 388 votes to 110, with 15 abstentions. In November, 1997, the Council of Ministers adopted the Commission's version of the Directive with very few changes. Holland voted against the directive and Italy and Belgium abstained; the rest all voted in favour. In a tense second reading vote, on 12th May, 1998, the EP approved the common position unamended. The EP's Green group's motion of intent to reject the common position garnered just 78 votes, primarily made up of Greens and Communists. This last minute Green attempt to kill the directive a second time was crushed by 432 MEPs. The Green's case was probably not helped by a demonstration in the EP's chamber by Green MEPs, involving pirate costumes and a banner stating "Stop Bio-Piracy". Commenting on the change in industry's tactics, and comparing its lobbying with that on the earlier, defeated proposal, one official remarked that they 'might have been familiar with the industry, but they did not understand the Parliament'.¹⁶

1998 and Beyond - Measures and Countermeasures:

Even though EU members were legally obliged to adopt the directive and, where necessary, adapt their legislation to fit it, by no later than 30th July 2000, France and several other member states did not do so, with only Denmark, the Republic of Ireland, Finland and Britain achieving this by the deadline. Unhappiness about the Directive's consequences also took the form of an action for its annulment under Article 173 of the EC Treaty submitted by the Government of the Netherlands and supported by the Italian and Norwegian governments. The grounds of the challenge were varied, although mainly procedural in nature. The main arguments concerned the choice of legal base, subsidiarity, breaches of international law, breaches of fundamental rights, and finally the Commission decision-making process.

The legal implementation issue was resolved by the EPO's Administrative Council, which, though under no obligation to do so, added new provisions relating to the Directive to the Implementing Regulations of the EPC in order to bring the EPC into line with the Directive. This made it now *de facto* applicable to all applications for European patents. The issue of the Dutch nullity suit was concluded when the ECJ threw out the case in 2002.

CONCLUSION

The key learnings from the European Biotechnology Patent Directive case are:

- **Know the arena and players:** Understanding which parties, if any, are likely to be pivotal is crucial to identifying lobby targets. In this case, the fact that Article 2 allows MEPs to vote with a certain degree of freedom from their party whip, greatly influences the target of lobbying action (party leaderships are no longer as attractive targets)
- **Have the right message:** Once lobby targets are identified, it is necessary to identify their key influences and ensure that the lobby message addresses these. A modification in the nature of the lobby message from a "Jobs and Competitiveness" message to the "No patents, No cure" stance was highly successful in this case
- **Build the right coalition and fragment the opposition**
 - The failure of the FEBC to address the "profit paradox" by strengthening their coalition during the first attempt gave Greenpeace and the opposing coalition's message added credibility

¹⁶ Quoted in Watson, R. (1997), 'In the eye of the biotechnology storm', *European Voice*, Vol. 3, No. 26, p. 11.

- FEBC's moves to neutralize the farming lobby with targeted concessions greatly weakened the coverage of the opposing coalition, while Greenpeace's moves to include developing countries did not strengthen their coalition as anticipated because these countries had little constituency influence on MEPs.

These lessons were clearly understood and have been applied by the life sciences industry to deal with subsequent challenges. Notably, in the case of the landmark 2001 ruling allowing embryonic stem cell research in the UK, patient groups were a heavily publicized lobby group, with the industry message being one of the necessity of stem cell research in order to develop therapies to some of the most persistent, emotional and debilitating conditions.

...."Human embryonic stem cell research, conducted within a clear ethical and regulatory framework, could play a crucial role in the development of a supply of islet cells for the cure of diabetes," says Annwen Jones, chief executive of the Juvenile Diabetes Research Foundation. His words were supported by the heads of the Parkinson's Disease Society, the director of the British Heart Foundation and the director of the Wellcome Trust, who said: "It would be a terrible shame if MPs allow misconceptions and misinformation to dash the hopes of tens of thousands of people suffering from a wide range of diseases." – "Stem Cell Decision Time for the UK", www.the-scientist.com, 18th December, 2000¹⁷.

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¹⁷ Also 'Therapeutic cloning to become a reality for Britain' BioMed central 18 August 2000
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APPENDIX 1: CURRENT CORPORATE FULL MEMBERS OF EFPIA (including the Emerging Biopharmaceutical Enterprises [EBE])

Abbott Laboratories, USA
 Actelion, Switzerland
 Akzo Nobel-Pharma, Netherlands
 Almirall-Prodesfarma, Spain
 AstraZeneca, Sweden/United Kingdom
 Aventis Pharma AG, Germany/France
 Baxter, USA
 Bayer AG, Germany
 Beaufour-Ipsen, France
 Biogen, France
 Boehringer Ingelheim, Germany
 Bristol Myers Squibb, USA
 British Biotech, United Kingdom
 Celltech, United Kingdom
 Centocor, USA
 Chiesi Farmaceutici, Italy
 Chiron, UK
 Control Pharma, Finland

Diosynth, Netherlands
 Eli Lilly & Co, USA
 Laboratorios Esteve, Spain
 Gencell, France
 Genesis Pharma, Greece
 Genetics Institute (AHP), USA
 Genmab, Denmark
 Genzyme, Belgium
 GlaxoSmithKline, United Kingdom
 Grünenthal, Germany
 Hemebiotech, Denmark
 Human Genome Sciences, USA
 Johnson & Johnson, USA

Leo Pharmaceutical Products, Denmark
 H. Lundbeck A/S, Denmark
 Medigene, Germany

Micromet, Germany
Menarini, Italy
Merck KGaA, Germany
Merck & Co, USA
Modex, Switzerland
Novartis, Switzerland
Novo Nordisk, Denmark
Orion Pharma, Finland
OTL Pharma, France
Pfizer, USA
Pharmacia Corporation, USA
Procter & Gamble Pharmaceuticals,
USA
Roche, Switzerland
Sanofi-Synthelabo, France
Schering AG, Germany
Schering-Plough, USA
Schwarz Pharma AG, Germany
Serono, Switzerland
Trophos, France
Laboratoires Servier, France
Sigma-Tau, Italy
Solvay, Belgium
UCB Pharma, Belgium
Wyeth, USA
Xion, France

APPENDIX 2: Trade Associations constituting the FEBC

AMEEP (food and feed enzymes)
CEFIC (chemicals)
CIAA (food)
COMASSO (plant breeders)
EDMA (diagnostic products)
ECPA (plant protection)
EFPIA (pharmaceuticals)
FAIP (Farm Animal Industrial Platform)
FEDESA (animal health)
FEFAC (compound feed)
FEFANA (feedstuffs additives)
EuropaBio (European Bio-Industries)
Animal Health Institute (AHI, USA)
Association of Veterinary Biologics Companies (AVBC, USA)
Biotechnology Industry Organization (BIO, USA)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Japan Bioindustry Association (JBA)

APPENDIX 3: Some Current and Potential Applications of Genome Research

Molecular Medicine

- Improve diagnosis of disease
- Detect genetic predispositions to disease
- Create drugs based on molecular information
- Use gene therapy and control systems as drugs
- Design "custom drugs" based on individual genetic profiles

Microbial Genomics

- Rapidly detect and treat pathogens (disease-causing microbes) in clinical practice
- Develop new energy sources (biofuels)
- Monitor environments to detect pollutants
- Protect citizenry from biological and chemical warfare
- Clean up toxic waste safely and efficiently

Risk Assessment

- Evaluate the health risks faced by individuals who may be exposed to radiation (including low levels in industrial areas) and to cancer-causing chemicals and toxins

Bioarchaeology, Anthropology, Evolution, and Human Migration

- Study evolution through germline mutations in lineages
- Study migration of different population groups based on maternal genetic inheritance
- Study mutations on the Y chromosome to trace lineage and migration of males
- Compare breakpoints in the evolution of mutations with ages of populations and historical events

DNA Identification

- Identify potential suspects whose DNA may match evidence left at crime scenes
- Exonerate persons wrongly accused of crimes
- Identify crime, catastrophe, and other victims
- Establish paternity and other family relationships
- Identify endangered and protected species as an aid to wildlife officials (could be used for prosecuting poachers)
- Detect bacteria and other organisms that may pollute air, water, soil, and food
- Match organ donors with recipients in transplant programs
- Determine pedigree for seed or livestock breeds
- Authenticate consumables such as caviar and wine

Agriculture, Livestock Breeding, and Bioprocessing

- Grow disease-, insect-, and drought-resistant crops
- Breed healthier, more productive, disease-resistant farm animals
- Grow more nutritious produce
- Develop biopesticides
- Incorporate edible vaccines into food products
- Develop new environmental cleanup uses for plants like tobacco

APPENDIX 4: Distributive spreadsheet analysis

http://www.kellogg.northwestern.edu/academic/biotech/articles/shail_appendix4.pdf