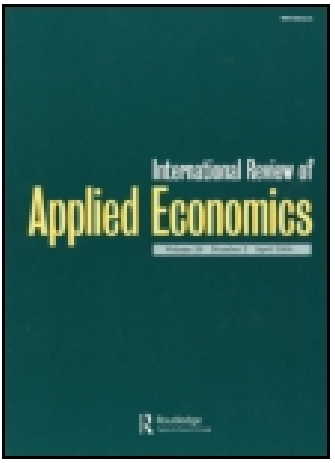

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The 1988 EC directive on biotechnological inventions and the UK biotechnology industry

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The 1988 EC directive on biotechnological inventions and the UK biotechnology industry*

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The article, based on a recent survey of UK biotechnology companies, highlights the complex interaction between the organization of R&D and the patenting policy in the biotech industry. Some of the more interesting findings include: the limited extent of private investment in biotechnological R&D; the existence of two markedly different R&D strategies (product- vs. process-based); the distinction between first- and second-generation patents and their effects on market structure. The core of the article deals with the likely effects on patenting behaviour of changes in patent law – both as envisaged in the October 1988 Directive and as suggested by recent theoretical research on the economics of patents. The Directive in its current form is reported to have no discernible effect on the extent and organization of R&D, whereas the industry's response to a series of hypothetical changes suggests that any definition or patentability standards has far-reaching repercussions on: (1) the allocation of resources between research and development; (2) the conditions of entry into the industry; (3) the balance of bargaining power between firms of unequal size (or pursuing different R&D strategies); and ultimately (4) the allocation of technological surplus between consumers and producers.

I Introduction

In October 1988 the European Commission produced a 'Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions' (henceforth Directive[1] with the explicit purpose of 'establish[ing] harmonized, clear and improved standards for protecting biotechnological inventions in order to foster the overall innovative potential and competitiveness of Community science and industry' in the biotechnological field (Direc-

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[1] European Commission (1988).

tive: 6). The aim of this article is to assess the likely impact of changes in patent law (both as envisaged in the Directive and as suggested by recent developments in the economics of patents) on the UK, and by extension, European biotechnology industry, relying on a survey carried out by the author in 1990 (La Manna, 1990). The article is organized as follows: Section I describes the methodology of the survey on R&D and patenting in the UK biotechnology industry and reports some of the main factual findings on the interplay between the organization of R&D and patenting behaviour. Section II assesses the industry's response both to the Directive in its current form and to a series of hypothetical changes in patent law. Section III concludes and suggests avenues for future research.

II Methodology and main findings

1 The survey

Two main data-gathering devices were deployed in the survey: a structured questionnaire[2] and follow-up interviews with senior R&D and patent executives. The companies surveyed include three multinational pharmaceutical companies, two major 'pure' biotechnology firms, the seeds division of a large chemical company, and the biotechnology department of a high-tech consultancy firm. The patent division of a food and detergents multinational company also co-operated by providing confidential documents on patenting policy. The sample covers a significant cross-section of the UK biotechnology industry, in terms of the spread of both company size and research activities. The 15-page long questionnaire aimed at eliciting information on 1) size and 'age' of the respondent company and especially of its biotechnology division; 2) patenting policy; 3) organization of R&D and its link with patenting; 4) perceived impact of the Directive in its current form as well as under a series of hypothetical scenarios.

2 A surprising finding: the missing investment in biotechnology

In view of the widely held belief that 'modern genetic engineering techniques offer enormous economic potential' (Directive: 9) and that a conservative estimate of the biotechnology market is $40 billion in 10 years time, one might have expected that leading UK companies engaged in biotechnology would devote substantial resources to research and development. Thus it comes as a surprise to find that members of the sample and, by extension, the whole UK biotechnology industry are investing very little in in-house R&D. In both absolute and relative terms, the annual budgets

[2] Copies of the questionnaire are available from the author on request.

of Biotechnology Divisions (BDs)[3] are tiny. For obvious reasons of confidentiality no precise figures can be disclosed; however, for large multinationals, the average ratio of the BD's annual budget to the annual budget of the overall R&D department ranges from 0.025 to 0.05, whereas for 'pure' biotechnology companies a BD annual budget in double figures (in £m) would be exceptionally high. As a rough indication of the amount of financial resources specifically devoted to biotechnological R&D in the sample, the combined BD budget of the top five companies does not exceed £60 million. This piece of quantitative information confirms the view, expressed by some senior R&D executives, that although biotechnological techniques cannot be ignored and could provide in the indeterminate future important scientific breakthroughs of great economic benefit, for the time being they have in no way fulfilled their early promise of wonderful panaceas. Indeed it may be surmised that very shortly the industry will undergo its first substantial shake-out, with companies rethinking their strategies, in terms of both optimal R&D routes and economic potential. However, it should be stressed that the quality of research undertaken by a typical BD is very high: the ratio of staff holding PhDs or above to total BD employment can exceed 0.5, with 0.4 being a fairly common value. In the case of pharmaceutical companies, the ratio of PhDs to overall research staff is significantly higher in the biotechnology division than in the traditional chemistry-based division.

3 Timing and structure of R&D and patenting in biotechnology

Judging from the survey, there are two broad options as far as R&D strategies are concerned. Biotechnology can be regarded as a set of 'enabling technologies' aimed at developing processes and techniques that can be transferred to product-oriented divisions within the company. Or, alternatively, companies may pursue from the outset a directly product-oriented R&D strategy. It turns out that patenting policy plays a completely different role depending on whether R&D strategies are process- or product-aimed. Under a product-aimed strategy, the R&D process undergoes five main stages as described in Figure 1.

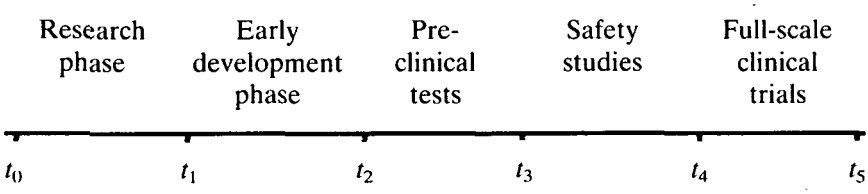

Figure 1 Product-aimed R&D profile

[3] The term BD refers to the part of the organization directly and exclusively responsible for the research, early and late development of biotechnology projects, and specifically excludes administration, production, marketing, etc.

In a typical product-aimed strategy the patent point lies at t_1 (or soon after it), the time period from inception to patent filing (i.e., $t_1 - t_0$) is rather short (18–24 months) and the investment in research is minuscule (1%–5% of overall BD budget). These facts do not fit comfortably in the standard patent-race model: whereas the short time to patent filing may be taken as evidence of the firms' attempts to establish priority, the tiny resources (in terms of both personnel and budgets) devoted to the research phase suggest that firms do not try to enhance their chance of winning the race to priority by increasing their investment in research.

4 Why do firms file for patents so quickly and after so little investment?

As noted in Section I.2 overall investment in biotechnology-related R&D is undertaken on a very small scale by the companies surveyed. This, of course, need not imply that, for a given overall R&D budget, the percentage of resources devoted to research (or, more precisely, to prepatenting activities) should be small. Two possible, mutually nonexclusive, explanations can be advanced for the puzzle of the missing investment in priority-enhancing activities.

According to one explanation, research is a highly focused search activity in a field known to be free from 'competing searchers', i.e., firms decide to enter a patent race after having established that they would face very few, if any, competitors. The obvious candidate for the likely mechanism that may enable firms to monitor each other's research projects is the informal scientific grapevine. This is the informal network of contacts (through meetings, academic conferences, etc.) whereby scientists exchange views on their current investigations. By its very nature this two-way information flow is quite difficult to model formally,[4] but its existence suggests that the traditional view that sees firms as shielding resolutely their research activities from the unwelcome gaze of competitors is incomplete and one-sided. At least in the biotechnology field it would appear that firms, on the one hand, exchange commercially sensitive information (without entering into formal information-exchange contracts, such as R&D joint ventures) and, on the other hand, do compete vigorously at some stage of the game. The appropriate formulation of the underlying game-theoretic relationships should encompass both collusive and nonco-operative stages (for an attempt in this direction, see La Manna, 1992).

Another explanation for low investment in patent-aimed research may lie in the uncertain legal status of patents. Firms may file for very broad and vague patents as soon as a new idea shows even a remote possibility of

[4] For an interesting attempt to model co-operative information flows within a nonco-operative framework, see Baumol (1990).

industrial applicability. In this perspective, filing for a patent can be interpreted as placing a territorial marker, to be used at a much later stage as a bargaining chip in establishing the validity of later (downstream) patents. This could account for the reported phenomenon of firms initiating an R&D project in a specific area in response to the filing for (or even the award of) a patent by a competitor. This, too, is a feature of patenting behaviour that cannot be explained in terms of the standard patent-race model.

5 Patents as sources of information

Traditionally, patent specification is regarded as the main source of information on competitors' R&D activities and this view is confirmed by the survey. All companies in the sample monitor patent databases at least on a weekly basis, some even daily. Most companies consider them as 'very important' or 'important' sources of information on their rivals' R&D. As patent specifications refer to a state of the art that is at least 18 months old, the motivation for intensive searches cannot be the gathering of scientifically relevant information. The reason why firms monitor so closely each other's patent activities is two-fold. First, patents are monitored as an *ex post* check on the reliability of the information gathered in the 'scientific grapevine'. Indirect evidence of the efficacy of the grapevine to diffuse unbiased information on research plans is provided by the fact that companies report very few instances of wholly unexpected patent specifications by direct competitors. Secondly, firms monitor patent databases to check not so much the R&D activities of their rivals, but rather their patent lawyers' interpretation of patent rules. Especially in an industry as young as biotechnology where there is not a long history of precedents to guide the courts in reaching judgement on competing patent claims, firms are not quite sure of the scope and validity of patents. Indeed, some R&D executives did report some 'surprises' in their patent monitoring, but in the sense that they believed their competitors' claims to be so broad (or so lacking in novelty) as to be most unlikely to satisfy the Patent Office's patentability criteria. As the rules for patentability become clearer (thanks to forthcoming reforms and to the accretion of legal rulings), the current trend towards filing for quite broad (and hence vague) and trivial (i.e., non-novel) patents may be reversed, leading to a fall in the volume of patents. This need not be considered as undesirable, for both the quality of patents and the percentage of worked patents can be expected to increase.

6 Early development and beyond

Having set a territorial marker in the form of an early patent application, a typical firm engaged in a product-aimed R&D strategy would then start

developing the most promising ideas discovered at the research phase. The aim at this stage is to obtain a product with commercially valuable characteristics that could then be subjected to initial efficacy tests (typically *in vitro* and on animals) and then to safety trials, in order to ascertain its nontoxicity. The amounts of financial and personnel resources allocated to these stages are significantly greater than at the previous one (with increases in both budget and staff numbers between 200% and 400%). In absolute terms, however, investment in early development, preclinical and safety trials is still small. Notice that second-generation patents may be produced at the development stage: these are patents that improve on early, priority-establishing, patents. The fact that R&D projects yield *generations* of patents and thus the patent covering a marketable product may be traced back to various 'mother' patents complicates the picture substantially and make policy recommendations very problematic. As a first approximation a distinction must be drawn between basic and final patents: the economic motivation behind each type of patent is different and so is the impact on either of changes in patent law (see Section I.9).

7 The cost of full-scale clinical trials

All expenditure prior to full-scale clinical trials pales into insignificance compared with the gigantic costs of clinical trials. These are largely fixed costs, in the sense that the type and extent of tests are determined by the regulatory agency and the time to completion cannot be shortened significantly by increased expenditures. To give a feel for the amounts involved in the introduction of a major new drug, a full-scale clinical trial costing £50 million would not be regarded as untypical. Some companies have whole departments working exclusively on the monitoring and analysis of clinical trials. The presence of these large fixed costs has obvious implications for the structure of pharmaceuticals-related biotechnology industry and for the relationships between research start-ups and the large multinational pharmaceutical companies.

8 Patents under a process-aimed R&D strategy

The role of patents changes dramatically under a process-aimed R&D strategy. Under this type of strategy, the main aim of research projects is to provide an 'enabling technology' in a form amenable to being turned into new products (or new methods of obtaining existing products) by other divisions within the company. This strategy is clearly inappropriate for small start-ups, even though, according to industry sources, some USA companies have tried to obtain patents on process inventions. These firms, however, have met with very little economic success, because in biotechnology there are usually many alternative routes to a given target end-

product and thus protection from imitation is very thin indeed. However, this does not mean that all large firms pursue process-aimed R&D strategies. On the contrary, the research strategies of these firms show remarkable and significant differences. It is impossible to determine whether this is due to the underlying scientific basis not having settled yet to a routine or to the fact that charismatic R&D executives subscribing to opposite views of the 'right' way of carrying out biotechnological research have not yet had their theories subjected to the test of commercial success. Whatever the reason, the biotechnology industry provides no support for the view that firms of similar (i.e., large) size aiming at the same target inevitably pursue similar research strategies.

The most striking feature of a typical process-aimed R&D strategy is that its success (or failure) is almost completely uncorrelated with patenting activity. Whereas under a product-aimed R&D strategy filing for (and eventually being awarded) a patent is a necessary condition for the successful completion of the project, a process-aimed programme may attain its objectives without having yielded a single patent. Although this may be an extreme case, in general, under a process-aimed strategy firms are willing to risk a loss of priority in order to delay having to disclose details on their processes (unlike the case of product-aimed projects, where, in deciding when to file for a patent, the trade-off between priority and disclosure is always biased towards priority). In some cases, firms may even decide not to patent at all and rely exclusively on secrecy. It may be wondered whether the price to be paid for relying on secrecy is the exclusion of the firms' scientists from the informal scientific grapevine described in Section I.4. Somewhat surprisingly, this is not the case: scientists employed by firms that rely on secrecy find that they can still participate to the scientific debate without having to reveal their discoveries, thus being able to feed their R&D executives with highly valuable information gathered from fellow scientists. Indeed, one such executive expressed amazement at the sort of detailed and commercially sensitive information disclosed by scientists employed by competitors.[5]

9 *Patentability standards and market structure in the biotechnology industry*

Although this is not explicitly recognized in the Directive, any change in patentability standards has a major effect on market structure. The link between the definition of patentability standards and the costs/benefits of entry in the industry is particularly strong in the case of the biotechnology industry, in view of the paramount importance of patents. As explained in Section I.4, the current patenting practice is to file for patents at the

[5] Because of the limited role played by patents in a process-aimed R&D strategy, we need not specify the time-profile of a typical R&D project.

earliest possible time in order to set a 'territorial marker'. These 'first generation' patents are then followed by a second round of much more specific and product-based patents.

The key policy question is whether a clearer definition of patentability standards would lead to an improved allocation of resources. To gain an intuitive understanding of the factors at work, consider the extreme case of the strictest patentability criteria, where the Patent Office entertains only application for specific, product-based patents. The effect of this regime would be to increase the entry cost in the industry.[6] It is not surprising that none of the companies surveyed favoured such a scheme, for they correctly predicted that their profits would fall. However, the industry-wide effect would be a reduction in the number of firms engaged in 'fast and cheap' research and increased investment in development by the remaining firms. It can be shown that the lower the cost of research, the more likely it is that a switch to product-based patentability standards would improve efficiency in the industry. Given the relatively low cost of the research phase (1%–5% of overall R&D budget), it may be surmised that a move towards a stricter interpretation of patentability criteria would generate welfare gains. All R&D and patent executives interviewed agreed in advocating a reduction in the uncertainty that currently surrounds the very definition of patentability standards in biotechnology. In view of the above comments, this unanimous view has to be qualified in the sense that the industry would welcome clearer patentability standards, provided this did not imply that more substantial investment in research and/or development would be needed in order to meet the new criteria.

It should be noted that the current uncertain status of 'first generation' patents may also have some indirect beneficial effects. Suppose that two firms were to file for very similar 'second generation' patents, based on vague 'mother' patents. It is likely that the two companies would refrain from entering into costly litigation over dubious priority claims and settle instead for a crosslicensing agreement. Conversely, the less uncertain the status of first generation patents the more likely a firm would be to pursue its priority claim through the courts in order to establish a monopoly position in the market. Therefore, if we take the view that a crosslicence based duopoly is more efficient than an exclusive-patent monopoly, the uncertainty surrounding first generation patents may turn out to be conducive to a more efficient allocation of resources. Of course, it should be acknowledged that the uncertainty on the status of 'mother' patents may have anti-competitive effects, in so far as it may discriminate against small firms, who may find resorting to litigation a prohibitively expensive exercise.

[6] For details, see La Manna, 1992: 176–85.

The general point that the Directive seems to ignore is that any definition of patentability standards inevitably affects: 1) the allocation of resources between research and development; 2) the conditions of entry into the industry; and 3) the balance of bargaining power between small and large firms. The Directive is based on the questionable assumption that any clarification of patentability criteria would lead to a Pareto improvement. Taking into account that different parties (e.g., consumers vs. producers, small vs. large firms, research-based vs. product-oriented companies) have conflicting interests, it is not obvious which policy objective would be maximized under any new set of patentability criteria.

III The British biotechnology industry and the Directive

1 General response to the Directive

All companies surveyed shared a common attitude to the very idea of a Directive aimed at defining patentability standards: it was generally agreed that the costs and benefits of such an exercise were highly asymmetric, in the sense that as compared with the status quo the costs of an industry-unfriendly Directive were reckoned to be much higher than the likely benefits of legislation in tune with the requirements of the industry. This, of course, should not be taken as evidence that the current state of affairs is considered satisfactory. On the contrary, all respondents and interviewees expressed dissatisfaction with the present uncertain status of patentability standards.

As to the general response to the Directive in its current formulation, the general view can be briefly but accurately summarized by saying that its perceived impact on the volume and quality of R&D is regarded as minimal. Some respondents rated the impact of the Directive to be nil and none thought it would affect 'very substantially' or even 'substantially' their research plans, with no change in their budget allocations as a direct effect of the Directive. Indeed, it is surprising that some firms expected their profitability to improve as a result of the proposed reforms. The same pattern of response is likely to apply to the biotechnology industries of other European countries, especially in view of the unanimous opinion amongst respondents that the Directive did not favour any one member state, providing a slight competitive advantage to all EC-based companies *vis à vis* the rest of the world.

2 Detailed response to specific provisions in the Directive

a Definition of patentability of living matter: This is, of course, a key and controversial element of the Directive and the great majority of companies surveyed expressed reservations on the definition of patentable matter

adopted in the Directive. Some respondents complained about the vagueness of the wording, believed to leave ample scope for differing interpretations. Other companies, instead, considered the wording relatively precise, but objected to its content, arguing that it was far too restrictive. The exclusion of plant and animal varieties was mentioned as an example of the excessive narrowness of the definition.

b Dependency license for plant varieties: Article 14 of the Directive is interesting, both at a theoretical level and for the response elicited from the companies surveyed. From a theoretical viewpoint, the striking feature of Article 14 is that, in the event of a potential patent infringement by the holder of a plant breeders' right, a compulsory licensing scheme is activated, with the royalty rate set so that it has 'regard to the nature of the patented invention and consistent with giving the proprietor of such patent due reward for the investment leading to and developing the invention'. This requires not only an assessment of the invention to determine whether 'significant technical progress' has been achieved but, more importantly, estimating the scale of the R&D investment 'leading to the invention'. The difficulties inherent in the scheme are legion. Given the collaboration in the production of knowledge (a research team typically works on more than one project at any one time, making use of facilities available to other research teams), the scope for 'creative accounting' is vast. The temptation to assign to 'the' invention costs jointly incurred is so great that profit-maximizing firms cannot be expected not to succumb to it. The interpretation of 'investment leading to the invention' is not free from problems, either. Should the investment in failed projects aimed at the same objective as the successful project be included? If not, the scheme would penalize the more innovative firms, willing to explore high-variance research avenues. If investment in dry holes is included, again this will increase the scope for inflating research costs. The most damaging criticism to Article 14 is that it is inherently contradictory. Either the scheme is not incentive-compatible, i.e., is predicated on the untenable assumption that firms would behave in a way detrimental to their own interests, or, if ways can be devised to elicit 'true' information on costs and benefits, then the scheme would be redundant. If the regulatory agency had full information, there would be no need to issue patents in the first instance: a first-best optimum could be achieved by rewarding firms with lump-sum payments and by making the invention freely available.

In view of the above comments, one might have expected that firms would not object to a scheme that could be easily manipulated to their own advantage. On the contrary, opposition to Article 14 is both intense and widespread. R&D executives agreed that the licensing scheme would be 'bad for the industry'. Nor was opposition confined to companies involved in biotechnological R&D – even a firm engaged in both biotechnology and

plant breeding deemed the scheme 'bad for all parties' and suggested that voluntary licenses should be introduced instead. This wholesale rejection of a potentially advantageous scheme is puzzling; however, one can advance some possible explanations. First, any research-based company may regard any investigation into its cost structure as an unwelcome intrusion, leading to the disclosure of commercially sensitive information, especially on the organization of research. Secondly, the scheme could be perceived to be open to abuse by the enforcing authorities. In the agency literature this is known as the 'hold-up problem': as the royalty rate has to be determined after the investment leading to the invention has been incurred, it would be optimal to set a zero royalty rate (making the invention freely available), because the firm would not be able to undo its investment. Thirdly, even discounting the possibility of this cynical behaviour by the enforcing agency, firms may fear that monopoly profits accrued in the period prior to the granting of licenses[7] could be taken by the courts as sufficient reward for their investment. Indirect support for this explanation is provided by the suggestion by many respondents that the monopoly period be extended as an alternative to the scrapping of Article 14.

c Practical provisions of the Directive: Judging from the responses by the companies surveyed, the biotechnology industry welcomes the practical provisions on the matter of deposit, access, and redeposit as detailed in Chapter 4 of the Directive, even though some respondents expressed the fear that the rules on access may be abused. The reversal of the burden of proof for biotechnological inventions was also generally welcome, except for a minority that felt this measure could be abused in order to prevent legitimate research by competitors.

3 Extending and changing the Directive: the industry's response to alternative scenarios

A large portion of the survey was devoted to eliciting the industry's response to a series of hypothetical changes to the Directive. The immediate reaction by most if not all respondents to the very idea of implementing often radical changes to the current patent system was one of wholesale rejection. However, in the course of extensive follow-up interviews a more varied and detailed pattern of responses eventually emerged.

[7] Paragraph 2 of Article 14 reads: 'A license [. . .] shall not be available prior to the expiration of three years from the date of the grant or four years from the date on which the application for a patent was filed, whichever period last expires'.

a Changing the patent term: As is well-known there is no economic rationale for a universal patent term, i.e., a single patent lifespan for all fields of human invention. Nor can a patent life of 20 years be justified in terms of a robust economic argument. Indeed a fixed 20-year patent term is an example of the 'tyranny of the status quo': although the current term may be regarded as nonoptimal, the costs of changing it outweigh the potential benefits.

However, in the case of patent protection for biotechnological inventions, it could be argued that there is scope for piecemeal intervention. As the biotechnology industry can be defined in fairly precise terms (i.e., the boundaries with contiguous industries are more clear-cut than is usually the case), in theory it should be possible to change the patent term just for biotechnology-related patents.

Two aspects of the replies on questions regarding a straightforward change of the lifespan of biotechnology patents are noteworthy. First, one might have expected that, if given the opportunity of having patent life changed with no offsetting changes in other dimensions of patents (e.g., scope, etc.), any profit-maximizing firm would choose a lengthening of patent life. Indeed, most respondents' preferred option was an extension to 30 years. However, some firms stated that no change was required. Secondly, none of the firms whose favourite options was an extension of patent life were able to quantify the benefits of the extension. Given the substantial nature of the change involved (a 50% increase in patent life), one might have expected that firms could compute at least the order of magnitude of the impact of a massive extension of patent life on profits and R&D budgets. Instead, firms were not able to quantify at all the benefits, stating that 'profits and R&D budgets would probably increase over time'. One possible explanation is that profits accruing in the distant future (i.e., from year 20 to year 30) are heavily discounted and therefore the impact of an extension of patent life is perceived as beneficial, but negligible.

b Changes to first-past-the-post patent system: the open registry scheme: The patent system discriminates sharply between firms engaged in R&D: the winner of the patent race obtains a prize in the form of temporary monopoly profits whereas all other participants obtain no reward and hence incur a loss (equal to their investment in R&D). In La Manna *et al.* (1989) it is shown that such discontinuous incentive scheme need not be optimal and that a more efficient allocation of resources can be attained by spreading more evenly the rewards from R&D. Firms surveyed were asked to consider the following scheme, that rewards 'fast losers' without attracting mere copyists. *The open-registry scheme:* Details of patent specifications are made public after a fixed term of, say, two years from the date of filing. For any given class of products/processes, patent applications within two years of the earliest application are considered

valid, irrespective of novelty. Under this scheme plagiarists are not allowed to copy inventions and genuine inventors have a higher chance of getting a return on the R&D investment, even if they do not manage to file first. The well-publicized case of Genentech vs. Wellcome[8] has shown rather dramatically the quasi-contemporaneous discovery of almost identical products is quite likely in fields such as biotechnology. The open-registry scheme highlights one of the crucial trade-offs in technology policy (a trade-off that the Directive appears not to have taken into account), namely the tension between providing incentives for firms to invest in R&D on the one hand, and encouraging the dissemination and utilization of new ideas on the other. It should be noted that if firms are risk neutral (risk averse), a switch to a multipatent scheme would reduce (increase) profitability.

Turning now to the response to the open-registry scheme, it is interesting to note that, in spite of the patent managers' in-built hostility towards any major change in patent rules (and the proposed *is* a radical change), firms were not unanimous in their opposition to the new regime. One of the predictions of the model referred to above is that small firms would be more likely to welcome the open-registry scheme, in so far as they are more likely to be more risk-averse than large, multiproduct corporations that can achieve a wider spread of risks. Quite revealingly, the one firm to report a likely increase in both profits and R&D budget in response to a switch to the open-registry scheme was a 'pure' biotechnology start-up company. Even the larger, multiproduct firms did not react uniformly to the proposed change: while some reported that profits would suffer from the change, even if accompanied by a lengthening of patent life, others were willing to accept the increased probability of a more competitive post-R&D market structure in exchange for a longer patent term.

c On the breadth of patents: It is only very recently that economists have turned their attention to dimensions of patents other than patent life.[9] One such dimension is patent breadth (also referred to as width, or coverage). How different should a product/process be in order not to infringe a similar patent? On this crucial aspect of the patent system there exist significant international differences, most notably the fact that the USA 'doctrine of equivalents' is not embodied in either European of Japanese patent laws.

[8] Using recombinant DNA technology, Genentech had discovered an artificial way to produce t-PA (human tissue plasminogen activator), a naturally occurring substance with the valuable property of being able to break down blood clots. By the early 1980s 'there were five principal research teams engaged upon research programmes the common objective of which was to produce t-PA using recombinant DNA techniques' (Thurston, 1989: 67). For comments on the legal and economic consequences of the judgment, see Thurston and Burnett-Hall (1988) and Thurston (1989).

[9] For a survey see La Manna (1992).

This issue is of paramount importance in biotechnology, as shown, for instance, in the alpha-interferon case in which the patent filed by Genentech differed from the gene developed by rival Biogen by 'a string of two dozen or so amino-acids, out of hundreds' (Sanger, 1984). Here, again, there is a trade-off between length and breadth of patents: the Patent Office has to choose between narrow but long patents or wide but short ones. The industry verdict on the desirability of extending the breadth of patents at the cost of a shortening of patent life is unanimous – all respondents deemed the short-life wide-breadth regime as injurious to profits.

In order to explain this remarkable uniformity of views, one has to consider the replies to a related question on the 'ideal' patent. When asked to design the profit-maximizing patent system, respondents did provide a more diversified response. Whereas all companies rejected the 'open registry' scheme and, predictably, none opted for a shortening of patent life, some regarded as best the current system, one firm selected a longer-patent wider-breadth as its preferred alternative, and the rest chose a straightforward lengthening of patent life, with breadth left unchanged. Incidentally, one senior patent executive confirmed the 'tyranny of the status quo' bias by commenting that 'any major change would cause too much uncertainty'. What set of assumptions would be consistent with the above set of responses? One (partial) explanation is that firms consider the current breadth of patents as wide (possibly as a result of the focusing devices provided by the informal scientific grapevine) and thus any shortening of patent life would be an uncompensated-for cost. Moreover, taking into account the substantial and apparently incompressible lag between award of patent and first commercialization, many companies take the view that the widening of breadth required to offset the already short term of patents would just not be feasible. However, resistance to change as well as a rather fuzzy understanding of the economic value of patents are also likely to account for the apparently nonprofit-maximizing behaviour of most respondents.

IV Conclusions

The article, based on a recent survey of UK biotechnology companies, highlights the complex interaction between the organization of R&D and patenting policy. Some of the more interesting findings include: the limited extent of private investment in biotechnological R&D; the existence of two markedly different research strategies (product- vs. process-based); the distinction between first- and second-generation patents and their effects on market structure. The core of the paper deals with the likely effects on patenting behaviour of changes in patent law – both as envisaged in the 1988 EC Directive and as suggested by recent theoretical research on the

economics of patents. The Directive in its current form has no discernible effect on the volume and organization of R&D, whereas the industry's response to a series of hypothetical changes indicates that any change in patentability standards has important repercussions on 1) the allocation of resources between research and development; 2) the conditions of entry into the industry; 3) the balance of bargaining power between firms of unequal size (or pursuing different research strategies); and ultimately 4) the allocation of technological surplus between producers and consumers. Finally, current economic theory cannot accommodate some of the patterns of behaviour highlighted in the survey, especially the phenomenon of the informal scientific grapevine and the aversion to wide-breadth but short-lived patents.

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