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# Patenting human genes: Reflections on the public debate

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**Abstract** The patentability of human genes has sparked a lively, and sometimes hostile, interest in a complex and evolving area of patent law. The debate has interesting characteristics, including an unusual mix of rational and essentially emotional arguments. Participants in it have aligned, and in some cases split, along unfamiliar lines; some examples of the treatment of the debate by the media are reviewed. The gene patent debate can be seen as part of a wider debate on the appropriateness of patents on compounds *per se* generally: if the pharmaceutical and bioscience industries wish to retain such protection, now is the time to lobby for their retention and to address the arguments put by those with opposing views.

**Keywords:** patent, law, genes, debate, public, media

## Introduction

The debate about the patentability of human genes has done something for patent law that no other issue has done within living memory, if ever: it has made it the subject of popular debate, and even discussion at the dinner party table. Much of the debate is spirited; some of it is hostile. The subject has become something of a lightning rod for those who have reservations about biotechnology and its role in society, about globalisation, about monopoly rights, about the influence of the private sector on public sector activities and various other of today's perceived ills. It has parallels with the debate about genetically modified foods, and it has given rise to a curious series of reactions from the media.

In this paper, I explore some of the facets of the debate, from my perspective as a participant in the debate through my chairmanship of the BioIndustry

Association's Intellectual Property Advisory Committee. I do not here seek to persuade anyone to any particular point of view; I aim to comment on the debate, not to further it, and to look at the direction in which it is heading. Such views as are incidentally put forward are my own, and not necessarily those of the BioIndustry Association or any other body.

In my exploration, I shall look at:

- the nature of the debate;
- its participants;
- the role of the media; and
- the context of the debate, and how it is evolving to encompass wider issues.

## The nature of the debate

One of the characteristics of the debate has been the shifting nature of the objections to the patentability of human genes. Partly this

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has stemmed from an increased awareness as the debate has progressed about what is meant by 'patenting human genes'. The BioIndustry Association (BIA) has always drawn a distinction<sup>1</sup> between genes in their natural surroundings in the human body (which are not patentable) and artificial DNA molecules containing human genetic information (which may be). By 'artificial DNA molecules' is meant non-natural molecules such as recombinant vectors in which at least partial copies of human genes are recombined with other sequences such as those that facilitate their manipulation or expression.

Another has been the mixture of visceral and rational objections that have been formulated. By their nature, the former tend to be broader than the latter. The most sweeping class of objections is that DNA is 'part of mankind's heritage', or some such formulation, and therefore should not be patentable almost on spiritual grounds (although religion is rarely invoked in the debate, except in the largely secular attack that scientists and patent attorneys are playing God). Such a point of view may come from those who may not be familiar with the limited nature of the monopoly that a patent confers. A common misconception is that a patent confers some kind of property right in the physical thing that is patented, whereas in reality it merely enables the patentee to prevent unauthorised commercial dealings in the invention.

A similar point of view can come from those who have a better idea about the nature of the legal right conferred by a patent, and may also realise how important, and therefore heavily used, patent protection is in an industry characterised by high costs of innovation and product development, as opposed to relatively low costs of imitation.<sup>2</sup> For those who are hostile to biotechnology generally, therefore, patents make an attractive focus for attention: hit the target and you hurt the industry.

Less sweeping and more pragmatic objections are either along the lines that the existing laws of patentability mean that

most genes are not patentable anyway (in which case, why legislate for non-patentability when the job is already done?) or that industry does not need patents on genes *per se* when patents on their uses are available. (But how available are they? And will all the objections go away if only uses remain patentable?) Alternatively, that a patent on a gene *per se* gives a reward to an inventor out of proportion to the contribution that he has made. Such objections are much more the stuff of rational debate.

This combination of the shifting nature of the debate and the mix of emotional and rational points has sometimes meant that answering the objections has been like trying to fight the Hydra: cut off one head and another two grow in its place. Truly a Herculean task.

It is my impression that the debate is raging strongest in Europe. This is not to say that others elsewhere in the world have not considered the issues, but rather that it seems to be more of hot topic in Europe than elsewhere. The EU Biotechnology Patent Directive<sup>3</sup> is a piece of legislation that specifically addresses the issue. One of the consequences of this being in large measure a European debate is that different countries with different industrial heritages tend to have different perspectives. And unlike in, say, the USA, the fact that business may support a particular position does not of itself carry much persuasion: Europeans have a more ambivalent attitude towards industry than North Americans.

This points to another facet of the debate. In many ways it has become part of a larger debate about the place of business and industry in society, and indeed about the nature and acceptance of the market economy itself. For a surprising number of people, 'profit' is something of a dirty word. More times than might be thought the debate raises questions of basic economic literacy, quite apart from those of science and law, which can be challenging enough on their own, given the rapid pace of change in the science and the complexities of the legal position.

## The participants

An analysis of the participants of the debate is interesting, not least because it shows some unusual alliances and some divisions along unexpected lines.

Chief among those on the 'pro' side is, not surprisingly, industry. The BioIndustry Association, the trade association for small and medium sized UK bioscience companies, has been in the lead of the debate in the UK. On the whole,<sup>4</sup> industry has been reasonably united in its views that:

- patents are important to the industry, and help ensure the transition from science to marketable products, particularly new treatments for disease;
- the patentability of genes should be treated no differently from the patentability of other invention;
- existing European patent law forms a reasonable basis for assessing patentability;
- not all genes are likely to be patentable, and under the normal operation of the existing law, fewer and fewer are patentable as time goes on.

Governments of countries without a strong 'green' movement but with strong bioscience industries have generally been supportive of this position. The UK Government is a prime example; and the EU Commission's motivation in proposing the EU Biotechnology Patent Directive seems to stem at least in part from a recognition that the bioscience has much to offer Europe in the new century.

Patients' groups, although a diverse constituency, have probably come more to be aligned with industry's position than against it.<sup>5</sup> Their primary interest lies, of course, in cures for their patients, and they are generally in favour of such means as they believe will be more likely to lead to them.

On the 'anti' side may be included those non-governmental groups and individuals who are generally not sympathetic, not to say antipathetic, to the industry on issues more general than gene patents. GeneWatch UK may be cited as an example.<sup>6</sup> Allied to

them, on this issue but probably not on many others, are various geneticists.<sup>7</sup> This alignment of scientists against the industry point of view has undoubtedly been a major point of interest in the debate, not least because it gives the anti-industry NGOs powerful, if temporary, allies.

And some governments and politicians are clearly anti-patents on genes. The Dutch challenge to the EU Biotechnology Patent Directive, which only recently was held unsuccessful,<sup>8</sup> reflects part of the unease of certain European governments in implementing the Directive, not least because of Article 5.2, which provides that isolated human genes may be patented (provided they fulfil the other requirements of patentability – Article 3.1). In the UK, the Fourth Report of the House of Lords Select Committee on Science and Technology, which dealt primarily with genetic databases, gave some consideration to patent issues. A conclusion of the Report was that patent rights to genes should '... continue to be granted only where a significant gene function has been established, and to ensure that the patent should cover only that function and direct extensions of it.' Of course, a patent that covers only a function of a gene is not a patent to the gene *per se*.

Finally, of course, the media have participated in the debate. Their role, at least as far as the broadcasters and the non-specialist press are concerned, has been so interesting as to merit deeper consideration.

## The role of the media

Broadcasters do seem to like an argument. People vociferously disagreeing with each other on camera makes 'good television', we are told. The fact that the protagonists may be talking past each other, rather than synthesising some larger truth from thesis and antithesis, does not seem to matter, and may be deemed (by the broadcasters) a good thing. When I was in the green room before the recording of a debate for BBC Television's *Heart of the Matter* programme, a production assistant came round each of us in turn to check that our positions were not

likely to change from those gleaned from the initial interviews. Good television or not, a truly valuable debate is surely one in which each can learn from the other's position and end up with a better, more informed, more thoughtful, even – heaven forfend – *changed* position. But the very set up of television debates does not, in my experience, encourage such a constructive outcome.

Journalists working in print operate in very different environments. With some exceptions, many national newspapers in the UK have well-defined constituencies, and they tend to write for their readership. To see how this works in practice, it is instructive to look at the supplement on gene patenting published by the *Guardian* on 15th November, 2000.

'Debate', thundered the accompanying leading article, 'is exactly what this issue needs.' So, did the supplement genuinely debate the issue? The title of the supplement, 'Patenting life', did not auger well, by being both emotionally charged and technically incorrect. Secondly, on a personal note, in my capacity as Chairman of the BIA's IP Advisory Committee I was interviewed at some length by a *Guardian* reporter as part of his preparation for the supplement. However, no word of my interview appeared in the supplement; in fact nothing putting forward the view of the BIA, the trade body in the UK for the bioscience industry, was to be found in the supplement.

Thirdly, where debate was reported, it was sometimes swamped by a careful use of out-take. For example, the article 'Agribusiness sows its seeds down on the pharm' on page 19 of the supplement recited the following concern:

Increasingly, what concerns critics of the ag-bio industry is the growing concentration of ownership in the hands of a relatively small number of major companies.

And that concern was addressed later in the article:

Not so, claims Professor John Hillman, of the Scottish Crop Research Institute, who claims that the big companies are relatively small players in the global seed supply and points

out that 'About 70% of the world seed trade is in the public sector. The other 30% is controlled by 10 multi-nationals and hundreds of niche players.'

Even allowing for the double helping of the pejorative verb 'claims', which invites disbelief on the part of the reader, the critics' point seems to have been totally disposed of. Yet what were the largest words in the article? The eye-catching out-take that reads: 'What concerns critics of ag-bio is ownership by the few.'

Small wonder that the supplement was described by Professor Lewis Wolpert, who is no supporter of patents on genes, as 'genetic pornography';<sup>9</sup> pornography is intended to titillate rather than inform.

What sort of debate did the supplement stir up in the *Guardian's* letters column? There were letters printed in support of the supplement's position. And the other side of the debate? For some reason, a letter submitted by the Chief Executive of the BIA was not selected for publication. A follow-up call to the *Guardian's* letters desk elicited the response that the issue had rather 'gone off the radar screen'.

Yet, in the curious way the UK press works, there was some form of response. It was not from the *Guardian* but from other newspapers. By a truly remarkable coincidence, the *Independent*, which competes with the *Guardian* in the politically left-of-centre broadsheet market, chose the very same day to publish an editorial on the patenting of human genes. Its conclusion – somewhat reluctantly but nevertheless clearly arrived at – was that: 'Patenting genes could be the best way to help us all.' A week later, the *Daily Express*, a popular press tabloid that has been drifting from right to left over recent years, published a similar pro-patents on genes comment: 'So perhaps reluctantly, and with great control, we must let the would-be gene patenters have their way.'

### The wider context of the debate

The debate on gene patenting has fed into a somewhat larger but closely related debate:

the appropriateness of patents on chemical compounds *per se*. This has arisen in part because industry has pointed out that patents on replicas of human genes, or part of them, are in principle no different from patents on replicas of small organic chemical molecules that exist in nature.<sup>1</sup> The response to that in some quarters has been along the lines that that, too, is wrong, on the grounds that patents on compounds *per se*, which may be granted on the basis of a single established utility (providing that the remaining criteria of patentability are also met), reward inventors with a monopoly disproportionate to the contribution made by them by way of their invention.

I have argued elsewhere that there would be an even greater mismatch between monopoly conferred and contribution made if patent protection were not available to compounds (specifically, those containing human genetic information) but was instead limited only to the use of the compound;<sup>10</sup> others have taken a contrary view.<sup>11</sup> But leaving that point aside, what is interesting to note for present purposes is the other factors that have been feeding into this wider debate.

One is the anti-globalisation campaign that has emerged over recent years. It has its extremist elements, as witnessed by the Seattle World Trade Organization (WTO) riots in November 1999 and the demonstrations in London on 1st May, 2001. However, as with many such movements it has more moderate supporters. A briskly selling paperback at a popular bookshop at Heathrow Airport (hardly a hotbed of anarchists) over the summer was 'Anti-Capitalism – A Guide to the Movement'.<sup>12</sup> In it is a closely reasoned critical article on pharmaceuticals patents. It was written by a policy advisor at Oxfam. Oxfam and other charities have also been active in the campaigns in South Africa and elsewhere to reduce patent protection for pharmaceuticals.<sup>13</sup>

And in a deeply ironic twist to this wider debate on patents on pharmaceuticals, legislators in the USA, that foremost champion of the rights of patentees, threatened to strip the German company

Bayer of its patent on ciprofloxacin (CIPROXIN<sup>®</sup> / CIPRO<sup>®</sup>) in the wake of the anthrax mailings in the USA in late 2001.<sup>14</sup> This action has of course lent considerable weight to those campaigning for WTO rules (WTO Agreement on Trade-related Aspects of Intellectual Property Rights, TRIPS) to allow countries greater flexibility in how they treat patents in the face of public health issues.

So the issue of the patenting of genes has been one of the factors that has opened up this broader question of the appropriateness of being granted and enforcing patents on compounds *per se* generally. The pharmaceutical industry has long relied heavily on such patents; if it wants to retain them, now is the time to begin lobbying against a threat driven by opposition on several fronts.

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#### References and notes

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2. There are inventions that can enjoy some form of 'protection' by being kept secret. However, this is not a viable option for inventions that are either certain or likely to be made public. In the genomics industry, it may be possible to keep secret annotated value-added sequences, or to rely on non-monopoly rights such as copyright and database rights to afford them some protection. In many cases in the biosciences, however, the monopoly protection afforded by a patent may be the only way of justifying, or attracting, the investment necessary for product development.
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