

Gene Patenting

The Issue

GSK invests heavily in research, including genomic and genetic research, that may lead to the discovery of new medicines and vaccines, and new methods of disease detection, prevention and treatment. Such investment would not occur, without a system allowing strong protection of inventions arising from this investment. The current patent system provides unrestricted protection by allowing patents to be obtained for all novel compositions of matter without discrimination, including gene sequences. The principle of patenting genes and DNA, and the scope of these patents when granted, is the subject of public debate, both in a legal and ethical arena. This paper outlines GSK's approach to patenting genes and articulates GSK's position on the issues being debated.

GSK's Position

- Genes, as they exist in living organisms, are not patentable whereas isolated sequences of DNA which exist outside living organisms can be patented provided they fulfil certain criteria. The criteria for patentability include novelty, non-obviousness/inventive step and utility/industrial application. GSK supports strengthening the guidelines on 'industrial application' to be consistent with the now higher standards of 'utility' in the US.
- The rights conferred by a patent are not "ownership" rights in the patented material, but rather a right to exclude others from undertaking certain acts with the invention; these typically include manufacture, sale and use.
- GSK believes that the practice of issuing patents in the field of genetics promotes research into this area; mandatory early publication of patent applications (irrespective of whether or not patents are ultimately granted) provides a stimulus for scientific and technological advancements that would not occur without such publication. Without the possibility of obtaining patent protection, it is far more likely that companies would keep inventions as trade secrets.
- GSK licenses its patents on favourable terms to academia and believes that patents on research tools should be exploited for the public good.
- GSK supports the existence of a research exemption in Europe and would support the introduction of a similar exemption from infringement into US patents law.
- GSK believes that the patent system as it currently stands works well and does not support any significant changes to it. In particular, GSK does not support the concept that patents on gene sequences should be restricted to the use outlines in the patent application.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

- GSK fully supports the European Directive on the Legal Protection of Biotechnological Inventions (98/44/EC) and we look forward to its rapid implementation across the European Union
- GSK respects and follows applicable laws and regulations regarding patenting and respects the patents held by other entities.
- GSK recognises that patenting isolated DNA sequences may raise a number of concerns and we are committed to discussing these in an open and constructive way with key stakeholders.

BACKGROUND

Terminology

Gene patenting is a commonly used but misleading term, as genes exist in living organisms and, by definition, are not patentable. An isolated DNA sequence which exists outside the body is, like any other chemical, patentable provided the usual conditions for patentability are met.

The Importance of Patents

Patents enable individuals, companies or institutions to protect their invention for a limited period of time (usually 20 years from the date of the patent application). During this period, others cannot manufacture, sell or use the invention without the agreement of the patent holder however in Europe the invention can be used without infringement in research aimed at further understanding the invention or how it works, or at developing improvements or new uses of the invention. The rights conferred by a patent are not ownership rights in the patented material, but rather a right to exclude others from undertaking certain acts with the invention. Patents therefore provide a time-limited reward for successful innovation and provide the holders with an opportunity to make a return on the investments which they made to come up with the invention.

Patenting Criteria

The criteria for patentability include novelty, inventive step ('non-obviousness' in the US) and industrial application ('utility' in the US). In Europe, there is an additional criterion in that the invention must not be contrary to public morality or 'ordre publique'. If something (or a method of making or using it) fulfils these criteria, then it should be patentable. Patent Offices and Courts around the world apply these same basic rules regardless of the subject matter involved.

As science and technology advances so the baseline from which inventive step is measured rises. As a consequence a ground-breaking innovation that was patentable 10 years ago with a broad claim may not be patentable today (it may be considered obvious today, because the state of the art has moved on) or may be patentable with restricted claims. The vast majority of human genes are now in the public domain and thus in themselves are now unlikely to be patentable.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

GSK and gene patenting

GSK's intellectual property (IP) strategy is aligned with its research strategies. GSK actively seeks patent protection for inventions where the resulting intellectual property is of discernible value to the company, whether these arise from our genomics, genetics or other pharmaceutical activities.

GSK regularly reviews its patent portfolio to ensure that it provides cost-effective protection for our commercial interests. As a consequence of a recent review, GSK has abandoned more than 50% of its human DNA patent applications in Europe.

GSK was an active member of the SNP (single nucleotide polymorphism) Consortium, a collaboration between industry and the UK's Wellcome Trust, contracting with academic institutions to identify and map SNPs. The information arising from the collaboration is a valuable research tool and has been placed in the public domain without IP restrictions. GSK believes that the value of SNPs lies not so much in their identification but in their association with diseases or patient response to medicines.

The Patent System and Innovation

Some have suggested that the granting of many DNA patents may stifle research in the area of genetics. GSK believes that this risk has been over-estimated. The common practice of mandatory early publication of patent applications (irrespective of whether or not patents are ultimately granted) provides a stimulus for scientific advancement that would not occur, or at least not so effectively, without such publication. Researchers around the world recognise published patent applications and patents as a valuable source of technical information, which provides a basis for further discoveries and inventions. Without patent protection this information would not be readily available to others and research would likely be conducted, if conducted at all, under great secrecy.

The opportunity to obtain patents on isolated DNA sequences (and the obligatory need for publication in at least Europe and Japan) stimulates, rather than impedes, research. Moreover, it is important to distinguish granted patents from the far greater number of published, unexamined patent *applications*, many of which are unlikely to result in granted patents. There are relatively few DNA patents that have been granted and often those that have been granted (mostly in the US) have claims that are significantly limited compared with the claims as filed with the original application. Many published patent applications have been withdrawn or abandoned by the applicant or rejected by Patent Offices. Furthermore, even if a patent is granted, it is still possible to challenge its validity or enforceability, or negotiate a licence under the patent.

In relation to GSK's DNA-related patents, we generally allow third parties, such as academic institutions, to obtain licenses on favourable terms.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

Additionally, in Europe, patent law provides for an "experimental use" exception from infringement. This allows both academic and commercial institutions to undertake further research on patented subject matter without infringement. Such research may itself lead to an invention, for which third parties are free to obtain their own patent protection. Patents of this kind are commonly referred to as "dependent patents" since they cannot be commercially exploited without a licence from the holder of the original patent. In addition, the holder of the original patent cannot commercially exploit the improvement or the new use without a licence from the holder of the dependent patent. This situation, which tends to stimulate cross-licensing, is inherent in the patent system.

European Directive on the Legal Protection of Biological Inventions

GSK fully supports the European Directive on the Legal Protection of Biotechnological Inventions (98/44/EC). Without the legal clarification afforded by the Directive, future investment in biotechnology in the UK and Europe could be seriously jeopardised. However, it is important to remember that the Directive is purely a harmonisation instrument; it does not break any new ground regarding what can be patented in Europe. To date many, but not all, Member States have implemented the Directive; GSK looks forward to its full implementation across the European Union.

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