
Patent issues related to influenza viruses and their genes

Report by the Director-General

1. Resolution WHA60.28, “Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits”, requested the Director-General “to commission an expert report on the patent issues related to influenza viruses and their genes”. Accordingly, a report was commissioned from WIPO in the form of a technical and factual review. The present report summarizes the main findings of that report.

THE GENERAL CHARACTERISTICS OF PATENT LAW

2. The legal rights afforded by a patent are based on patent laws that are purely national in scope (some regional systems do provide for regional patents with effect under national laws). Patents do not have extraterritorial effect, so that in general a patent granted in one country has no direct legal effect elsewhere. In the case of a technology, patents do not give a positive right to its use; they only entitle the patent holder to take action to prevent third parties from using it. These entitlements are not absolute, and exceptions and limitations are provided for various public policy reasons. There has been a special focus on such exceptions and limitations in the field of public health, given concerns about access to medicines, freedom of research, and the need to prepare for regulatory approval of medicines.

THE PATENT COOPERATION TREATY

3. Generally speaking, when patent protection is sought in a certain country, a distinct application must be filed and the patent granted in that country (or within a relevant regional system, such as that administered by the European Patent Office). There is, therefore, no such thing as an international patent as such, and each national system is unique for the patents that have force in that country. One important international arrangement is the Patent Cooperation Treaty, a WIPO-administered system which provides a uniform procedure for filing an international application for protection in a Contracting State or States to the Treaty. This system keeps open the possibility of subsequently securing a national or regional patent in the States that have adhered to the Treaty. A distinct step must be taken, however, within a specific time to request specific action within the relevant national or regional system before the application can mature into an enforceable patent. The Treaty provides one means of monitoring global patenting activity, but, as not all relevant patent applications are filed through the Patent Cooperation Treaty system, its coverage is necessarily only partial. Historically,

most patent applications have been filed in a relatively small number of countries, and most patents have not been protected in the majority of developing countries, leaving the invention in principle free for use in those countries. This historic trend is rapidly evolving, however, as patent systems in some developing countries experience sharp increases in the range and quantity of activity.

VIRUSES AND GENES AS PATENTABLE SUBJECT MATTER

4. National patent laws lay down specific criteria for inventions to be considered eligible for patent protection, or for “patentability”. The standard requirements generally include novelty, inventiveness or non-obviousness, and utility or industrial applicability, as well as adequacy of disclosure of the invention. How these criteria are applied in practice varies considerably between different countries. However, the naturally occurring influenza virus in its original state is unlikely to be considered in itself to be fit subject matter for patents in any jurisdiction, either because a claim relating to a wild virus as such would fail to satisfy basic patent law requirements for a true invention (it would typically be considered a mere discovery of naturally occurring biological material), or because of specific legal exclusions for this subject matter under national patent laws. The situation is more complex when it comes to patents that in some way claim genes isolated, extracted or derived from viruses and related genetic information, or that claim potentially new uses or applications of genes or genetic information. Again, national practice varies considerably, and only the broadest trends can be sketched out in a brief study.

TRENDS IN PATENTABILITY OF GENE SEQUENCES

Genes as patentable subject matter

5. In some countries laws specifically provide that isolated genetic material, such as gene sequences, may be considered patentable inventions (as long as they meet the other criteria for the granting of a patent) even if corresponding genes occur in nature. This situation typically arises when it is considered that the isolated gene or genetic material may serve a distinct useful purpose. In some legislations, however, bare genes are ruled out as patentable subject matter.

Non-obviousness

6. Considerable debate continues on the subject of gene patenting, but some countries are moving towards the view that the simple act of identifying gene sequences and cloning them through regular techniques is not inventive and therefore not patentable. This trend responds in part to rapid advances in gene technology which have greatly simplified and made routine much of the process of sequencing and cloning gene sequences.

Utility or industrial applicability

7. National patenting practices also differ considerably on this point, but the trend is towards denying patent protection for bare gene sequences as such, in the absence of any clearly disclosed and defined new function associated with the gene sequence.

STATISTICS ON PATENTING

8. An initial patent survey on the extent of patent activity specifically related to influenza viruses and their genes has recently been completed, pending a broader analysis of the patent situation. Initial results show an acceleration of patenting activity broadly related to H5N1 and other avian subtypes of influenza viruses and their genes. Indeed, nearly 85% of all international applications in the Patent Cooperation Treaty system referring to avian influenza or H5N1 viruses have been published by WIPO's International Bureau since 2000, and more than 30% of all published international applications referring to the virus were published in the first eight months of 2007 alone. No firm conclusion can be drawn from this crude general measure. However, this undoubted rapid upturn in patenting activity epitomizes both the promise and the challenges of the patent system – it reveals the growth in applied research and investment of resources in this public health concern – but it points to a complex field of potential patent rights that are difficult to analyse particularly with regard to assessing the substantive reach of the patent (the freedom to operate).

PATENTING ACTIVITY RELATING TO THE H5N1 SUBTYPE

9. The initial survey also showed that patenting activity related to the H5N1 subtype of Influenzavirus A recently increased rapidly, especially in the context of vaccines, diagnosis and treatment. This increase results from the involvement of increasingly numerous and diverse parties, in the public and private sectors. The subject matter of patents and patent applications covers recombinant gene sequences, other extracts from and derivatives of the viral genome, new genetic constructs making use of such material, and broader technologies for the production of vaccines and treatments that in some way make use of genetic material (without claiming it directly as an invention).

10. Few patents or patent applications claim H5N1 genetic material as such, although some cases exist and require closer examination, since, if granted, patents on this material could conceivably constrain the use of that genetic material in products that would need to use it. Many more patents or patent applications cover specific uses of the genetic material in the context of diagnosis, vaccines and treatment, but even if granted would not legitimately constrain parallel development of alternative uses of the same genetic material.

11. By way of example, many existing vaccine-production methods of various kinds and steps in the preparation of vaccines are not covered by patents. Moreover, those patented in some countries are not patented in many others, leaving the technology legally free to be used. Much recent patenting activity covers emerging technologies that are as yet unproven for mainstream production (and are not approved by regulators), but may be of benefit in the future.

PUBLICATION OF GENE SEQUENCES

12. The early, open publication of a gene sequence of a newly-isolated strain of influenza virus would, in itself, preclude obtaining patent protection for those genes in the form as published. At the same time, it would facilitate research and development on the broadest possible base, but would also mean a loss of the ability to control or influence future use of the sequence data, for instance in research on diagnostics, vaccines and treatments, because the sequence data would unambiguously reside in the public domain, free for all to use.

USING DISCLOSURE FOR GREATER TRANSPARENCY

13. The results of the initial survey of existing patent applications show that applicants already disclose the strains of viruses used in developing or implementing the claimed invention. Standard terminology and nomenclature for virus isolates and their gene sequences are used. Existing patent search technologies allow identification of such patent applications on publication and monitoring of new applications well before they proceed to examination or a patent being granted.

ISSUES RELATING TO BREADTH OF PATENTS

14. At least as important as obtaining a factual overview of patents that are relevant to influenza virus and its genes is understanding the breadth of such patents – in particular, the implications of patents on research technologies or seed virus preparation that would be necessary to be used for the production of vaccines.

REGULATORY EXCEPTIONS

15. “Regulatory use exceptions” to patent rights in a number of national legal systems may apply directly in pandemic influenza preparedness. In essence, such provisions let third parties take steps reasonably related to securing regulatory approval for products (such as making generic copies of vaccines or influenza treatments), including pilot production runs if this is required for regulatory approval, even while a patent remains in force, provided the preparations are limited to securing advance regulatory approval and do not amount to commercial-scale production for regular distribution.

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