Patent pools as a solution to the licensing problems of diagnostic genetics

*United States and European perspectives*

Advances in diagnostic genetic testing have resulted in the ability to diagnose an increasing number of genetic diseases through the use of multiple genes and/or gene fragments oftentimes displayed on microarrays. The field of drug discovery has also benefited from the use of microarrays containing multiple genes, antibodies, antigens or whole cells, in order to evaluate drug responses, side effects on metabolism and pharmacogenomic profiles. These advances have been accompanied by an increasing number of patents covering not only the genes and their fragments but also new diagnostic or research methods and microarrays.

Some commentators have predicted that this increase in patents pertaining to diagnostic/evaluative genetic testing has and will continue to prevent clinicians and researchers from developing and using these tests to benefit patients and further drug discovery. Potential road blocks to the widespread use of genetic testing technologies are said to result from (1) patentees exercising their right to exclude the use of their patented technology by anyone other than themselves or their exclusive licensee (‘exclusivity’) and (2) the need by potential users of genetic testing technology to acquire multiple licences to an ever increasing number of patents owned by different patentees (‘stacking’). The problems of licence exclusivity and patent stacking appear particularly acute in the area of multiplex arrays.

Several solutions have been proposed to address the concerns arising out of patenting of diagnostic genetic testing technology. For example, in the US it has been proposed that the United States Patent and Trademark Office (USPTO) apply the existing statutory requirements for patentability more stringently to the field of genomics, or that the Court of Appeals for the Federal Circuit, the most specialised patent court in the US, should apply its non-obviousness standards as stringently to human gene patents as it does to other advancing fields of technology. Other proposed solutions include compulsory licensing or legislative exemptions for diagnostic testing.

We propose in this paper that the use of ‘patent pools’ may overcome the negative consequences of ‘exclusivity’ and ‘stacking’ in the field of diagnostic genetics as well as its applications in drug discovery. After providing some common definitions, we will analyse patent pools from both the US as well as the European perspectives and will conclude by looking at the legal and practical requirements for patent pools in both regions of the world, concluding that they are very similar.
**Patent pools**

A patent pool is an arrangement in which “two or more patent owners agree to license certain of their patents to one another and/or third parties”7. Critical to the structuring and implementing of patent pools are the definitions of complementary, competing, blocking and essential patents. Complementary patents are for “technologies that may be used together, and are not substitutes for each other”8. Two different patents, each on a different Single Nucleotide Polymorphism (SNP) for the same disease would be complementary. Competing (also known as substitute) patents cover technologies that substitute for each other9. A patent on a SNP and another one on an antibody might be competing technologies to diagnose the same disease. A blocking patent “block[s] another if [the latter] can not be practised without infringing on the basic patent”10. A patent on an isolated gene and all its fragments might be blocking to all genetic testing for a disease. Essential patents have been defined as ones having “no technical alternative”, and are useful “only in conjunction with other pooled patents”11. An example would be a patent on the critical SNP or the gene correlated to a disease. The distinction between complementary and competing technologies is not always crystal clear, since technologies may be partly competing and partly complementary.

The electronics industry is quite familiar with the concept of patent pools, through its standard-setting bodies for the manufacture and sale of, for example, DVDs12 and MPEGs13. Standard-setting has been an integral element of each of these two and other electronics patent pools. The lack of industry standard setting bodies in the genetic diagnostic field (and in biotechnology in general) has led to questions as to whether pro-competitive patent pools can be developed for the industry. We believe structuring and implementing diagnostics patent pools may be facilitated by institutions such as the American College of Medical Genetics (ACMG) which are considering and issuing consensus statements detailing the genes and/or fragments deemed necessary to adequately predict or diagnose a genetic condition14. For example, in 2001, the ACMG set the criteria for, and selected a standard panel of, mutations which are recommended for screening cystic fibrosis carriers15. Standard panels for the genetic testing of many other diseases could, and most likely will, be set by the scientific community and medical organisations within the next few years.

**European Union perspectives on patent pools**

On May 1, 2004 the Technology Transfer Block Exemption Regulation (TTBER) entered into force in the European Union16. The TTBER provides a safe harbour for agreements that, in principle, fall under the prohibition of Article 81(1) of the EC Treaty17. Such safe harbour exists for agreements that, while restricting or distorting competition within the common market, would be allowable because they promote technical or economic progress. The TTBER does not cover patent pools, but the individual licences granted by the pool to third party licensees may benefit from the TTBER safe harbour when the conditions set out in the TTBER are fulfilled.

The European Commission has addressed patent pools in its Guidelines on the application of Article 81 (Article 81 Guidelines) to technology transfer agreements that may or may not fall under the scope of the TTBER18. The Commission states that patent pools can produce pro-competitive effects, in particular by reducing transaction costs and by setting a limit on cumulative royalties to avoid double marginalisation19. ‘One-stop licensing’ of the technologies in the pool is particularly important in the Commission’s view in sectors where intellectual property rights are prevalent and where, in order to operate in the market, licences need to be obtained from a significant number of licensors20. This is certainly the case in diagnostic testing.

In the Commission’s view, the competitive risks and the efficiency-enhancing potential of patent pools depend to a large extent on the relationship between the pooled technologies and their relationship with technologies outside the pool. The Commission states that, when due to efficiencies stemming from the integration of two technologies, licensees are likely to demand both technologies, the technologies are treated as complements even if they are partly substitutable21. A patent pool composed solely or predominantly of substitutive technology amounts to a price fixing cartel22 and therefore is not allowed under Article 81 EC.

The creation of a patent pool that is composed only of technologies that are essential, and, therefore, by necessity also complementary, is generally allowed under Article 81 EC. The inclusion of non-essential patents in a pool, however, may give rise to competition concern. The Commission finds that the inclusion of non-essential patents in a pool may cause a risk of foreclosure of third party technologies23. Also, the inclusion of non-essential

**References**


9 Id.

10 Id.


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15 Id.


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15 Id.


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If there are multiple patented fragments or SNPs which cover different segments of a gene involved in a particular polymutational disease (i.e., a disease that is correlated to more than one mutation or more than one gene), and only a small number have some degree of diagnostic value, then these would be considered essential for the patent pool. A pool for the diagnostic genetics of such disease should only contain these patented fragments or SNPs. The patents will be essential if they are chosen so that they cover or ‘read on’ the standard panel of mutations or genes (or other biological materials, such as antibodies or antigens) recommended by a consensus setting body such as the ACMG, or similar medical organisation.

2. Any blocking positions should be included. If, for example, a company were to have a dominating patent on a purified gene involved in breast cancer, including all fragments that hybridise to it, it would be critical to include that patent in the pool so that any problems caused by blocking later patents on valuable SNPs can be eliminated. If the blocking patent is not included, the pool may not cover the essential patents and may be anti-competitive.

3. No aggregation of competing patents and setting a single price for them. Consider diagnostically useful genes or gene fragments X1a and X1b which cover a similar area of genetic material and which are owned by different patentees. Allowing both patents into the pool could run the risk of the two patentees colluding on the price for the licence. This type of situation is less likely to happen in the application of a patent pool to diagnostic genetics of a polymutational disease because there should not be two patents on the same area of genetic material; if there were multiple ones, only one should be selected.

4. Only valid and unexpired patents in the patent pool. There ought to be a mechanism to vet patents of dubious validity. It is relatively easy to mandate that if a member’s only patent expires or is invalidated by a third party, it is necessary for that member to replace the invalid or expired patent with a new patent which meets the patent pool criteria in order to remain as a member of the pool. However, absent an invalidation event, the pool participants might agree that if prior art or argumentation not previously considered by the US or European Patent Offices is brought to one the members’ attention, the pool has the responsibility of either obtaining an opinion of counsel that the patent remains valid and enforceable, or, in the US, request re-examination of the patent before the USPTO, or both.

5. An independent expert(s) is required. We recommend the formation of an independent committee of experts consisting primarily of representatives from commercial and clinical institutions, as well as attorneys who are experts in biotechnology patent law and antitrust law. The committee’s tasks will include selecting the patented genes, fragments or SNPs considered complementary, essential and/or blocking to the patent pool. The committee may treat recommendations issued from a consensus-setting body such as the ACMG as establishing a ‘standard’ to be implemented in deciding which patents are essential, and complementary but not substitutive.

What terms, including pricing, should a diagnostic pool offer?

6. The pool should promote the dissemination of technology. A patent pool should not restrict innovation. Several ways to accomplish this are: 1) licences offered to the patent pool by its members should be non-exclusive so that individual members may still offer outside individuals a separate licence to their essential patents43. This will, in effect, help prevent the anti-competitive effects of ‘tying’ or requiring multiple licences to be taken when only one is desired; 2) assure non-discriminatory pool licensing on the same terms and conditions to all would-be licensees44; and 3) allow for receipt by the pool of a narrow grant-back clause from the licensees45. Under such a grant-back clause the licensor agrees to offer back to the patent pool a non-exclusive licence to any of its own essential improvement patents at a fair and reasonable royalty46. A successful grant-back clause will be narrowly drafted so that it only encompasses those essential future patents of the licensor that are commensurate with the technology of the patent pool licence47. This agreement prevents the licensor from extracting the benefits of the patent pool while holding out its own essential patents48.

7. Do not disadvantage competitors’ downstream markets that use the pooled technologies as inputs. The US DOJ approved the MPEG and DVD patent pools partly because each proposed pool had limitations to prevent foreclosure of competition in the downstream market49. These pools had a “reasonable” royalty which was a “tiny fraction” of downstream product prices or “small relative to the total costs of manufacture”50. The determination of how...
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43 See supra, n. 8, at 48-50.

48 Id. 49 Id. 50 Id. 51 Id. 52 Id. 53 See n. 13, supra.


59 See supra, n. 8, at 48-50.

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“small” or “reasonable” a royalty is has been inconsistent because of the lack of standard royalty rates and multiple interpretations of “reasonable”51. It has been suggested that a percentage cap should be implemented for pools so that the royalties do not grow to be excessive over time. This is so because even though a royalty may have been “small” or “reasonable” at the beginning, the cost of producing the downstream product decreases with time52.

8. Pool members must be prohibited from colluding on prices outside the scope of the patent pool licence. A patent pool on diagnostic genetics should discourage collusion among the licensors or licensees in any market53. In the MPEG-2 patent pool the US DOJ noted approvingly that confidentiality provisions existed which prohibited the patent pool licensors and licensees from exchanging competitively sensitive information54. Also, the DOJ acknowledged that because the royalty rates were to be reasonable, it was unlikely that they could be used to facilitate collusion of prices for downstream products55.

Conclusions

Based on the US DOJ Guidelines/Business Review letters, as well as the Article 81 European Guidelines, we suggest that patent pools for diagnostic genetics can be formed without running afoul of anticompetition laws in either region of the world.

One obstacle to forming any patent pool will always be to find incentives for the critical patent holders to provide their patents to the patent pool instead of going at it alone56. The biggest incentive for the holders of essential patents especially blocking ones to join with other essential patent holders rather than going at it alone, will occur once consensus-setting bodies like ACMG greatly expand the diseases for which it makes recommendations and sets standards. If a well established and respected entity such as ACMG deems it important enough to issue a consensus statement regarding a handful of mutations necessary to adequately predict a disease or condition, then the relevant patent holders will recognise how crucial it is that all of these mutations be tested simultaneously, and offer assistance by agreeing to participate in a patent pool. Going at it alone will become the less favoured mode of doing business. Other incentives include a fair distribution of income generated from the pool57 and the ability for members to operate freely among the pooled patents58.

Pools crafted in this manner may well resolve potential roadblocks to the widespread use of the new genetic testing technologies. As a result, the financial and social value of patent pools will become apparent to the diagnostic industry and to other industries that utilise diagnostic or evaluative tests, such as for example the use of microarrays in drug development. The new genetic and evaluative testing technologies will then be more broadly available to all.

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