How IPRs, like Nature, Abhor a Vacuum, and What Can Happen When They Fill it - Lacunae and Overlaps in Intellectual Property

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From time to time some activities which many believe are already or should be, protected by intellectual property, prove in fact not readily to be the subject of any particular IPR. In contrast a particular activity may sometimes be the subject of multiple overlapping IPRs. The former situation can produce responses such as attempts to stretch existing IPRs beyond what might be thought to be their natural limits, or suggestions for the introduction of new IPRs. The latter situation can involve attempts to draw boundaries as between IPRs to minimise overlap between them. This paper examines various examples of such situations, including those of computer programs and pharmaceuticals, and considers what one can learn from them.

Keywords: Intellectual property, IPR, copyright, design, patent, computer program, pharmaceuticals, confidential information, regulatory data protection

An intelligent observer knowing little or nothing about intellectual property but looking at the TRIPS Agreement might well be excused for believing that Sections 1 through 7 of Part II of it, devoted as they each are to different types of intellectual property right (IPR), reflect some coherent, policy-based differentiation as between such rights. But members of the intellectual property community know that matters are not so simple. These rights have differing historical origins and there are differing justifications offered for their existence.

From time to time some activities which many believe are already, or should be, protected by intellectual property, prove in fact not readily to be the subject of any particular IPR. In contrast, a particular activity may sometimes be the subject of multiple overlapping IPRs. The former situation can produce responses such as attempts to stretch existing IPRs beyond what might be thought to be their natural limits, or suggestions for the introduction of new IPRs. The latter situation can involve attempts to draw boundaries as between IPRs to minimise overlap between them. This paper examines various examples of such situations and considers what can be learnt from them.

Designs and their Interface with Copyright

Designs have for long presented interface problems for intellectual property law, overlapping as they can with copyright (insofar as they may well themselves be, or where three dimensional, may also be versions of drawings which may themselves be, copyright works) and with patents (inssofar as they have functional aspects). The longstanding difficulty with designs, and even with the very rationale for having a protection regime for designs that is separate to that of patents and copyright (or for that matter unfair competition) is evidenced by manner of their treatment in the Paris Convention, which until its Lisbon revision of 1958, did not even require that they be protected. Even then Article 5 quinquies of the Paris Convention, introduced at that revision, simply mandates the protection of industrial designs without either saying what they are, or how they are to be protected. Even then Article 5 quinquies of the Paris Convention, introduced at that revision, simply mandates the protection of industrial designs without either saying what they are, or how they are to be protected. Articles 25 and 26 of the TRIPS Agreement go a little further and add some specifics, but only a few.

The UK provides a good example of the problems of the interface as between designs and copyright. The most recent manifestation of this is Sections 51 and 52 of the Copyright Designs and Patents Act 1988, which between them had the practical effect of excluding cumulative protection as between these respective IPRs to the fullest extent permitted by the Berne Convention. Section 51 was a reaction to the previous UK legal framework that had permitted cumulation (albeit accidentally rather than in response to a conscious policy choice) between copyright and designs. This however had resulted in what was
perceived to be the undesirable consequence of conferring copyright protection indirectly on wholly functional designs that themselves lacked copyright protection because they were neither sculptures or applied art but which were copied directly from engineering drawings which did benefit from copyright. The USA has also faced interface issues between copyright and designs and so in Mazer v Stein, the Supreme Court held that the registrability as a ‘design patent’ of a statuette used as a lamp base did not bar copyright subsisting in it as a work of art.

However, the long and unresolved international history of such problems with designs suggests two things: firstly that such problems may not in fact matter very much in that field, and/or secondly, that no-one knows, or at least no-one can agree on, how to resolve them. So, recognising that there may not therefore be much that can be learnt from the design experience, let us move on to a more recent historical lacuna in protection in another field, that of computer programs, which has been filled, in rather different ways, by two IPRs – copyright and patents.

**Computer Programs and their Protection by Copyright and by Patents**

Although it is now universally recognised, and is indeed enshrined in international treaties, that copyright protects computer programs, this was not always so. Thus in the EU it was not until after the passage in 1991 of Directive 91/250/EEC on the legal protection of computer programs that Germany protected computer programs by copyright and even in the USA the issue was initially highly controversial. Indeed the need for any intellectual property protection for these was at one time questioned. But accepting that copyright protects computer programs is the easy part. What does this mean in practice? Clearly, it will be an infringement of such copyright to reproduce a program exactly, ‘bit for bit’, but to what extent can copyright confer wider protection, on matters such as the ‘look and feel’ of a program as against another written in a wholly different computer language, or the interfaces that are required for one program to emulate the functionality of another? This boils down to the age-old question in copyright of where one draws the line along the continuum between mere ideas (not protected by copyright) and their expression (protected by copyright) – the ‘idea-expression dichotomy’. This is a particularly challenging issue in the context of a utilitarian creation such as a computer program.

The USA was the first jurisdiction to explore how far copyright could be stretched to go beyond the simple protection of expression, with Whelan Associates Inc v Jaslow Dental Laboratory Inc, in 1986 providing the high water mark of expansive interpretations of the protection afforded by copyright for the ‘structure, sequence and organisation’ of computer programs. Such protective scope was cut back a few years later in Computer Associates International Inc v Altai Inc with its three step ‘abstraction-filtration-comparison’ test, the application of which resulted in a holding that copyright did not subsist in the computer program interfaces in issue. The ‘abstraction-filtration-comparison’ test has since been widely used, but it would seem unlikely that that situation reflects anything other than a grudging acceptance of it, given that since 1990 there has been less pressure to stretch the boundaries of copyright as a means to protect the principles that underlie computer programs because patents, as outlined below, have become, at least in the USA, an ever more important and effective way of achieving this.

Europe has also seen its share of such copyright litigation, although it is only very recently that such issues have reached its highest court, the Court of Justice of the EU (CJEU). This, in Case C-406/10 SAS Institute Inc v World Programming Ltd, held, inter alia, that ‘neither the functionality of a computer program nor the programming language and the format of the data files used in the computer program in order to exploit certain of its functions constitute a form of expression of that program and, as such, are not protected by copyright in computer programs.’

Patents would seem, in principle, better suited than copyright for protecting the principles that underlie, or the functionality of, a computer program. However, courts in different jurisdictions have been reluctant to accept the patentability of computer programs. Thus, although in the USA there is no express statutory exclusion of computer programs from patentability, the development of the law in this area has not been free of incident. The Supreme Court got it off to an unpromising start, from the perspective of those seeking to protect computer programs with its 1972 decision in Gottschalk v Benson, which many interpreted as holding computer programs unpatentable. The patent application in question concerned a process for converting numerical data from one format to another in a general purpose computer, where the only novelty lay in the computer...
program by which such process was undertaken. In *Parker v Flook*, the Supreme Court applied this principle to find a patent application for the automated re-calculation of ‘alarm limits’ for conditions such as temperature and pressure in engines to be unpatentable, but in 1981 in *Diamond v Diehr*, it took a more permissive approach to computer program patenting, since when it has never directly addressed the matter again. In *Diamond v Diehr*, the Supreme Court explained that *Gottschalk v Benson* had concerned a mere mathematical algorithm, but here the fact that the process, for determining when to stop curing rubber with reference to various temperatures monitored earlier in the process, involved algorithmic computational steps, did not deprive it of patentability.

However, it was not until the 1990s that the scope for using patents to protect computer programs, and latterly business methods, became more widely recognised and US law became more permissive of such patenting although the scope for protecting business methods, at least where not implemented on computer, was subsequently limited by the Supreme Court in 2010 in *Bilski v Kappos*. The developments in the 1990s were the result not of any decision of the Supreme Court, but rather of decisions of the lower, specialist patents court, the Court of Appeals for the Federal Circuit. As a result, patents have been granted for a wide range of computer-related inventions in a variety of fields. However, in recent years, there has been a developing unease over certain aspects of computer program patenting in the USA, although the main concerns have been reserved for business method patents. Moreover, the economic view as to the value or otherwise of patents in software would seem to be at best agnostic. Thus, in 2006, the economist, Robert Merges concluded that ‘whatever the effects of patents on the software industry ... they have not killed it.’ Two years later however Bessen & Meurer however singled out software patents for especial criticism from an economic perspective.

In Europe the controversy over patenting computer implemented inventions, as they tend to be termed by the European Patent Office (EPO), is compounded by Article 52(2) of the European Patent Convention (EPC) which not only expressly excludes from patentability ‘programs for computers’ but also, amongst other things, ‘mathematical methods’, ‘methods for performing mental acts ... or doing business’ or ‘presentations of information’. However, by Article 52(3) EPC these exclusions only apply to the extent that a patent or application ‘relates to that thing as such’. Recognising that much that would have been regarded as patentable previously should not be excluded from patentability simply because it is implemented by means of computer program, the EPO has adopted a narrow interpretation of the Article 52(2) EPC exclusion in the case of computer programs. It has been able to grant numerous patents for many computer-implemented inventions by focusing increasingly on the need for the invention to have ‘technical character’ and instancing some of the other Article 52(2) EPC exclusions, such as that for business methods, as examples of cases in which there is no technical character.

To a degree however this approach is also a response to pressure from applicants who have been more readily able to secure such protection in other jurisdictions, such as the USA, as recognised by the English Court of Appeal in *Aerotel/Macrossan*.

*Th[e] pressure on the European patent regimes to permit patents to business methods and computer programs* in part stems from the fact that, following *State Street* (business methods) and *Alappat* (computer programs) people have been getting patents for these subject-matters in the USA. Since they can get them there, they must as a commercial necessity apply for them everywhere. If your competitors are getting or trying to get the weapons of business method or computer program patents you must too. An arms race in which the weapons are patents has set in.

The race has naturally spread worldwide ...

The apparent exclusion of computer programs from patentability in Europe resulted for many years in sterile controversies as to what was, and what was not, a ‘computer program as such’, the effect of which was to distract attention in this field from analysing and developing the law as to the real issues that patent law is relatively comfortable addressing and which are met daily in other fields of industry – namely what is obvious over the prior art, and what is the legitimate scope of claim given the underlying contribution to the art. Thus, many of the objections of those in the computer programming community to many applications for computer program-related patents, once analysed, have actually been on the basis that they were obvious, or sought claims of
over-broad scope given the inventive contribution. Such objections, which are often well founded, are better addressed directly, rather than by seeking to use them to justify a broad interpretation of the exclusion for computer programs. Indeed, that is what EPO examination practice for computer implemented inventions now involves, conflating the examination of inventive step with that for excluded subject matter, and then excluding from such analysis anything non-technical, such as a business method.\textsuperscript{26}

**Pharmaceuticals and the Interface between Patents, Confidential Information and Regulatory Data Protection**

Patents have traditionally been seen as the most important IPR protecting pharmaceuticals and other high value but easily replicated chemicals and other life sciences products. But invention, which is what patents protect, at least in the traditional sense, given their limited term of protection,\textsuperscript{27} is becoming of less importance in a society that increasingly values the often vast and ever increasing investment involved in proving safety and efficacy in order to secure regulatory approvals in such sectors. Article 39.3 of TRIPS mandates the protection of regulatory data and thus this investment, and so reflects a relatively new IPR which has emerged out of the law of trade secrets when applied to the regulatory frameworks that prevent such products being marketed without prior authorisation.

Regulatory data protection can thus confer protection on such investment even where there is no patent protection at all, or the patent protection is weak, which can be an especial problem in practice where no patent protection is available as a new chemical entity or other new active substance but the only protection available is instead to a new salt or physical form, a new formulation, a new synthetic process or a new use of an old substance. Such ‘second generation’ patents are in practice at much greater risk of having their validity successfully challenged on grounds of lack of inventive step than are patents to a new chemical entity or other new active substance, because patent validity is keyed less to the work done in developing inventions to take them to market or in proving that inventions are safe and efficacious than it is to devising them in the first place, making patents a poor proxy for protecting the costs and delay associated with generating such proof. Such patent validity considerations have no bearing on the position under regulatory data protection, which may therefore provide the sole protection for a medicinal product. The fact that patents can only provide a limited protection, and thus a limited incentive only, for much important work that is done in securing a marketing authorisation, was recognised in the English patent case \textit{Merck & Co Inc’s Patents}.\textsuperscript{28} Here the trial judge observed, when finding certain patents to the medical uses of alendronate, a compound used to treat medical disorders of excess bone destruction, to be invalid:

Accordingly I hold both patents invalid. I do so with some regret. Merck have only had a few years’ exclusive exploitation of alendronate. They must surely have had to make a very considerable investment and incurred considerable risk in bringing it to market. And mankind is better off as a result. But the patent system does not confer monopolies on those who develop obvious or old products, even if they have never been exploited. A workable system for that might be a good idea, particularly in the field of medicine and analogous fields.

In fact, unbeknownst to that trial judge, in regulatory data protection such a framework already exists, which for example in the UK provided longer effective protection than did the patents that were in issue in this particular case.\textsuperscript{29} Rewarding as it does the investment made in generating the data required to prove to the satisfaction of a regulatory authority that a product is safe and efficacious, regulatory data protection as an IPR has developed most, and become of the greatest importance, in those highly regulated sectors in which product safety and efficacy is paramount, namely pharmaceuticals and agricultural chemicals (such as pesticides and herbicides), which is reflected by its being only mandated for those two sectors by Article 39.3 TRIPS.\textsuperscript{30} Regulatory data protection works by, during the period of protection conferred on the regulatory data, preventing subsequent applicants for a marketing authorisation for the same regulated product from relying, either directly or indirectly, on the data filed in support of the original marketing authorisation without the consent of the party which filed such data in the first place in order to secure the original marketing authorisation. As it is in general uneconomic for subsequent applicants to generate their own such data independently, this effectively confers a \textit{de facto} right in respect of a particular regulated product in favour of the first applicant during that period.
Although the protection of regulatory data has its origins in the law of confidential information or trade secrets, and indeed is addressed in the same article of TRIPS as mandates their protection, it has become a separate right which has now to be analysed separately. It is important to recognise this distinction because for public policy reasons, whether in order to discourage repeat clinical trials on the same pharmaceutical or for reasons of transparency and freedom of information, much regulatory data must be used by regulators, or summaries of it publicly disclosed. The competing considerations to be balanced as between trade secret protection and regulatory data protection are different, and the balance struck in one should not affect that struck in the other. For example, whilst there would seem to be no compelling reason why the protection afforded to confidential information should not be unlimited in duration, regulatory data protection ought to be limited in term to avoid the need for repetitive testing, which whether on animals or people is undesirable from an ethical perspective. This allows a second applicant, seeking authorisation from the appropriate regulator to market a similar product, itself to rely on the first applicant’s regulatory data after an appropriate period.

Subject to questions as to its term, it might at first sight be thought that there should be no need for a separate legal regime to protect regulatory data because the data it protects might be considered an appropriate subject matter for protection under the law of confidential information. This is because, seen from a common law perspective, regulatory data is typically confidential in nature, and is communicated to regulatory authorities in circumstances importing an obligation of confidence. However, trade secrets law in its conventional sense has proved inadequate to the task of protecting data filed with regulatory authorities against its use for the benefit of third parties. Firstly, the issue has not been that of the disclosure of such data, but rather of its use, although nowadays considerations as to freedom of information make a limited measure of disclosure inevitable, which has the potential to undermine the initially confidential nature of the data in the strict sense. Secondly, as to the use of data, one question is whether what the regulatory authorities in fact do, especially when merely relying on the existence of such data, without actively cross referring to it, is a ‘use’ in the sense controlled by the relevant law of confidential information? Thirdly, even assuming that such reliance does constitute such use, is there in effect some ‘public policy’ or ‘implied permission’ defence that permits such use?

This is an issue that has been explored to a degree in litigation in various common jurisdictions. On the public policy issue, or implied permission issue, the courts of England, Australia and New Zealand came to similar conclusions in the various Cimetidine cases, which demonstrated the difficulties faced by those who file confidential regulatory data in seeking to use traditional concepts of confidential information to prevent the regulatory authorities cross referring to the originator’s file, or relying on the mere fact of the existence of the earlier authorisation, when assessing an application for the approval of an equivalent medicinal product by a generic competitor. Thus the decision of the UK House of Lords in the English Cimetidine case confirmed that the information was confidential and that although it would have been a breach of that confidentiality to have disclosed it to third parties or to use it for purposes unconnected with the function of the regulatory authorities, that was not the case here as the regulatory authorities had the right and the duty to make use of such information as those who file regulatory data have voluntarily supplied to them, for the purpose of discharging their statutory duties. Thus ‘...the licensing authority should not be deterred from exercising its rights and powers so as to ensure public safety...’. Likewise in the USA, Ruckelshaus v Monsanto Co showed the reluctance on the part of the courts to impose an unqualified restriction on the use by the regulatory authorities of the data filed with them. The decision is now set to be revisited in the context of the recently enacted Biologics Price Competition and Innovation Act of 2009, which establishes a regulatory pathway in the USA for ‘biosimilars’ of complex biotechnological pharmaceuticals such as monoclonal antibodies. This has now been challenged as unlawful taking in so far as it would involve reliance on trade secrets in regulatory filings made before the 2009 Act became law.

However, as it stands the regulatory data protection system for medicinal products at least in Europe and as mandated by Article 39.3 of TRIPS provides only limited compensation for the shortcomings of the patent system. Firstly TRIPS specifies no minimum term of protection, and although that in the EU confers 10 years marketing exclusivity on a newly authorised pharmaceutical active, which can
sometimes extend beyond patent term (and during it provide a much more certain form of protection) most other countries confer only 5 years protection, although such protection conferred on actives other than biotechnological products in the USA is in practice extended by ‘patent linkage’ discussed below. Secondly, regulatory data protection is in general only available for data filed in support of a new chemical entity or other new active substance, and thus data filed in support of a new indication, new formulation or new dosing schedule of an already authorised active, is not in general protected. Such an approach confers no incentive to extend indications for already authorised medicinal products, and instead encourages work on new medicinal products which may in practice be no better than those which they come to replace, and whose benefit lies not in their contribution to public health but in the potential that they provide to attract better protection, both in terms of regulatory data and by the patent system.

Such shortcomings are however met, both in the USA and the EU, by yet another type of marketing exclusivity, albeit one not mandated under TRIPS, namely, that available in Europe for ‘orphan medicinal products’ and in the USA for ‘orphan drugs.’ Such regimes are needed to encourage authorisations to be secured for pharmaceuticals that treat only very small patient populations, and so require further incentives over and above the norm to be developed in view of their small potential market. The exclusivity, which in both the USA and the EU lasts for 10 years after the first marketing authorisation for an active for a particular orphan indication, is effective against a second applicant seeking an authorisation for the same (or in the EU a similar) medicinal product, for the same indication, and a new authorisation as an orphan medicinal product can be secured for a new indication for an already authorised medicinal product, provided that such new indication reflects a sufficiently small patient population. The exclusivity in the EU for such orphan medicinal products goes further than regulatory data protection because it not only protects the data submitted by the entity which secures the first such orphan authorisation but also prevents a second applicant for authorisation, during the period of orphan drug marketing exclusivity, from securing its own authorisation even on the basis of its data.38

Notwithstanding the fundamental conceptual differences between patents and regulatory data protection, some links between them have been created under various national implementations. Thus, the regime in the USA for granting authorisations for medicinal products (and as required by many bilateral or regional Trade Agreements between the USA and third countries) creates a linkage between the two systems, which has the effect as applied in the USA (although not necessarily as implemented by its trading partners) of extending the effective term of protection. The current regulatory data protection regime in Europe, which applies to new actives for which the application for a marketing authorisation has been filed since November 2005, permits no such linkage, and indeed the European Commission regards attempts to try to impose pressure on regulators to delay authorisations based on patents and so to seek to treat them as a proxy for the courts in which patents are enforced to be an abuse of the regulatory system, which should be concerned solely with matters of safety, efficacy and quality. Thus in the EU the mere application for a marketing authorisation does not, in and of itself, constitute an act of patent infringement and a marketing authorisation may be granted to any party that complies with the applicable technical requirements without thereby infringing any patent. But Europe was not always free of patent linkage, although its linkage under its pre-2005 regulatory data protection regime was one that unlike that in the USA detracted from, rather than enhanced, the protection conferred on regulatory data. Thus it gave EU Member States in their national implementations the option not to confer regulatory data protection for medicinal product ‘after patent expiry’ although this begged the question as to which particular patent this meant (or did it mean all of them) where there were multiple patents.38 Perhaps because the provision was so obviously inherently defective, it was implemented by very few EU Member States, and even those that did so, such as Denmark, rapidly abandoned it because no reliance was in practice ever placed on it. However, and whether patent linkage detractions from or strengthens the protection conferred on regulatory data it is suggested that it is not desirable to link two such different forms of protection.

**Mutual Exclusions to avoid Overlap and New IPRs to Fill Perceived Lacunae**

The examples above would suggest that overlap as between IPRs is not too great a problem in practice and that attempts to limit it by means of mutual exclusions (for linkages) do more harm than good, focusing attention on boundary issues that can rarely
satisfactorily be resolved and which distract attention from the central, well understood and well recognised, validity issues that are relevant for each type of IPR, and which when properly applied will limit the scope of such IPRs, and so reduce any untoward consequences of overlap.

Another good example of the problems that can arise when provisions are introduced into intellectual property legislation specifically aimed at avoiding overlap between IPRs is provided by patents and plant varieties. Consistent with Article 27(3)(b) of the TRIPS Agreement, Article 53(b) EPC excludes from patentability ‘plant or animal varieties or essentially biological processes for the production of plants or animals’, a provision which was aimed at avoiding overlap, as to plants, with the UPOV regime of plant variety protection. However, the Enlarged Board of Appeal of the EPO has held that this does not exclude from patentability inventions as to genetically modified plants which are claimed at the species level or more generally, as these are not claims to a single variety.\(^{39}\) Thus the result of a formalistic provision aimed at avoiding overlap is a formalistic response that wholly deprives such provision of any purpose.

Moreover, the above examples also suggest that no great harm comes of stretching an existing IPR to cover a new activity that is perceived to require protection, even where, as in the case of trade secrets and regulatory data protection, the IPR evolves into a different IPR. In some cases, civil law countries with their more flexible concepts of unfair competition than common law ones may be better placed to do this. The alternative approach of inventing new IPRs, if it can be done at all, which often politically it cannot, has not been notably successful. An early example of this as discussed above was design protection, but two recent unsuccessful examples of invented IPRs are the semiconductor chip topography right, enshrined in Section 6 of TRIPS, and the EU database right, which probably fortunately, never got into TRIPS as TRIPS post-dated it.\(^{40}\)

The former was a highly technology specific response to a particular perceived lacunae in some countries’ laws. Indeed so technology specific was it that it no longer has any relevance, reflecting as it did a moment in time when integrated circuit layouts were still relatively simple and their appearance was capable usefully of being copied, rather than their functionality being replicated by computer design.\(^{41}\) Patents instead constitute the most important protection these days for integrated circuits. The ‘\textit{sui generis}’ database right was the EU response to a perceived lack of protection for databases, but which has never been taken up by any other country in the world despite adopting the reciprocity ‘stick and carrot’ approach.\(^{42}\) Most of the litigation relating to it has concerned not its intended beneficiaries (who would seem to operate satisfactorily elsewhere in the world without its ‘benefits’ but rather by using contractual terms to protect their interests), but instead the creators and exploiters of sports fixtures, who have tried, generally unsuccessfully, to use it to secure rights in information relating to such fixtures.\(^{43}\)

Are there other IPRs in gestation to which these considerations can be applied? One is television format rights, which are not readily protected by copyright as doing so can involve protecting more of the idea than its expression, although it has to an extent been possible to protect these in some jurisdictions by unfair competition laws.\(^{44}\) Others are traditional knowledge and traditional cultural expressions; if, and in so far as rights reflecting these, enforceable not only from the point of view of securing the freedom to continue to do what has been done before, but also to prevent others from copying it, might be considered to be worthwhile from a policy point of view, what form should such rights take; should they be entirely new IPRs, or should they be modified versions of existing ones?\(^{45}\)

**Conclusion**

Where does this leave us? It is suggested that, given that they each protect different things and approach the question of protection in different ways, it is inevitable that there will in practice be situations which different IPRs cover the same activity. Although this can in one way be seen as an undesirable complication, legislative attempts to avoid such situations by trying to draw artificial boundaries as between different IPRs are likely to do more harm than good. Whether or not they succeed in achieving that aim, what is inevitable is that such legislated boundaries will lead to surreal disputes of an almost philosophical nature as to where precisely such boundaries lie, which disputes distract attention from the central issues that intellectual property offices and courts should be concerning themselves with when assessing the subsistence or validity and the protective scope of IPRs. Legislative attempts to introduce entirely new types of IPR to fill perceived lacunae merit considerable scepticism, and the
creative application of existing types of IPR to cover such situations (as in the case of computer programs), or accepting the evolution of IPRs out of existing legal frameworks (as in the case of regulatory data protection) is likely to be the better approach.

References

1 Ladas Stephen in Patents, Trademarks, and Related Rights – National and International Protection, Vol 2 (Harvard University Press), 1975, notes (at page 829) that ‘the formation of a special branch of industrial property for designs and models is a historical accident’ which he then traces back to the interpretations placed by the French courts on a law of 1806 introduced in response to complaints, made to Napoleon by the manufacturers of Lyon when he visited that city, that the French copyright law of 1793, although broad enough to cover any kind of design, was in practice inadequate for their purposes.

2 Articles 2(7) and 7(4) of the Berne Convention. The decision of the Court of Justice in Case C-168/09 Flos SpA v Semeraro (CJEU 27 January 2011), interpreting Article 17 of Directive 98/71/EC on the legal protection of designs, would seem however to suggest that the current UK approach to cumulation may be inconsistent with EU law, as observed by Lionel Bently in April 2012 in his Fordham lecture ‘Harmonisation by stealth’, http://fordhamip-conference.com/wp-content/uploads/2010/08/Bently_Harm- onization.pdf (14 May 2012). Unconnected to this, the UK Government has recently proposed the repeal of Section 52.

3 British Leyland Motor Corp v Armstrong Patents Co [1986] UKHL 7 (UK House of Lords), in which the House of Lords had to invent a ‘non derogation from grant’ principle in order to avoid what evidently to it was the unpalatable result of protecting car manufacturers against replacement exhaust pipes supplied by third parties as copies of the underlying engineering drawings for them.


5 The court in Mazer v Stein did however note, but did not comment on, holdings by lower courts that utility patents (ie, ‘patents’ in international terminology, as opposed to ‘design patents’, or ‘registered designs’ in international terminology) and copyright were mutually exclusive.

6 TRIPS, Article 10(1) and WIPO Copyright Treaty 1996, Article 4.

7 This has now been replaced on codification by Directive 2009/24/EC on the legal protection of computer programs.

8 Compare the pre-Directive case of Inkasoprogram (BGH 9 May 1985 GRUR 1041, (1986) 17 IIC 681), imposing a standard of originality that in practice computer programs could not meet, with the post-Directive case of Accounting Program (Buchhaltungsprogram) (BGH 14 July 1993, (1995) 26 IIC 127), which held that computer programs were capable of meeting the ‘author’s own intellectual creation’ standard of originality mandated by the Directive, so that copyright was capable of subsisting in them.

9 For a recent historical review of the controversy then and of developments since by an author who was also involved with such controversy in 1984 see Samuelson Pamela, The uneasy case for software copyrights revisited, George Washington Law Review, 79 (6) (2011) 1746, questioning the economic case for conferring copyright protection on computer programs but concluding that ‘copyright protection has, in fact, become so deeply entrenched in software protection law and in software industry’s expectations that it will be with us and the software industry for decades to come, regardless of whether it really is (or is not) economically necessary.’

10 Lahore James, Dworin Gerald& Smyth Y M, Information Technology: The Challenge to Copyright (Sweet & Maxwell, London), 1984, p. 89.

11 This is a distinction which now has basis in Article 9(2) of the TRIPS Agreement, providing that ‘copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such’ and repeated in Article 2 of the WIPO Copyright Treaty 1996.


15 A current example of such controversy is provided by the action brought by Oracle against Google for copyright and patent infringement, the trial of which, at the time of writing in May 2012 is taking place in the Northern District of California. A jury decided on 7 May 2012 that Google had copied portions of the Java code (intellectual property rights associated with which are now owned by Oracle, having purchased Sun Microsystems in 2009) when developing its Android operating system. However the jury, despite having been asked, offered no view on whether such use was subject to the fair use defence.


17 Case C-406/10, SAS Institute Inc v World Programming Ltd (CJEU 2 May 2012). For the judgment of the English court that made the reference to the CJEU, see [2010] EWHC 1829.

18 Gottschalk v Benson (1972) 409 US 63.


22 Notably Arrhythmia Research Technology v Corazonix (1992) (holding that a patent application relating to a ‘computer-implemented’ technology or process, rather than merely to an abstractly described algorithm, was in principle patentable), In re Alappat (1994) (holding a computer program for a technique for reducing the jaggedness of computer displays and which was in essence an algorithm, to be patentable), State Street Bank v Signature Financial Group (1998) (holding a portfolio management system to be in principle patentable) and AT&T Corp v Excel Communications (1999).


Aerotel v Telco [2006] EWCH 997; *Macrossan’s Application [2006] EWHC 705 (Patents Court); Aerotel v Telco Holdings Ltd & Macrossan’s Application [2006] EWCA 1371 (English Court of Appeal).

Case G-3/08, *Programs for Computers* (EPO Enlarged Board of Appeal, 12 May 2010), and Guidelines for Examination in the *EPO* (April 2010), Part C, Chapter IV—4, 2.3.6.

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However one of the patents in issue in this case was for a new dosing schedule (seven days as opposed to one, with a concomitant difference in dose), and neither the pre 2005 regulatory data protection law in Europe nor the current one that replaced it protects new data in support of new dosing schedule for an old active, as was confirmed under the old law in the unsuccessful challenge to the grant of a marketing authorisation to a second applicant in *The Queen on the application of Merck Sharp and Dohme Limited v The Licensing Authority (acting by the Medicines and Healthcare products Regulatory Agency, and Approved Prescription Services (UK) Ltd, Generics (UK) Ltd and Arrow Generics Ltd [2005] EWHC 710 (Admin) (Moses J, 28 June 2005).* The EU also confers protection on regulatory data filed in support of authorisations for animal feed additives, new chemicals irrespective of their utility, and health claims on foods.

Article 39.2 TRIPS mandates the protection of confidential information. There are however considerable disparities in the manner in which countries do so (even within the EU) and in the remedies conferred (for example are they enforced in the criminal or civil courts) and between the legal bases for such laws (are they seen as contractual or equitable, as tends to be the case in the common law jurisdictions, or are they seen as species of unfair competition, as tends to be the case in civil law countries).

Smith Kline & French Laboratories Ltd v Attorney General [1989] FSR 418 (New Zealand), In re Smith Kline & French Laboratories Ltd [1990] 1 AC 64 (England); Kline & French Laboratories (Australia) Ltd v Secretary to the Department of Community Services and Health and Alphapharm Ltd v Secretary to the Department of Community Services and Health [1990] FSR 617 (Australia).

Ruckelshaus v Monsanto Co, (467) US, 986, 1019-20 (1984). This case was analysed extensively in the Australian *Cimetidine* case cited above.

In contrast the EU has since 2005 had a regulatory pathway for the authorisation of similar biotechnological medicinal products.

Citizen Petition dated 2 April 2012 filed on behalf of Abbott Laboratories with the US Food and Drug Administration requesting that the latter ‘not accept for filing, approve or discuss with any company, or otherwise take any action indicating that the agency will consider, any application or investigational new drug application’ for a biosimilar that cites, as its reference product, the monoclonal antibody Humira (adalimumab).

For applications filed in the EU since 2005 for the authorisation of medicinal products based on a new active, Article 10(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC confers 10 years of protection after the date of first authorisation for an active as against generic applicants being able to market their products, which is extended by one year if one or more new therapeutic indications are authorised during the first 8 years which are ‘held to bring significant clinical benefits in comparison with existing therapies’. But there is no protection for data filed for example in support of a yet further new indication or a new formulation or dosing schedule of an already authorised active.

As to the EU, see Regulation 141/2000.


Case G-1/98, *Novartis II / Transgenic Plant* (EBA 20 December 1999 – OJEP 3/2000 p 111) holding, inter alia that ‘A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties’.

Established in particular by Chapter III of Directive 96/9/EC.

The only reported litigation anywhere in the world of which the author is aware concerning semiconductor chip topographies was in the USA in the late 1980s - *Brooktree Corporation v Advanced Micro Devices* (795 F Supp 491; 10 USPQ 2D, USDC Southern District of California 1988 - denying preliminary injunction; and [1989] 2 EIPR D-30; [1990] 11 EIPR D-221 – reporting jury verdict finding infringement).

It was open to the EU to adopt this approach because the database right is not, for the purposes of TRIPS, an ‘intellectual property right’ and so the requirement of national treatment does not apply.


As to traditional cultural expressions see the Republic of South Africa’s *Intellectual Property Laws Amendment Bill*, B8B-2010, for an example of the extensive amendments that are proposed to be made to existing intellectual property laws ‘so as to provide for the protection of relevant manifestations of indigenous knowledge as a species of intellectual property.’