What is the database sui generis right?

Estelle Derclaye
Commentary

The Uses and Abuses of Health Related Compulsory Licenses - Helen Disney & Meir P. Pugatch*

What do Aids, anthrax and avian ‘Flu have in common, aside from their obvious threat to human health? Well... they also seem to be linked to what the average Joe would consider a highly technical and a rather tedious issue - compulsory licensing (CL).

Every few years, and usually in the midst of a fraught public debate or in times of public hysteria, the issue of CL captures the public eye, admittedly much to the delight of those of us dealing with IPRs. The consequences, however, of short-term thinking and ‘instant-cake solutions’ such as swiping use of CL, may be extremely severe, and require therefore discussion. While the issue of CL is spreading like fire - across all fields of technology - we thought it appropriate to discuss it in the context of the current scare: bird ‘Flu.

For the sake of simplicity we can state that, in the field of IPRs, there are two types of licensing – voluntary and compulsory.

The first – the voluntary type of licensing – is designed to allow the IP owner (the licensor) to grant other parties (the licensees) permission to use the subject matter of their IPRs in various forms and for various purposes, all of which are defined under the terms of the license. Indeed, licensing is considered one of the strongest facets of IP activities and of technology transfer in general. The Economist argues that in America alone, technology licensing revenue accounts for an estimated $45 billion annually. Worldwide, the figure is around $100 billion and growing fast.1

The second type - the compulsory license - is the result of an external intervention, usually by government or an equivalent authority, which forces the IP owner to grant a license to a third party or parties, based on the conditions set by that authority. Quite often a compulsory license is just a nicer term to the appropriation of IPRs by the granting authorities; with the exception that with CL there may be (not necessarily) some amelioratory forms of compensation to the IP holder.

It should be noted that CL is by no means a new tool. Even in the US, where there is no statutory legislation of CL, there are mechanisms that allow for different forms of CL and even the appropriation of IPRs, such as in the cases of national security (weapons of mass destruction) government-funded inventions (so-called ‘March in Rights’ in Bayh-Dole Act), and antitrust.2 Today, however, these forms of CL represent the exception rather than the rule, as indeed noted by the US Supreme Court: “compulsory license is a rarity in our patent system...[and] has never been used on a broad scale.”3

This leads us to a more practical question: if CL is a coercive form of knowledge transfer, in which circumstances should we use it? This is a fundamental issue in the debate over CL and public health. And although the answers are never easy


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or clear-cut, we nevertheless believe that there are at least two fundamental policy considerations that should be taken into account.

First, there is a need to focus on the circumstances of the case. Is the problem at hand associated primarily with commercial aspects, or is it an expression of a market failure generated by the mere granting of IP rights? A market-oriented economy should as far as possible avoid intervening in commercial negotiations between owners and users of IP-based products. Greater caution should be exercised in cases that concern commercial negotiations by the government itself, vis-à-vis IP owners. Brazil, for example, has been known to explicitly use the threat of CL in HIV/AIDS medicines against pharmaceutical companies when negotiating the prices of these drugs. Some may argue that the threat of CL is a perfectly legitimate negotiating tool aimed at achieving the best prices for the Brazilian public. But according to this logic, why grant IPRs for these products in the first place if the government does not intend to respect the right of the IP owners to successfully commercialise their products? If a country is committed to IP protection, it should refrain from constantly threatening to virtually nullify these rights when negotiating issues of a commercial nature, such as prices. Certainly there are other more subtle and positive negotiating tools that can be used by a country such as Brazil, which is by no means an underdog in such negotiations, and which has enough purchasing power to negotiate a fair price for its public.

On the other hand, if a market failure occurs that requires massive and immediate production of a patented medicine – say, in the light of an unexpected outbreak of a life threatening pandemic, such as bird ‘flu, or a bio- terror attack, such as the use of anthrax - then CL mechanisms may be considered based on two conditions:

- That the quantity of the medicines required is beyond the production capacity of the company owning that medicine and that the company is both unable and/or unwilling to solve the problem of production (for example by providing a voluntary license).
- That the company refuses to take into consideration the sudden increase in demand when negotiating prices with the governments.

In both the cases of the anthrax threat (in the aftermath of 9/11) and the current scare of bird ‘flu, pharmaceutical companies have pledged to cooperate with the government in order to solve the above problems, without being forced to license their patents.

Second, there is a need to seriously consider whether the use of CL can actually solve the problem at hand, or at least be a significant component of the solution. Too often the issue of CL is mentioned and advocated for the sake of political capital.

Take, for example, the 2001 Declaration on the TRIPS Agreement on Public Health (as part of the Doha Development Agenda), and the August 2003 Agreement on the implementation of Paragraph 6 of the declaration (focusing on the manner in which least developed countries with no manufacturing capacities can import generic substitutes to existing patented pharmaceutical drugs). There is a wide consensus that these decisions made the use of CL much easier and ‘flexible’ under the TRIPS regime (this time delighting critics of...

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IPRs. But the evidence suggesting that, aside from diluting the level of IP protection provided under TRIPS, the use of CL actually promotes access to medicines in these countries is not favourable, to put it mildly.

This however should not come as a surprise, as the challenges facing the least developed countries in the area of healthcare, including medicines, are formidable and much more fundamental than the issue of patents and CL. Suffice it to quote the World Health Organization: “One third of the world’s population continues to lack regular access to essential drugs. In the poorest parts of Africa and Asia, this figure rises to over 50%. The reasons are well-known and include inadequate financing and poor health care delivery. This is especially so given that total pharmaceutical expenditure, as well as other health expenditure, is linked to the economic development level of a country, and tends to increase only when GDP increases.”

The fact is that pharmaceutical patents are probably the least problematic aspect of the issue of access to essential medicines for poor people in less developed countries. In fact, of the 300 drugs listed by the WHO on its Model List of Essential Drugs (2001), less than five percent (fewer than 20) are under patent protection anywhere in the world.

CL is a policy tool that should be used with great caution and in extreme conditions – none of which exist in the current case of the bird ‘flu. It is time to put the CL issue back to rest!

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**Know IP - Stockholm Network Monthly Bulletin on IPRs**

**Topic of the Month**

**Intellectual Property Management in FP7 Projects - Frank Moeschler & Denis Dambois**

**Introduction**

The European Commission currently manages the 6th EC Framework Programme for research and technological development (FP6 – 2002-2006). Under this Framework Programme, a budget of about 17 billion Euros is made available principally to fund collaborative R&D projects carried out by consortia of companies and research organisations such as universities.

A typical project has a 3 to 5 year duration and involves from 3 to dozens of organisations. Its budget may range from 1 to several million euros and, typically, 50% of its eligible costs are funded by the European Union. More information can be found at the European Commission website: [http://europa.eu.int/comm/research/fp6](http://europa.eu.int/comm/research/fp6).

The European Commission is currently preparing the 7th Framework Programme, (FP7) which should last from 2007 to 2013 and for which a budget of more than €60 billion has been proposed (but not yet adopted).

Intellectual property (IP) issues are evidently important in such R&D projects, and they play a role not only during a given project (ownership and protection of results, access rights between participants) but also subsequently (with an impact on the exploitation of the results).

Following several consultations with users of the EC research Framework Programmes, this paper summarises some of the stakeholders’ and Commission’s preliminary views.

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* Frank Moeschler, Denis Dambois, European Commission, DG Research
regarding the development of the IP provisions for the next Framework Programme (FP7).

It should, however, be noted that the Commission has not yet adopted any official proposal regarding the Rules of Participation, which would then need to be negotiated with the Council and the Parliament. Accordingly, this paper should be considered as being purely informal and provisional.

In addition, this paper relates only to the ‘mainstream’ instruments, i.e. it does NOT include RTD (what is this?) actions relating to Articles 169 (joint initiatives of Member States) or 171 of the Treaty (joint undertakings) such as the Joint Technology Initiatives or the future European Research Council

**Role of IP provisions in FP projects**

It may be useful to remember that, in the Framework Programme, the IP provisions have two main objectives:

- To promote the successful execution of a project (e.g. by making appropriate access rights available to the participants to perform their R&D tasks).

- To promote the dissemination and, in particular, the exploitation of results (through specific provisions regarding the ownership of results and granting of licenses, etc.), not only during but also, in some cases, long after the end of a project.

To this end, the IP provisions define minimum conditions regarding the knowledge put into and resulting from FP projects (this is due to the fact that all knowledge falls within a category of intellectual property – be it copyright, a design, a patent or a trade mark).

These provisions determine who owns a result; who can use it; who can publish it, and what access parties have to each others’ background (i.e. what they all have to bring to the table at the beginning of a project).

In the early EC Framework Programmes, the IP provisions of the model contract were rather prescriptive – it was a ‘one-size fits all’ contract, under which all participants were subject to strict rules and had limited manoeuvrability to agree between themselves on more flexible provisions suiting their own particular concerns.

This regime was subject to extensive criticisms from all parties – both large and small companies, and universities.

Under FP6, several changes occurred to remedy this situation – the IP provisions of the model contract became a set of minimum conditions to which participants had to adhere and various decisions regarding IP were left to the consortia to negotiate and agree in a separate agreement (the consortium agreement).

This new flexible approach was welcomed by the vast majority of participants, though some (in particular SMEs) faced problems when negotiating such consortium agreements with their co-participants. However, this is often due to a lack of in-house legal expertise or of negotiating experience (especially given the large size of some projects) and not to the provisions themselves.

During the FP7 consultations on IP, all parties highlighted the need for as much continuity as possible, with simplifications and clarifications taking place in specific, well-defined areas to further improve the existing system.

The main comments made and options discussed during such consultations are set forth below.

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1. Continuity was deemed essential in order to avoid confusing participants and to make it easier for former participants to take part in FP7.
Common Problems encountered in FP6, and options considered

1. Pre-existing know-how - Under FP6, participants were permitted to exclude specific pre-existing know-how from the obligation to grant access to other participants (prior to signature of the EC contract). However, this new option was misunderstood by many, leading them to unnecessarily attempt to exclude virtually all of their pre-existing know-how (instead of relying on the existing limitation that access has to be granted to a participant only if this is needed either to carry out the project or to use this participant’s own results).

Related to this was the definition of pre-existing know-how that included both background and any knowledge acquired in parallel with the project (‘side-ground’). Such ‘side-ground’ was very difficult to exclude as opportunities after the signing of the contract were very rare.

For this reason, there is broad support among stakeholders to review the definition of pre-existing know-how in such a way as to exclude side-ground. To avoid any confusion, pre-existing know-how could then be renamed ‘background’. In addition, the mechanisms for excluding background could be reviewed, for instance, in such a way as to make it possible to rely on a ‘positive list’ approach identifying explicitly which pieces of background are available for access by others (some participants are already doing this under FP6, although this conflicts with the reference to the exclusion of specific pre-existing know-how).

2. Requirements to notify the Commission - Under FP6, there are different situations in which participants must give prior notice to the Commission (and to the other participants), mainly before transferring ownership of results and before making publications. This is considered to be a burden by many participants, and the Commission’s right to object has rarely been enforced.

Thus, in most of these cases, it is envisaged to remove the requirement to notify the Commission.

3. Transfers of ownership to a specific third party - Under FP6, each and every intention to transfer ownership required a notification (to the Commission and the other participants), even when such a transfer was to be made, for instance, to the mother company of one of the participants. Industrial participants consider this to be an unnecessary burden, especially if all other participants agree to the principle of such transfers.

A corresponding simplification could be envisaged for FP7, which would again reduce the notification requirements.

4. Default joint ownership regime - FP6 provides for joint ownership of project results where the participants cannot clearly identify separate parts and in SME-specific projects. In such cases, agreement has to be reached between the joint owners regarding the management and exploitation of the results concerned, and the sharing of any costs and revenues.

However, in the absence of any such agreement, the respective national IP laws apply. The discrepancy amongst them may cause serious management problems; in particular, some of them prevent licensing to a third party without the agreement of the other joint owner(s).

Accordingly, it may be useful to introduce a default joint ownership regime, which would apply in the absence (or pending the conclusion)
of a specific joint ownership agreement.

5. Exclusive licenses - Under the current (FP6) provisions, truly exclusive licenses cannot be granted, since participants may be required to grant certain access rights to each other up to two years after the end of a project. In certain cases (especially in the pharmaceutical sector), this may be detrimental to the exploitation of a project’s results.

During consultations, stakeholders appeared to be in favour of a removal of this limitation, provided that all other consortium members agree.

Funding of IP expenses

In FP6, the costs relating to management of knowledge, including activities to disseminate the results and to protect and manage intellectual property (filing of patent applications, etc.), are potentially eligible for funding, under the same conditions as R&D tasks. In particular, their eligibility requires that they be necessary for the execution of the project (including for promoting the use of its results). The same principles should be applicable to FP7 projects.

Assistance to users

Many participants (especially SMEs and academic institutions) face problems when they need to negotiate and agree on IP provisions in consortium agreements, given the complexity of some issues, their lack of expertise and the potential implications of their choices.

It appears that a large proportion of the problems faced by certain FP participants regarding IP issues do not result from the IP provisions themselves, but from a lack of expertise by some SMEs and academic institutions regarding IP management and negotiation, which is aggravated in the larger projects.

To address these difficulties, a number of measures (existing and new) will be available under FP7:

* Personalised assistance to consortia

FP7 participants, in case they do not have access to knowledge/IP management professionals in-house, could regularly have access to the services of external consultants¹ in order to assist them regarding these issues.

* IP-Helpdesk²

This existing free-of-charge service should continue to provide legal assistance regarding IP issues to FP participants.

* Guidelines

The existing IP guidelines³ (relating to FP6) will be revised and expanded into a specific version for FP7, which should be available by the launch of FP7.

The existing (draft) checklist for consortium agreements⁴ should also be updated for FP7.

Conclusion

Through its global design but also through its IP provisions, it is expected that FP7 will be particularly simple and user-friendly.

In particular, the revised IP provisions should ensure an enhanced exploitation of FP7’s results and, accordingly, for an enhanced impact on European competitiveness.

¹. Such exploitation experts could take various guises: IRC network members, Patent Agents, etc....
What is the Database Sui Generis Right? – Estelle Derclaye

In 1996, the European legislator created a new intellectual property right, which exists nowhere else in the world: the database sui generis (Latin for “of its own kind”) right, also known as the “database right”.

The Database Directive (the piece of legislation providing for the right) had to be implemented in all Member States by 1st January 1998. This meant that all national legislatures had to transcribe the Directive’s provisions into their national laws by that date to avoid being fined by the European Commission. Given that the States also had to abide by the Directive’s terms, they were left with no flexibility to interpret it in a manner more suiting of their national needs. (The Directive did allow for three non-compulsory exceptions - we’ll come back to them later). Thus, it is relevant to still talk of the Directive since all its provisions are to be found almost word for word in national laws.

The objective of the European legislature was to harmonise copyright laws relating to databases and to introduce a new right to protect the investment in making a database, i.e. collecting, verifying and/or presenting its contents. Copyright law only protects the structure of the database, not the investment that went into collecting the materials. While other types of protection were possible, such as misappropriation (a form of unfair competition), the Commission preferred a totally new right as it found it too difficult to start harmonising the 15 (at the time) Member States’ unfair competition laws.

A worrisome new IPR...

The Directive protects databases which are defined broadly as being collections of ‘independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means.’ Databases can therefore be in any form, e.g. on paper, CD-ROM or online. It has even been argued that supermarkets, rooms, stone collections, even carnival processions, could be databases. And this has not yet been clarified by the European Court of Justice (ECJ), who gave its first ruling interpreting the database right in November last year.¹ Surely databases must be protected, but if everything can be a database, then the law is going too far. To be sure we will have to wait for another European judgment, but this may take some time.

Databases which meet the requirements can be protected by

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¹ See cases C-46/02, C-444/02, C-338/02 and C-203/02, all available at www.curia.eu.int For comments see e.g. T. Aplin “The ECJ Elucidates the Database Right” [2005] Intellectual Property Quarterly 204; E. Derclaye ‘The Court of Justice interprets the database sui generis right for the first time’ [2005] European Law Review 420.
copyright, by database right or both. Generally, databases will not be protected by copyright because they do not fulfil the conditions. To be copyrightable, databases must be original in their selection or arrangement of materials. Thus, the structure of the database will be protected by copyright, but not the contents. Many databases are exhaustive, which means they will not be copyrightable. Many others are arranged in a common way, e.g. by chronological or alphabetical order, which makes them ineligible to copyrights as well. This is mainly why the database right was introduced. Generally, the value of the database lies in its contents and not so much in its structure.

Of course, database owners can protect their non-copyrightable databases by the law of confidential information or as trade secrets. Article 13 of the Directive leaves other laws unaffected including contract and trade secrets law. Therefore be it protected or not by the database right or copyright, the database maker can keep the information secret, e.g. license its use only to one or a few persons. In addition, if the database owner does not want to license its database even under a confidentiality agreement, he has no obligation. Therefore some information may never be known to the public, thereby shrinking the public domain. A classic example is a company’s customers list. Under human rights law (the public’s right to information, protected by article 10 of the European Convention of Human Rights and the American First Amendment), nobody is forced to disclose information they do not want to disclose. Besides, sensitive information is protected in both legal systems by the right to privacy.

To be protected by the database right, the database maker must prove a substantial investment in obtaining, verifying or presenting the materials. What is an investment is not further defined, but it can be in time, labour or money. What is a substantial investment is also left undefined in the Directive and again the ECJ has left it so. Many national courts have interpreted the requirement as being rather low. For example, a few days work or a few hundred pounds or euros may be sufficient to qualify the database. At this point, the right is already worrisome as it may encompass so much with so little at such a cost for society or so it would appear. But there is more. Once the maker can prove he is protected, he has the right to prevent anyone from extracting (read: copying) and/or reutilising (read: communicating to the public) a substantial part of the contents of the database. What is a substantial part is also vague. The ECJ has, however, at least made the link between the substantial investment and the substantial part, i.e. a substantial part is one that reflects a substantial investment. However, as seen above, we are not sure what a substantial investment is and it may be quite low, so this clarification is not entirely satisfactory.

The exceptions to the right are scarce and narrow. And as we said earlier most of them are optional. This means that states may or may not decide to implement them in their laws. There is one mandatory exception and three optional ones.

The mandatory exception allows users to extract and reuse insubstantial parts as long as they do not do it repeatedly so that it becomes a substantial part. Under the three optional exceptions, lawful users (i.e. those who have acquired a lawful copy of a database) may (1) extract a substantial part of the contents of the database for private purposes (but only if a non-

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1 These two rights are very close to the copyright rights of reproduction and communication to the public.
electronic database), (2) extract a substantial part for teaching and research (but not reuse it, so what’s the point? and only for non commercial purposes) and (3) extract and reuse a substantial part for the purposes of public security or an administrative or judicial procedure. This varies from Member State to Member State. In some (e.g. France) there is no research and teaching exception. In others (e.g. the United Kingdom), there is no private extraction exception. Thankfully, some countries implemented them all (e.g. Belgium). Nevertheless, even the optional exceptions balance the strong protective aspects of the right less than they seem at first. Indeed, they can be contractually overridden. This means that database makers can bind users by contracts which do not allow them to make use of their exceptions.

The right lasts for 15 years. This is quite long (almost as long as the patent term), considering the fact that no other condition apart from ‘substantial’ investment is required (contrary to patents). But the list of alarming aspects is still not complete. If the database maker spends some more time updating his database (i.e. he invests substantially in the obtaining, verifying or presenting of the elements), he gets another 15 years on it, and so on. It is unclear whether it includes the elements of the ‘old’ database or only of the ‘new’ one. Again, the ECJ has not ventured in this complex, albeit very important question. Thus, because of all these provisions, it is possible that some information will never be part of the public domain. Is this really true? Let’s find out.

But not so worrisome...

As we can now see, what is particular about the database right is that contrary to other intellectual property rights, it protects investment as such. Patent and copyright laws surely do protect investment in creations, but require many conditions as well. In patent law, conditions such as novelty, inventive step and industrial applicability are necessary for an invention to be patentable. Neither ideas nor presentations of information are patentable. In copyright only original expressions are protectable; all banal expressions and ideas are free as the air to use. Trade marks only protect a sign as identifying a product or a service, leaving non commercial uses of the sign free. In addition, these rights are limited by numerous exceptions and in time. But with the database right, apart from the conditions of being a database which has required a “substantial investment in obtaining, verifying or presenting information”, no other condition is required and it can last forever.

Thus the maker can forever block the use of information because he has invested and re-invested in its collection, verification or presentation. Didn’t we say that information and ideas are free for all to use in intellectual property law? Isn’t the database right a property right on information, which is in fact what IPRs do not do? Some have pretended so¹ and they were half right. This is why.

As the ECJ clarified (when interpreting the term ‘obtaining’), the database right does not protect databases of created information. And this is where (and only where) real monopolies on information occur. If a database is made of elements already present in the public domain, anyone is free to do the same. They must not copy but they can go ahead and make even an identical database by making the same efforts as the first database maker. Databases of created information, such as horse racing and

football fixtures (the databases in litigation before the ECJ) and many others like television programmes, telephone directories, transport timetables, event listings, etc., remain unprotected by the database right and thus by IPRs. The ECJ has also ruled that even if there is a substantial investment in the verification or presentation of created data, if this investment cannot be separated from the creation of the data (and this is very difficult to prove, as the cases before the ECJ showed), the database is not protected. As we have seen, this absence of IPR protection does not prevent database makers from using contract, e.g. through the use of confidential information, to protect them, which they will no doubt do. However, contracts are less strong than IPRs. Since databases of created data will almost always remain unprotected, information monopolies will be rare. Users will generally have a way of finding elsewhere the same information as the one included in the database if the price of accessing the database is too high or access is denied (but this will rarely happen since there will be competition in the market).

Conclusion

Therefore, the right is not as bad as it first seems, once this big gap in the protection is revealed. But it still needs a lot of refining. The scarcity of exceptions and the renewal of the term contradict all intellectual property rights’ paradigms. Also it does not seem right to protect databases made of tangible objects. These need to be addressed at legislative level as it will take time, if the opportunity ever comes again, to have it clarified by the ECJ. May this short note be a call for the European authorities to launch a revision of the Directive in this direction.\footnote{Note that article 16(3) of the Directive forces the European Commission to submit a report on the application of the Directive every three years after the implementation deadline.}

News

New Think Tank is Launched – INTERTIC: the International Think-Tank on Innovation and Competition

INTERTIC, the International Think-tank on Innovation and Competition (website www.intertic.org), is a new organisation coordinating research on innovation and competition founded by Prof. Federico Etro from the University of Milan and other international economists from European and American academic institutions and think-tanks.

The purpose is to coordinate and promote research by a group of independent economists working on the subjects of innovation, competition, market structure, protection of intellectual property rights, industrial policy, anti-trust analysis and other economic themes of relevance to the understanding of markets, especially in the New Economy.

The aim is to become a point of reference for academic and professional economists, students, researchers from related fields, policymakers and journalists interested in these issues and in the promotion of free market ideals in the New Economy.

The INTERTIC website includes:

Research Section focused on the academic research on theoretical and empirical aspects of relevant issues concerning innovation, competition and the New Industrial Organization, that is the industrial economics and policy for the New Economy;

Policy Section focused on the policy-oriented research which will be useful
for policymakers, journalists and anybody interested in rigorous studies at a non technical level concerning innovation and competition.

Media Briefing Section focuses on short commentaries on recently debated issues mainly aimed for journalists.

The Scientific Board of Intertic includes K. Zigic (CERGE, Prague), S. Martin (Purdue University, USA), I. Pottebaum (MIT, USA) J. Zeira (Hebrew University, Jerusalem), and other international economists.

The main subjects of research and debate include: Analysis of competitive and oligopolistic market structures; Analysis of market structures characterised by relevant investments in innovation and network effects; Analysis of specific industries in the New Economy; Anti-trust analysis for the Old Economy and for the New Economy; Industrial policies for innovation; protection of Intellectual Property Rights; Relationship between interoperability issues and protection of IPRs with particular reference to the software industry; Industrial policy for the New Economy.