Popping Patented Pills: Europe and a Decade’s Dose of TRIPS

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POPPING PATENTED PILLS: EUROPE AND A DECADE’S DOSE OF TRIPs

-- David Vaver* and Shamnad Basheer**

This paper considers some features of Europe’s approach to medicine, public health and patents as it has developed during the decade since TRIPs came into force. It then reviews what rights users have in relation to such patents and what duties right holders may owe users. The following issues are discussed:

1. How patents on medicines are viewed in Europe;
2. How TRIPs has affected European law;
3. How bilateral agreements since TRIPs have affected Europe;
4. How user rights should be viewed under TRIPs;
5. Whether patents in the public health field are a special case.

1. How patents on medicines are viewed in Europe

Some political and economic facts influence Europe’s approach to drug patenting. First, pharmaceuticals are big business. The largest pharmaceutical businesses after those of the US and Japan are in Germany, France and the UK. The UK alone sells 7% of the world’s pharmaceuticals, is the third largest direct exporter, and is said to account for 10% of world pharmaceutical R&D expenditure. The business is heavily concentrated in relatively few companies, and the trend towards greater concentration has continued in the decade since TRIPs. A penumbra of smaller entities is also involved in researching and producing new products, especially in biotechnologies.

Secondly, general European policy is to make health care available to all or most of the populace regardless of ability to pay. The state, which carries a large part of the cost of supplying medicine and health care, is keen on keeping drug prices low. European policy therefore involves finding the right trade-off between two competing goals: encouraging the drug industry to innovate through the lure of the high profits patents can generate, while keeping health care costs socially affordable.

Thirdly, the standard story driving European policy is that, without patent laws, the pharmaceutical industries could not survive in their present form; we should get little research into new medicine, jobs would be lost, public health would suffer, so everyone would be worse off. Whatever the truth of this tale, the patent laws have

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1 By “Europe”, we mean roughly members of the European Economic Area (i.e., European Union member states and members of the European Free Trade Association – currently Norway, Iceland and Lichtenstein) and members of the European Patent Organisation.

certainly shaped the pharmaceutical industry, and it in turn has shaped the laws of which it is a major beneficiary.

It was largely big pharma that pushed the US, EU and Japan to include patent provisions in TRIPs, and big pharma was largely responsible for the contents. It continues to influence how TRIPs is enforced and renegotiated. The US trade representative sounds little different from a drug company executive when he or she negotiates, issues press statements, or puts countries on dreaded “watch lists”. Big pharma is also a major force behind the strategy of bilateral free trade agreements that include patent provisions designed to keep the generic drug industry off balance.

European governments have largely accepted the arguments of big pharma that not only are patents necessary to encourage the production of better medicines, but that those patents must also be strong. They must give their holders firm control over the research, development, production and marketing of their new medicines nationally and internationally. Ever more and better medicines will thus be produced. The conservation movement’s motto that “less is more” is not big pharma’s – unless “less” means (i) less governmental interference in how pharma runs its business, and (ii) less rights for others to access patented inventions.

Despite consumer and public policy group pressure, the story just sketched seems to reflect official EU policy: witness the post-TRIPs European directive on patenting biotechnological inventions (“the biotech directive”). This 1998 instrument, itself the product of over a decade of bitter wrangling, presents the argument for strong patents in its recitals. Although the directive deals only with biotechnologies, the substitution of “medicines” for “biotechnology” would still accurately reflect European thinking:

Biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community’s industrial development. In particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable. Effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology. …

The development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world. The patent system should likewise be used to encourage research in these fields. International procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted. …

Substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health [and] safety…

Significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced... Consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system.

Since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or ‘orphan’

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4 The recitals form more than the background story of the directive. They influence how the directive and the national laws made in its shadow are interpreted.
diseases, the Community and the Member States have a duty to respond adequately to this problem.\textsuperscript{5}

One finds in these paragraphs the \textit{yin} and \textit{yang} of European drug patenting policy pre- and post-TRIPs, including:

- strong patents for the industry;
- regulation to further public health and safety;
- an eye to exports;
- an eye to helping health care in developing countries.

Not all these aspirations have been fully realized in practice. The goals of regulating drugs and helping developing (including least developed) countries have taken a back seat to strong patents, exports, and licences for those who can afford them.

For the pharmaceutical industry, perhaps two out of four is not bad; for public policy, it is no passing grade. As a highly profitable industry, big pharma is an aggressive lobbyist, litigator and strategist. Whatever tactics achieve the ultimate goal of maximizing profits are employed. When it comes to drug approvals, the transaction costs of securing country-by-country approval are trotted out as an unreasonable burden that must be avoided. Here big pharma has pushed for and largely succeeded in getting Europe-wide recognition of a single central approval. When it comes to drug pricing, however, the tactic of “divide and conquer” operates. Perversely, poorer countries typically end up paying more than richer countries. So in 2005 a month’s supply of Prozac cost €18.49 in Italy and €40.48 in Slovakia.\textsuperscript{6} The obvious remedy is a single centralized European purchasing agency. Yet that prescription is not pushed by big pharma, for the transaction costs of negotiating country by country are as nothing compared to the gains derivable from territorial price discrimination. Meanwhile Prozac is less available in Slovakia than in Italy. If one makes the large assumption that prescribing more Prozac is on balance a good thing,\textsuperscript{7} the prospect of more depressed Slovaks and more elated Italians seems suboptimal public policy.

2. How TRIPs has affected European law

(a) Changes to EU or EPC law

European Patent Convention (EPC) members and the EU have taken various measures to implement TRIPs. Thus, the EPC was updated in 2000 to ensure, \textit{inter alia}, TRIPs compliance.\textsuperscript{8} The definition of invention was amended to include all fields of technology.\textsuperscript{9} What exactly falls within the concept of “technology”

\textsuperscript{5} We have removed the numbering and “whereases” and changed the punctuation to let the recitals flow as prose. The relevant recitals quoted are 1, 2, 3, 11, 14, 17, and 18.


\textsuperscript{7} Cf. R. Moynihan & A. Cassels, \textit{Selling Sickness: How Drug Companies are Turning Us All into Patients} (2005).

\textsuperscript{8} Act Revising the Convention on the Grant of European Patents (Munich, 29 November 2000) (“EPC 2000”). The EPC 2000 will take effect by December 2007 since the necessary 15 states have now ratified it.

\textsuperscript{9} As required by TRIPs, art. 27.1.
nevertheless remains uncertain. Presumably some deference will be paid to national or regional practices in areas such as genetics.

EPC 2000 also included a subtle but significant change in the provision under which applications are monitored for compliance with principles of morality or \textit{ordre public}. Previously applications could be rejected if “exploitation” or “publication” of the invention would contravene morality or \textit{ordre public}. Now rejection can occur only if “commercial exploitation” of the invention would so contravene – a less irksome barrier for applicants.\footnote{So EPC 1973 art. 53(a) monitors “inventions the \textit{publication} or exploitation of which would be contrary to \textit{ordre public} or morality”; EPC 2000 art. 53(a) monitors only “inventions the \textit{commercial exploitation} of which would be contrary to \textit{ordre public} or morality…” (our italics). The change, following TRIPs art. 27.2, was already reflected by 1998 in art. 6.1 of the biotech directive, above note 3. See further, text below accompanying n. 63 ff.}

Another, less substantive, change is the switching of categories for the exception disallowing patenting of methods of medical treatment. Previously, the EPC categorized such inventions as unsusceptible of industrial application; now they are unpatentable \textit{tout court}.\footnote{The “method of medical treatment” exclusion in EPC 1973 art. 52(4) is shifted to EPC 2000 art. 53(c).} Mirroring TRIPs, the change implies that exclusion is for public health policy reasons.\footnote{Case No. G0001/04, \textit{Diagnostic Methods} (Enlarged EPO Bd. App., 15 Dec. 2005), para. 10.} Countries which treat medicine as a business more than a social service may feel more relaxed with this placebo.

European directives to harmonize patenting standards for biotechnologies and civil remedies for intellectual property infringement were issued in 1998 and 2004 respectively.\footnote{Biotech directive, above note 3; directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, OJ L 157/45. For criticism of the latter directive, see W.R. Cornish \textit{et al.}, “Procedures and Remedies for Enforcing IPRs: the EU Commission’s Proposed Directive” [2003] 10 E.I.P.R. 447.} Apart from ensuring TRIPs compliance, the avowed object was to reduce distortions in trade and promote the smooth operation of the internal market.

Implementation of the biotech directive proved particularly controversial. While the European Patent Office (EPO) quickly moved to make the standards of the biotech directive equally the standards of the EPC, a significant number of member states remained unhappy with the concept of patenting life forms and continued to resist the directive. The European court of justice dismissed a constitutional challenge to the EU’s competence to pass such a law\footnote{Case C-377/98, \textit{Netherlands v. Parliament and Council} [2001] E.C.R. I-7079. The challenge was initiated by the Netherlands and supported by Norway and Italy.} but resisting states were slow to respond. An exasperated European commission finally brought default proceedings against ten member states. The ECJ quickly found the defendants to be in default. The offenders eventually fell into line, except for Latvia and Luxembourg, which

\textit{See Re CFPH LLC’s Patent Applications} [2005] EWHC 1589 (Pat. Ct.): “Many have tried to frame an acceptable definition [of technology], but to the best of my knowledge none have succeeded. It is like the equally vexing question, “What is Art?” The hard truth is this: concepts of that sort have no existence, and words of that sort have no meaning, except by human convention; but human beings are hopelessly in disagreement at the margin.”
continued to procrastinate. National implementation has anyway not been uniform, so that the overall harmonizing purpose of the directive has not been achieved.

Another EU directive in 2004 to regulate drug marketing has some impact on intellectual property rights. First, it states that drug testing by third parties during the patent term for the purpose of seeking regulatory marketing approval does not infringe any patent on the drug. This feature represents a sharp volte-face in EU policy. Pushed by its big pharma clients, the EU had in 1999 brought a TRIPs complaint against a similar provision in Canadian law, and also against Canada’s allied provision permitting generic companies to make and stockpile drugs for the last 6 months of a patent to enable marketing immediately the patent expired. A WTO panel ruled the stockpiling provision violated TRIPs but testing for regulatory purposes did not.

The decision on testing was hardly surprising. After all, German courts had concluded that the exception in German patent law covering experiments (mirroring a Community Patent Convention provision) allowed generic companies to conduct such trials, and US law had contained a similar provision (the so-called Bolar exception) for some years. So too had the laws of a number of states that joined the enlarged EU in 2004. The change in EU policy means that the generic industry can now test anywhere within the EU without having to shop for a friendly state or go offshore.

Secondly, the 2004 directive established a standardized 10-year term of exclusive data protection for newly approved pharmaceutical products – effectively a new genus of intellectual property right. This provision implemented the TRIPs requirement that undisclosed data submitted for pharmaceutical marketing be protected against unfair commercial use. Its essence is captured in an “8+2+1” formula:

(i) A generic applicant can file for approval on the 8th anniversary of the patented product’s approval but will not get authorization until 2 years later, on the 10th anniversary.

(ii) Pharmaceutical companies can get another year’s protection for a new therapeutic indication having a “significant clinical benefit in

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18 Thus, France and Germany, neither of which seems keen on gene patents, provide that patents on gene sequences are limited to the specific disclosed function of the gene, not all functions: French Intellectual Property code, arts. L 611-18 and L 613-2-1, inserted on 6 August 2004; German law on implementation of the biotech directive (BGBl Nr. 6/2005, p. 146), in force as from 28 February 2005. This limitation does not apply generally to product patents.


22 Roche Products Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858, 863 (Fed. Cir. 1984), held that the experimental use exception under US common law was not broad enough to let Bolar develop and submit a generic product for regulatory approval before the expiry of Roche’s patent. In the US, the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585) introduced an exception overruling Bolar.

23 TRIPs, art. 39.3. The level of protection for such data is contentious, with developing countries seeking a higher threshold than required in developed countries.
comparison with existing therapies” if the indication is gained within the first 8 years of marketing a product.\(^{24}\)

Thirdly, the sort of strategy for which AstraZeneca was recently caught out, where the initial marketing authorisation is changed to hamper generic or parallel trade competition,\(^{25}\) is targeted by a provision that the initial authorisation for a product covers any additional strengths, pharmaceutical forms, administration routes and presentations, including variations and extensions.

Finally, a directive proposed in 2005 sought to criminalize intentional large-scale intellectual property infringements as part of the fight against counterfeits, including medicines.\(^{26}\) The proposal went beyond TRIPs requirements and included patent infringements.\(^{27}\) This last feature drew criticism from a variety of patent-sensitive industries including generic drug makers, who saw in it one more stick with which big pharma, could, with little cost or risk to itself, beat them mercilessly.\(^{28}\) The proposal was withdrawn in December 2005, partly prompted by a ruling from the European court of justice that EU power over criminal law was less than plenary.\(^{29}\) The return of a revised proposal, presumably sans patents, was promised for early 2006.\(^{30}\)

(b) TRIPs and the European Patent Convention

One area where Europe has fallen short on TRIPs is in that treaty’s relationship with the EPC. All EU and EFTA states belong, along with others, to the EPC, but the EPC is not an instrument of the European Union. The question has therefore arisen whether EPC administrators and tribunals are bound by TRIPs. The quick and obvious answer would be, surely yes. Those members of the World Trade Organisation who are also EPC members must surely owe a WTO obligation to ensure that the EPC is TRIPs compliant.

The quick and obvious answer is nevertheless wrong. Unlike the EU and its member states, neither the European Patent Organisation nor its Office, is a WTO

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24 The old EU directive, now replaced by 2004/27/EC, provided 10 years’ data exclusivity for products subject to the EMEA centralized procedure, and 6 to 10 years for products going through member states’ mutual recognition procedures, as each member state decided. National discretion is now eliminated to avoid disparity: “What the EU Pharmaceutical Review Legislation Means for the New Member States”, EU Bulletin (Hogan and Hartson, 1 March 2005).

25 In June 2005, the European competition commission found AstraZeneca had abused its dominant position by obtaining longer patent terms – so-called supplementary protection certificates – from national patent authorities by deception. It had also misused rules and procedures applied by national medicines agencies responsible for issuing market authorisations, by selectively deregistering authorisations for Losec capsules in Denmark, Norway and Sweden to block or delay entry by generic firms and parallel traders. A fine of €60 million was imposed – and duly appealed: EU press release, “Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs” (IP/05/737, 15 June 2005).


27 TRIPs art. 61 requires criminal proceedings to apply “at least in cases of wilful trademark counterfeiting or copyright piracy”.


29 Case C-176/03, Commission v. Council (13 September 2005), holding that the Community legislator may enact criminal sanctions only to the extent necessary to ensure compliance with Community rules and regulations.

member. Consequently, an enlarged EPO board of appeal ruled in 2004 that the EPO can ignore TRIPs and, indeed, any other treaty not specifically mentioned in the EPC.31 The case involved a drug patent applicant who claimed priority from a filing in India at a time when India was a member of the WTO but not the Paris Convention. TRIPs requires WTO members to recognize the Paris Convention, including its provisions on priority dates. Yet the board of appeal held that the EPC laid down a complete code of priority rules. Only filings in Paris Convention, not WTO, states were mentioned. Saying the EPO was bound only by the language of the EPC and not TRIPs, the board rejected the priority claim.

While the revised version of the EPC in 2000 corrects this anomaly by including priority claims based on filings in WTO countries,32 the question remains whether or not European states are in breach of their TRIPs obligations in this respect until the revised EPC comes into force in 2007. Is it enough for EU members to state that their national laws allow WTO nationals priority, while denying them the full benefits of EPC filings?

(c) Europe and the Doha declaration

Pharmaceuticals and public health are not just issues for Europe or developing countries. World health is involved. Consider the continuing saga of the AIDS epidemic in Africa, and more recently the outbreak of bird flu that may, it is feared, mutate into a virus that infects humans. Governments around the world are taking emergency measures, including the stockpiling of anti-flu drugs. A patented antiviral drug controlled by Roche is in demand after having lain dormant for years. Roche has been hesitating to license others willing to take up the slack. The matter may yet resolve itself but meanwhile poor nations cried foul. One knew trouble was afoot when the drug was being bid for on eBay at up to 6 times its usual retail price.33

If indeed there is a pending emergency and not one cooked up by the media (at time of writing, it is still hard to tell where the truth lies), then what should have been done seems reasonably clear. An emergency should not have to be played out according to the whims of the board of directors or licensing department of a right holder. The rule should be “make and use now, pay later.” In the daily world, that’s called buying on credit, and every seller who has plenty on stock is happy to let anybody with a bank account take goods on their promise to pay. In the world of patent law, however, that’s called infringement, and any patentee who cannot supply the market can refuse to allow others to make “his” product, however much cash the intending buyer offers.

The fear of hold-up is one reason why TRIPs allows compulsory licensing and “public non-commercial use” of patents,34 and why most nations – including those of

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31 AstraZeneca’s Appn., G 2/02 & 3/02 (Enlarged EPO Bd. App., 26 April 2004). The decision suggests the EPO is also not bound by the European Convention of Human Rights 1950 – an important point, given the recent ruling that an unregistered trade mark is not protected as “property” under ECHR art. 1: Affaire Anheuser-Busch Inc. c. Portugal (No. 73049/01, Eur. Ct. HR, 11 Oct. 2005). A patent application, at least until grant, seems to be in the same situation.
32 EPC 2000, art. 87.
34 TRIPs, art. 31(b).
Europe – have these palliatives in their national laws.\textsuperscript{35} In an emergency, national laws may follow the “use now, pay later” principle. The United States has long had such a law on its books,\textsuperscript{36} and its threatened use in 2001 during the anthrax scare helped make treatment become available more quickly and cheaply than the patent holder initially seemed willing to do.

The US law is not confined to emergencies. Nor is the law of some EU states. For example, the UK government can authorize anyone to work a patent “for the services of the Crown”, a broad term that includes “the production or supply of specified drugs and medicines”.\textsuperscript{37} The government must compensate the right holder for losses flowing from not being awarded the contract to make or supply. But if the right holder had no existing capacity to take on the contract had it been offered, the compensation awarded is likely zero.\textsuperscript{38} This rule mirrors the general law of damages under which the victim of the breach of an obligation recovers only his actual, not his notional loss. Presumably the rule complies with the TRIPs obligation that patent holders must have “adequate remuneration” for a “public non-commercial use”.\textsuperscript{39} Adequate remuneration does not mean windfalls from the public purse.

The problem for many developing countries is a lack of capacity to make their own drugs, even (possibly especially) in an emergency; so they must rely on imports. But TRIPs forbids compulsory or governmental use that is not “predominantly for the supply of the domestic market of the Member authorising such use”.\textsuperscript{40} So the UK could not authorize working a patent predominantly to export a needed drug to a developing state, even in an emergency. A developing state could authorize the import of drugs for an emergency or public non-commercial use, but the drugs could come only from a state where the drug was unpatented or licensed for export by the local patent holder, or where stocks were available as a byproduct of compulsory licensing or public working for domestic use.

The difficulties in obtaining patented medicines at a reasonable price were highlighted in 2001 when the compulsory licensing schemes of South Africa\textsuperscript{41} and Brazil\textsuperscript{42} were challenged in legal proceedings. Both cases collapsed in the face of intense international pressure, and were one reason for the Doha ministerial
declaration on TRIPs and public health in 2001. The declaration was intended to make it easier for generic drugs to be manufactured and exported at low prices to the countries that desperately needed them.

It took another two years for an interim mechanism to emerge to implement the Doha declaration. In August 2003, the EU helped broker a deal under which the WTO general council waived the TRIPs requirement limiting the import of patented drugs from offshore generic companies, subject to strict conditions to discourage arbitrage. The waiver ran in favour of least-developed countries, and other nations that advised the WTO they wished to take advantage of it. Recently, in the run up to the WTO ministerial conference in Hong Kong, members approved changes that would convert this temporary waiver into a permanent TRIPs amendment.

Individual European nations could have taken advantage of this waiver by passing their own laws to allow quick export of cheap drugs to needy states. Competition among states would have likely produced the most effective law. Instead, the European commission proposed an implementing regulation to supplant national initiatives. The initial proposal made the process of getting a compulsory licence so unattractive that few sane generic suppliers would likely have used it. Fortunately, several rounds of amendment removed many objectionable features, and the European parliament duly approved the proposal in December 2005.

The regulation has its good points. It covers exports to all poor countries, whether members of the WTO or not. Normally, before filing for a licence, the applicant must submit evidence of unsuccessful negotiations with the right holder within the past 30 days; but this requirement does not apply to cases of national emergency, extreme urgency and “public non-commercial use”. Moreover, a vague duty to remunerate the right holder adequately has been changed to a liability for a maximum 4% of the total price paid by or for the importing country, a figure that

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43 Declaration on the TRIPS Agreement and Public Health (WTO Doc WT/MIN(01)/DEC/2 of 20 November 2001).
46 This will be formally incorporated into TRIPs if two thirds of WTO members ratify the change by 1 December 2007. The waiver remains in force until then:
www.wto.org/english/news_e/news05_e/trips_decision_e.doc.
48 E.g., contrary to the Doha waiver, the original proposal required the intending applicant to negotiate with the right holder before filing a licence application, even where the WTO member had declared “a situation of national emergency or other circumstances of extreme urgency.”
49 Covered non-WTO countries are those appearing on the OECD Development Assistance Committee’s list and having an annual per capita GDP of under SUS 745: Proposal, above n. 47, art. 4(c).
46 Ibid., art. 7(2).
50 Ibid., art. 9(a). Whether this sum should be adjusted where multiple patents or right-holders are involved is unclear.
may well become the rule of thumb in the ordinary compulsory licensing case. To benefit fully from these provisions, importing states will no doubt ensure their laws include broad governmental use powers like those of the US or UK.

The problems with the scheme are mainly procedural. It is meant to encourage swift and easy licensing. That object could have been attained by a “licence of right” scheme, where the application is granted virtually automatically on provision of the bare minima required by the WTO waiver. Any appeal would not affect continuing manufacture or supply. But the regulation has not taken this route. The model adopted is the typical national compulsory licensing scheme. After application, right holders can comment and provide relevant information, and applicants can correct errors. “Any decision” of the tribunal and any “disputes concerning compliance with the conditions of the licence” can then be appealed under national law. Appeals may be given “a suspensory effect.”

The standard theory behind a scheme of this sort is that few will need to use it in practice: right holders will prefer to negotiate their own deals rather than be stuck as a compulsory licensor under imposed terms. The problem is that this sanguine theory rarely worked in practice, and especially where pharmaceuticals were involved. In the heady pre-TRIPs days of compulsory licensing in Canada, pharmaceutical companies found it more profitable to oppose virtually every application and appeal or seek judicial review, often several times, on every possible and sometimes impossible point. Delay was the name of the game. The applicant might eventually be worn down by rising costs and passage of time, and in any event the patentee got to enjoy its monopoly fully for a few more months or years while the application was tied up in the legal system.

This scenario may not reoccur under the new scheme, but chances are quite high that it will. Other countries -- Canada, India and China -- have set up their own regimes. The country with the most efficient scheme may turn out to be the major exporter of this class of generic medicine.

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52 Ibid., art. 8.9 (a). The 4% figure (of the net selling price of the drug in dosage form) was long the “rule of thumb” in Canada for compulsory licensing of patented medicines before the scheme was abolished in the early 1990s and replaced by “light touch” price review: e.g., Eli Lilly & Co. v. Canada (Commissioner of Patents) (1992) 42 C.P.R.(3d) 34 (Fed. Ct.).
53 Ibid., arts. 5a & 9.
54 Ibid., art. 15.
55 See Cameron & Berger, above n. 41 at 446, noting a South African example where the threat of compulsory licensing caused a drug company to issue a ‘voluntary’ licence. They also note that all four cases where a court was asked to grant a compulsory licence failed: “if the regulatory framework was easier (and less risky) to use there seems little doubt that such licences would more readily be sought” (ibid.).
57 For a recent Canadian example, see Merck & Co. Inc. v. Brantford Chemicals Inc. 2004 FC 516 at § 21, where, in dismissing Merck’s attempts before both the patent office and the federal court to prevent a compulsory licence request from being served on it, the court observed: “it is obvious that the original motion and this appeal were brought for delay purposes and that Merck never had a realistic chance to succeed on either of its arguments.” Undeterred, Merck appealed again, unsuccessfully: Merck & Co. Inc. v. Brantford Chemicals Inc. 2005 FCA 48 (Fed. C.A.).
58 So has Norway, but whether or not its wings will be clipped by the EU regulation remains to be seen.
3. How bilateral agreements since TRIPs have affected Europe

Europe does not presently compel other states to increase the level of patent rights beyond TRIPs, in the way the US is acting. Rather, its policy seems to be to ensure that the domestic law of its trading partners is framed to comply with most recent international norms: TRIPs of course, but also the Paris convention and the patent cooperation treaty. For countries wanting to join the EU, the early adoption of laws that mirror the EU’s is a sort of pre-entrance test.

There is a subtlety to this stand-back policy. The US is left to do the running on raising the patent hurdles in free trade agreements as part of its overall strategy to raise global intellectual property levels of protection. One purpose is to stack the deck even higher in favour of big pharma in its never-ending war against generic imitators, wherever they are and wherever they market or export their products.

The US may negotiate the national and regional free trade agreements bilaterally, but the agreements also benefit Europe, including foreign companies with European bases.

Consider the issue of what categories of inventions are patentable. Once a new standard of patentability becomes part of domestic law and is extended to that country’s nationals because of a bilateral trade agreement, that country must, under the national treatment requirements of the WTO agreement or Paris convention, also extend that standard to the nationals of all other WTO and Paris Convention states – including European states. At some point, the standard may become so prevalent as to become a new norm of international law. The stage is then set for the inclusion of such a term in the next round of TRIPs negotiations, causing non-observance to become subject to sanction under TRIPs disputes resolution procedures.

How bilateralism affects international standards may be examined by considering the question of patentable subject-matter – what kind of inventions are patentable – a little more closely.

The US plainly regards the exceptions to patentability contained in the EPC as a piece of European quirkiness that does not belong in a “proper” patent regime – i.e., a regime that looks like its own. So, when negotiating a free trade agreement, the US starts by insisting that all “technology” be potentially patentable (as TRIPs art. 27.1 provides) and then goes on to demand the elimination of all exceptions that TRIPs allows states to make to this general provision. The TRIPs provisions are now what allows EPC states, the EU and its members to continue comparable exceptions in the EPC, in EU directives (such as the biotech directive) and in national laws.

The most important medical exceptions are of course those which allow “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” to be excluded from patentability (“the medical exception”). Of lesser, but still some, importance is the “public order” provision allowing members to exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

60 TRIPs, arts. 27.2 & 27.3(a), largely mirroring EPC arts. 52(4) & 53.
61 TRIPs, art. 27.3(a).
62 TRIPS, art. 27.2.
In the US-Chile Free Trade Agreement (FTA) of 2003, one finds that Chile can no longer carve out these exceptions from patentability. The Agreement requires all technology to be patentable but it also eliminates the power of either party to include a medical or public order exception.63

At first sight, the US-Australia FTA of 2004 is different: the medical and public order exceptions can continue.64 But analysis reveals this “concession” to be no concession at all. Before the FTA, Australian courts had already signalled their intention to allow the patenting of virtually anything despite an exception that allowed refusal of patents that would be “generally inconvenient.” This language, a hangover from the first English patent law of 1624, was rendered almost meaningless by a 2001 Australian court decision which allowed methods of medical treatment to be patented for the first time.65 The court seemed hard pressed to think of anything that would be too “inconvenient” to be patented.

Clearly, US negotiators gambled that the FTA would not prompt Australia to reverse the course its courts had taken with overt approval from the usual pro-patenting suspects. The negotiators gambled right. Apart from retaining its ban on patenting human beings and biological processes for human generation, Australia did not amend its patent law to take advantage of any of the TRIPs exceptions from patentability.

Consider also the US-Central American FTA,66 where a patent owner can have the term of the patent extended where the grant was unreasonably delayed. Five years after application or three years after a request for examination is treated as an unreasonable period except where the patent owner causes the delay.67 A pharmaceutical patent may also be extended where the need to get marketing approval results in an “unreasonable curtailment” of the drug’s first commercial marketing.68 Those provisions are familiar in both the US and Europe, but none is mandated by TRIPs or any other international treaty.

Three points may be made on the inclusion of TRIPs-plus standards in bilateral agreements as they affect relations between Europe and other states:

(1) Different standards can create inequality, and here they do, at least at the margin. Europeans can patent in TRIPs-plus nations what they may be unable to patent at home. Conversely, TRIPs-plus nationals may be unable to patent in Europe what they can patent at home. Europeans can also freely imitate and use in Europe and elsewhere whatever is disclosed in such TRIPs-plus patents. If that technology is developed to produce TRIPs-qualifying technology, it may be patented in Europe without the foreign TRIPs-plus patentee’s consent and without compensating him.

The small piece of good news here for TRIPs-plus countries comes from the course of EPO decisions on the patentability exceptions. The EPO cannot legally

63 US-Chile FTA 2003, art. 17.9.1.
64 US-Australia FTA 2004, art. 17.9.2.
67 Ibid., art. 15.9.6(a).
68 Ibid., art. 15.9.6(b). So if it takes 3 years to get a drug approved, 3 years need not automatically be added to the patent term. Only unnecessary delays should result in an “unreasonable” curtailment. What delays are unnecessary and unreasonable will prove an interesting question.
adopt the maxim endorsed by the US supreme court, and currently enthusiastically followed by the US patent office, that “everything under the sun that is made by man” is patentable – a test that has led to the patenting of computer programs, business methods and ideas, including most recently a method of calculating the pay of company executives, even if the sum can be done on one’s fingers instead of a computer.69 As one US text says “[i]t is hardly an exaggeration to say that under current law, if you can name it, you can claim it.”70 Only the presence of the TRIPs exceptions in the EPC prevents the EPO from directly parroting the US approach.

But the EPO is doing the next best thing. It has implicitly adopted the maxim that “almost anything under the sun that is made by man” is patentable.71 This legerdemain is accomplished by interpreting the EPC exceptions very narrowly.

Take the provision in EPC art. 52(4) that “diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application”. EPO decisions indicate that if the method is only part of making a diagnosis, in that it produces only interim results and not an actual diagnosis, or if it is performed outside the human body (e.g., on blood samples taken from the body), then it is outside the exception and patentable.72 That niggardly approach is applied to all the exceptions – except exceptions to exceptions. So, for example, the exception in EPC art. 54(5) to the patentability exception in EPC art. 52(4), allowing patenting of any substance or composition for use in a diagnostic or medical method, is interpreted broadly.73 It has been said that “[a]n exception to an exception is apt to produce messy jurisprudence”;74 and so it does here.

The result nevertheless is that in practice only a relatively thin slice of material is not patentable in Europe where it would be patentable in the US.

(2) A larger piece of good news for nations that wish to maintain TRIPs exceptions to patentability is that they should be able to implement and apply them more broadly than does the EPO. TRIPs does not require its exceptions to be read as narrowly as the EPO reads the EPC counterparts. For example, TRIPs should not prevent states from excluding from patentability both partial and entire diagnoses, whether performed on or outside the human body, whatever view the EPO may eventually take on the issue.

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69 Ex p. Lundgren, 76 USPQ 2d 1385 (PTO BAI 2005).
71 The technology must of course also satisfy the other standard criteria that it be new and non-obvious and involve a technical contribution.
73 Method of Administration of IGF-1/Genentech Inc., Case No. T 1020/03-3.3.4 (EPO Tech. Bd. App., 29 October 2004). The claims were for the use of insulin-like growth factor (IGF-1) in preparing a medicament to be administered to mammals “so as to sustain its biological response in the treatment of a chronic disorder in the mammal” and a treatment regime consisting of intermittent periods of administration of a “therapeutically effective” amount of IGF-1. The board allowed the patenting of second medical use claims directed to the use of a composition for manufacture of a medicament for a specified new and inventive therapeutic application, where the novelty of the application might lie only in the dose to be used or the manner of application.
(3) A state that cannot, under a TRIPs-plus treaty, exclude material for medical and public order grounds may nevertheless be able to exclude it for other reasons. US courts until the late 20th century interpreted the “utility” that is required for a US patent to include “social” utility. Patent laws were not passed to encourage socially useless or detrimental inventions. The examples given in early 19th century US case law included “a new invention to poison people, or to promote debauchery, or to facilitate private assassination.” These inventions and a miscellany of others, such as inventions promoting gambling or deceptive practices, remained unpatentable as late as 1977.

An invention to poison people should be considered unpatentable as contrary to ordre public or morality under the EPC. A nation should be able legally to adopt a definition of utility that would exclude such an invention as “not useful” – that is, unless a TRIPs-plus agreement positively forbids this or redefines utility exhaustively.

Whether a state could go further and bring other medical or public order exceptions under “utility” is unclear. Thus, New Zealand’s exception to patentability – the “generally inconvenient” ground also found in Australia – has been interpreted, contrary to the position taken by Australian courts, to exclude methods of medical treatment. The same result could follow to the extent concepts of “general inconvenience” and inutility overlap, as ontologically and teleologically they may.

4. How user rights should be viewed under TRIPs

In a useful article, Professor Correa lists what he calls “exceptions” or “exclusions” to patent rights that by international practice seem acceptable under TRIPs art. 30.

Those provisions, which are all important in the public health context, include:

- acts done privately and on a non-commercial scale, or for a non-commercial purpose;
- use of the invention for research;
- use of the invention for teaching purposes;
- experimentation on the invention to test or improve on it;
- preparation of medicines under individual prescriptions;

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76 The practice was changed by Re Murphy, 200 U.S.P.Q. 801 (PTO Bd. App. 1977). The US courts have continued dismantling this wide concept of utility. So a patent on a device that could be used to deceive consumers was allowed because the device might not be so used in fact; possible police offences should not trouble the minds of patent office examiners: Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999): “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.”

77 E.g., the definition of utility in art. 17.9.13 of the US-Australian FTA of 2004 does not appear to be exhaustive.


79 TRIPs art. 30 reads: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”
- experiments made for the purposes of seeking regulatory approval for the marketing of a product after the expiration of the patent;
- use of the invention by a third party that had used it *bona fide* before the date of application of the patent.  

The only contentious point about this list is the description used for it: “exceptions” or “exclusions”. The usage is common enough; indeed the marginal note to TRIPs article 30 calls these permitted activities “Exceptions to Rights Conferred”. Yet the usage is potentially mischievous and should be avoided.

Nothing in TRIPs eliminates the basic idea that patents involve a balance of rights between patent holders and the public. Nor does TRIPs affirm the out-dated idea that patents are natural rights. Most nations accept that patents are there to encourage innovation and disseminate practical knowledge. Rewarding inventors, while preserving a lively public domain for the public – non-inventors – to browse and think (and perhaps even also become inventors), is a means to that end.

TRIPs itself affirms the notion of balance in article 7; intellectual property rights should:

> contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The US similarly maintains in its constitution, in a provision that no treaty can remove or modify, that patents are there to “promote the Progress of Science and useful Arts”.  

Intellectual property law is not just the law of intellectual property right holders; it must take into account, and may be subject to, other imperatives. Thus, the biotech directive provides in recital 16:

> Patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.

Another recital recalls that rights and obligations recognized by the European Convention on Human Rights 1950 and by national constitutional traditions must be respected, as must principles of *ordre public* and morality. Human rights may adjust to intellectual property in some respects, but so must intellectual property rights adjust to them. TRIPs art. 7 is one way to achieve this. After all, TRIPs is just a trade treaty. Trade is not superior to everything else. Crudely put: a dead person needs no rights, least of all a right to trade. To have and to exercise a right to trade presupposes the existence and enforcement of other enabling rights.

How then is the balance of rights between intellectual property holders and users to be conceptually established? Certainly not by referring to the activities of users as “exceptions” or “exclusions”, and proceeding to interpret “rights” broadly and “exceptions” narrowly. Canadian jurisprudence suggests an answer. Canada is a significant jurisdiction particularly because it embraces both common law and civilian

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81 US Const., art. 1(8), cl. 8.
82 Biotech directive, above note 3, recitals 43, 37 and 39.
traditions, including those of intellectual property. In a 2004 decision involving copyright, the Canadian supreme court unanimously declined to analyze the right of users to deal fairly with copyright works as an exception. Instead it preferred a concept of “user rights” that formed an integral part of the balance that produced the copyright system. For what balance is achieved by weighing “rights” against “exceptions”?

Two citations from the court’s judgment indicate the approach. The first is its approval of a passage from one of its earlier decisions:

The Copyright Act is usually presented as a balance between promoting the public interest in the encouragement and dissemination of works of the arts and intellect and obtaining a just reward for the creator . . .The proper balance among these and other public policy objectives lies not only in recognizing the creator's rights but in giving due weight to their limited nature. In interpreting the Copyright Act, courts should strive to maintain an appropriate balance between these two goals.

The second passage applies this balance:

Before reviewing the scope of the fair dealing exception under the Copyright Act, it is important to clarify some general considerations about exceptions to copyright infringement. Procedurally, a defendant is required to prove that his or her dealing with a work has been fair; however, the fair dealing exception is perhaps more properly understood as an integral part of the Copyright Act than simply a defence. Any act falling within the fair dealing exception will not be an infringement of copyright. The fair dealing exception, like other exceptions in the Copyright Act, is a user’s right. In order to maintain the proper balance between the rights of a copyright owner and users’ interests, it must not be interpreted restrictively. As Professor Vaver, [in Copyright Law (2000)], has explained, at p. 171: “User rights are not just loopholes. Both owner rights and user rights should therefore be given the fair and balanced reading that befits remedial legislation.”

As an integral part of the scheme of copyright law, the s. 29 fair dealing exception is always available.

What is true of copyright is no less true of patents and any other intellectual property. TRIPs art. 30 may refer to exceptions to patent rights but in fact these exceptions constitute the rights users hold against patent holders. In this way, the “balance of rights and obligations”, to which TRIPs art. 7 alludes as an objective of intellectual property law, is given practical effect in the patent field.

5. Are patents in the public health field a special case?

Not only must the concept of user rights be clearly recognized in the field of health care patents, but so also must these patents be recognized as special cases.

Health care patents are not the same as patents for improvements to toasters. Health care patents deal with human life and health. These values are not mere market commodities like toasters. The holders of health care patents certainly have rights; they may also fairly be placed under a duty to deal, and a duty to act reasonably in their dealings, in the light of the subject-matter of their patent.

In former days certain activities were regarded as involving special duties. The innkeeper could not refuse to provide food and lodgings to the passerby who needed to stay the night and had money to pay. The keeper could not ask an outrageous sum even if (particularly if) his inn were the only one for miles. His spot

84 Ibid., paras. 48-49.
monopoly placed him under a special duty to deal, and to deal honestly. So it was with common carriers: they were bound to carry goods but could not legally charge more than a reasonable price for the service. If they did, the excess was recoverable if paid under protest.\textsuperscript{85}

Similarly, the salvage vessel which comes to the aid of a person hanging on to a plank in the middle of the ocean cannot charge any sum it likes to rescue him. If it does, the result may be an unconscionable bargain that is universally held unenforceable. There is no legal or moral duty on the rescued victim to pay anything beyond a reasonable price for the service. What is reasonable depends on the effort involved, and what is necessary to provide a reasonable incentive for others to act according to the golden rule.\textsuperscript{86}

Why should not the provision of patented health care products be similarly conceived?

In October 2005, the \textit{Economist} prefaced a special survey on patents and technology with a quote from one of its issues from 1851:

\begin{quote}
The granting [of] patents ‘inflames cupidity’, excites fraud, stimulates men to run after schemes that may enable them to levy a tax on the public, begets disputes and quarrels betwixt inventors, provokes endless lawsuits… The principle of the law from which such consequences flow cannot be just.\textsuperscript{87}
\end{quote}

Today's \textit{Economist} is more accepting of the system. Yet we can recognize the contemporary truths contained in that passage from 1851. In the health care field, as in others, the challenge is to create a system where “the principle of the law” does in fact create “just” consequences.

\begin{footnotes}
\item[85] R. Goff & G. Jones, \textit{The Law of Restitution}, 5\textsuperscript{th} ed. (1999), 325.
\item[86] Cf. \textit{ibid.}, ch. 18, dealing primarily with salvage of ships at sea.
\end{footnotes}