Non-voluntary Licensing of Patented Inventions:
History, TRIPs, and Canadian and United States Practice

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The term 'non-voluntary' or 'compulsory' licensing refers to the practice by a government to authorise itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy. In other words, the patentee is forced to tolerate the exploitation of his invention by a third person or by the government itself. In these cases, the public interest in broader access to the invention is considered more important than the private interest of the right holder to fully exploit his exclusive rights.

Historically, non-voluntary licensing arose to ameliorate the patentee's risks of forfeiture that derived from numerous restrictions on the use of patented inventions in early domestic and international laws. The first major improvement of the patentee's status in this regard was the abolition of forfeiture for merely importing patented articles into countries that practised this restriction. Once the risk of forfeiture for imports had been attenuated, the most important obligation that the laws of many countries imposed on patentees was the duty to 'work', i.e. exploit the invention in the countries granting patents. Obliging foreign patentees to work each and every patent locally is often economically inefficient. Nevertheless, most countries opted for a local working requirement to favour domestic development and the protection of national industries.

Article 31 leaves considerable leeway to impose non-voluntary licensing for any legitimate purpose.

However, forfeiture of patents as the sanction for non-working often generated still other social costs, especially when investment or know-how was insufficient to enable competitors to produce the disclosed invention by their own means. For these and other reasons, states gradually adopted a system of compulsory licensing as the primary sanction for non-working instead of forfeiture.

As states familiarised themselves with the remedy of compulsory licensing in cases of abuse, especially of non-working, another unintended consequence was that they increasingly resorted to this same remedy to restrict the powers of the patentee even in the absence of abuse. They did this for a variety of reasons that were generally supposed to promote the public interest. Compulsory licensing was of particular interest to countries seeking to regulate patents covering medicinal products and food products. About one hundred countries recognised some form of non-voluntary licensing in their patent laws by the early 1990s.

Non-voluntary Licenses and TRIPs

During the Uruguay Round, when it came to determining the rules applicable to non-voluntary licensing of patented inventions under TRIPs, the negotiators found it difficult to reach a consensus. The principal limitations on a patentee's exclusive rights are the relatively narrow set of exceptions covered by Article 30 and the rather broad possibilities for imposing non-voluntary licenses under Article 31. Account must also be taken of Article 27.1, which requires patents to be available 'and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.' This non-discrimination provision lies at the centre of the debate regarding the continued legitimacy of the working requirements under TRIPs, which remains controversial and unsettled.

Apart from questions pertaining to either the grant of a compulsory license for failure to work or the grant of such a license to prevent abuses of the patentee's exclusive rights, strenuous efforts were made to formulate some criteria that might limit the Members' powers to grant non-voluntary licenses on other grounds, particularly the broad and generic ground of promoting the public interest. However, every attempt to narrow these grounds during the Uruguay Round negotiations ran afoul of the state practices of leading developed countries, including those of the United States where the government and its contractors are broadly authorised to make use of patented inventions without the patentee's permission and without access to injunctive relief to prevent infringement.

The final text of Article 31 indirectly vindicated the public interest as a ground separate from the category of abuse, and leaves considerable leeway to impose non-voluntary licensing of patented inventions for any legitimate purpose and without undue constraints. In particular, any government that seeks to bring a patentee's practices into line with its own policies, especially with regard to disciplining the prices at which the patented articles are to be locally distributed, can achieve its aims within the confines of Article 31. Indeed, as recent experience in both Brazil and the US demonstrate, the mere threat of a non-voluntary license may obviate the need to issue it in practice.

A number of cautionary observations are in order, primarily because the flexibility embedded in Article 31 is not boundless, and other provisions in TRIPs may further constrain it. For example, care must be taken to work around the requirement of non-discrimination in Article 27.1, which seems to impede the imposition of non-voluntary licensing on unreasonably broad subject-matter categories. Thus, a government presumably could not impose compulsory licensing on medicines in general without some compelling justifications; but it could impose such licensing on medicines reasonably deemed to be 'essential' if other requirements of Article 31 were satisfied.

The practical ramifications of Article 31 may ultimately depend on a combination of state practice at the local and regional levels and subsequent legislative or judicial action at the international level. The Doha Declaration on the TRIPs Agreement and Public Health is a case in point. The Declaration attempts to clarify the flexibility already embodied in the TRIPs provisions concerning the use of non-voluntary licenses to address public health problems, and may help to alleviate certain misunderstandings that previously clouded these issues. For example, the drafters 'reaffirm the right of WTO members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility ... to protect public health, and, in particular, to promote access to medicines for all.' To this end, they expressly declare that, 'each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'

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The Declaration also rectifies the misguided notion that states must proclaim a full-fledged national emergency in order to grant non-voluntary licenses for patented pharmaceutical products. On the contrary, the Declaration expressly recognises the right of each Member 'to determine what constitutes a national emergency or other circumstances of extreme urgency.' This characterisation, when made in good faith, triggers the waiver of any duty to negotiate with the right holder under Article 31(b) prior to the granting of compulsory licenses.

Unfortunately, the Declaration does not resolve one important question concerning the right of importing states to treat products initially sold under a compulsory license in the exporting state as parallel imports covered by paragraph 5(d). Because these patented products were initially sold without the consent of the patent owner, one line of authorities holds that the doctrine of exhaustion cannot technically apply. If so, the exported goods produced under a non-voluntary license abroad could infringe the local patentee's exclusive right to import the goods in question under territorial law.

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If it turns out that patented pharmaceuticals distributed under a compulsory license cannot be exported as parallel goods within paragraph 5(d) of the Declaration, then they remain subject to Article 31(f), which literally limits such exports to 49.9 per cent of the total supplies distributed under the compulsory license in the local market. Since only a few developing countries can manufacture technically advanced medicines, these legal impediments hamstring the ability of these countries to assist other poor countries lacking local manufacturing capacity that issue compulsory licenses to acquire essential medicines.

Can developing countries with manufacturing and export capabilities impose compulsory licenses on patented medicines for the purpose of assisting other developing countries that lack manufacturing capabilities to import essential medicines under compulsory licenses of their own, without violating the patentee's rights under the TRIPs Agreement? Unfortunately, the Declaration provided no clear legal machinery for resolving this dilemma and merely 'instructed the Council for TRIPs to find an expeditious solution to this problem' before the end of 2002.

As a result, the Declaration did not expressly empower states capable of manufacturing generic drugs under compulsory licenses to act as the agents of states lacking such capacity. It did not authorise the former to meet the latter's needs by imposing compulsory licenses for this purpose notwithstanding the export limitations of Article 31(f), nor did it concede that the exceptions to the patentee's exclusive rights under Article 30 may implicitly allow the exporting state to impose compulsory licenses in order to assist other states for such purposes. Instead, the Declaration leaves these and other possible options, including a US proposal for a moratorium on dispute settlement actions for violations of TRIPs standards incurred when states address public health crises, to future action by the Council for TRIPs which must adopt an enabling solution before the end of 2002.

The Canadian and US Approaches

Since both Canada and the US have a rich and interesting experience in the use of non-voluntary licensing, a survey of this experience might shed light on the opportunities and challenges that countries generally face in the actual use of this legal instrument.

Canada made extensive use of non-voluntary licensing of patented inventions in the recent past, when it still regarded itself as a not fully-fledged industrialised country. Moreover, Canada pursued this strategy vigorously with respect to pharmaceutical and food patents, and it was instrumental in the establishment of a generic medicine industry in that country. Indeed, a compulsory licensing scheme was used aggressively to promote the production of generic pharmaceuticals, and this scheme reportedly produced some of the lowest consumer drug prices in the industrialised world. Between 1969 and 1992, 613 licenses were granted to import or manufacture medicines under such licenses.

Also of interest is Canada's reliance on statutory regulation of non-voluntary licensing, with particular regard to both abuse of patent rights and public interest objectives. In practice, however, the only type of 'abuse' that consistently drew attention prior to the 1990s was a failure to work patents locally. Otherwise, non-voluntary licensing of patents in the public interest was largely confined to food and medicines under the special legal regimes that were repealed in the late 1980s and early 1990s. Even in the past, in other words, Canada largely refrained from using non-voluntary licenses to address other forms of abuse or competition law issues generally. Since the 1990s, moreover, Canada has made little use of compulsory licenses for any purpose, and in line with its more pro-patent policies has lately advocated caution in the use of such licenses by other countries.

Historically, the situation in the US differed widely from that of Canada. To begin with, the US never adopted a general statute to regulate non-voluntary licensing of patented inventions either on grounds of misuse or on public interest grounds. On the contrary, courts and commentators frequently express pro-patent sentiments hostile to the very concept of non-voluntary licensing.

In practice, however, the federal courts made aggressive use for most of the twentieth century of non-voluntary licensing to regulate misuses of patent rights and antitrust violations involving the exercise of such rights. Since 1988, though, the federal appellate courts have imposed relatively few non-voluntary licenses under either rubric. However, the Federal Trade Commission has made extensive use of such licenses, often in consent decrees bearing on corporate mergers and acquisitions.

The US has also made far less use of non-voluntary licensing on public interest grounds than Canada, although limited statutory and common-law bases for issuing such licenses continue to exist. At the same time, the US has always relied heavily on the non-voluntary licensing of patented inventions to facilitate public, non-commercial uses by the government and its agents, a practice that the Canadian authorities have less frequently emulated. The bulk of the non-voluntary licenses issued for government use pertain to national defence. Nevertheless, the US has also used this same legal tool to reduce the costs of certain medicines and to advance both environmental and economic development goals, including major projects to dam rivers and generate electricity.

Non-voluntary Licensing: A Two-edged Sword

Policymakers should bear in mind that the issuance of a non-voluntary license cannot normally impede a patent holder from entering the market in competition with the licensee. So long as the former complies with local competition law, he may possess

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the economic and technical power to make life difficult for the latter. Moreover, so long as domestic competition laws do not impede it, the foreign patent holder can purchase or merge with his local competitor, in which case all strategy conflicts will soon vanish.

A state's ability to use local competition laws to regulate IPRs otherwise protected under TRIPs could eventually be called into question. In negotiations on the intersection between trade and competition policy, developing countries must remain vigilant in order to preserve the autonomy they need to curb the excesses of overly protectionist IPR policies.

Other variables must also be taken into account. One is the continued extra-legal pressures that may be exerted against those who resort to non-voluntary licenses. Developing countries that wish to retain their autonomous powers to exploit the flexibility inherent in the TRIPs standards will sooner or later have to devise appropriate national and regional strategies for sustaining and enhancing this autonomy.

Another particularly worrisome variable derives from ongoing initiatives to harmonise the substantive rules of international patent protection. Developing countries must take the steps necessary to gear up for the current substantive harmonisation exercise. There is a considerable risk that the flexibility residing in the TRIPs standards that now favours those developing countries which know how to exploit it could be squeezed out by high-protectionist standards incorporated into a new international treaty on patents. Beyond these technical considerations, there lie deeper, unanswered questions about the relative social costs and benefits of compulsory licensing of patented inventions as an instrument of economic development. The customary assertion of some economists that the use of compulsory licensing will depress investment in needed R&D requires careful and sceptical evaluation. Many inventions emanating from the technology-exporting countries today still respond to short-term needs and incentives primarily operative in OECD markets. Their sales to developing countries may represent windfall rents, which selective compulsory licensing could reduce with little impact on foreign R&D investment decisions.

At the same time, firms hit by compulsory licences may decide not to make future technology available in developing-country markets, which could lessen the possibilities for growth that voluntary imports, licensing or direct foreign investment might otherwise provide. Moreover, one propelling goal of an integrated global market is to provide incentives for R&D investments that could benefit all participating countries. Undue distortion of market forces could discourage aggregate investments in R&D, especially investment that might yield particularly big payoffs in developing countries. With these risks in mind, however, one should not assume without further investigation that the compulsory licensing of any particular patented inventions will necessarily or automatically discourage any particular investment in R&D.

What seems clear is that compulsory licenses may be used more effectively in some circumstances than in others. Selected non-voluntary licenses can yield positive results when used to address emergencies or to remove specific technology supply bottlenecks. They can be used to root the production or adaptation of appropriate technologies in qualified local facilities and to prod particular foreign companies into negotiated transactions involving IPRs that adequately respect local needs and conditions.

But even these presumptively beneficial uses of non-voluntary licenses impose social costs of their own, and policymakers must take these into account. For example, aggressive use of compulsory licenses to address emergencies may obscure other possible courses of action, such as regulatory and cooperative measures, that might persuade foreign producers to invest in local production facilities with greater long-term prospects. Similarly, any short-term benefits ensuing from the use of compulsory licensing as an instrument of technology transfer must be weighed, not just against the costs of imports, but also against the possible loss of licensing agreements or direct investments that might ensure continued access to better technology over time. The ability to grant non-voluntary licenses does not necessarily mean such licenses should actually be granted, at least without taking stock of the social costs that may, in the end, outweigh the benefits of this action. Excessive reliance on non-voluntary licensing could also adversely affect the interests of budding domestic inventors who fall afoul of rules prohibiting discrimination or of the government's own eagerness to intervene in the domestic market place. Above all, there are very real risks that ill-considered resort to non-voluntary licensing could discourage foreign investment and the transfer of advanced technologies by making other economic environments more attractive to firms in technology-exporting countries.

On balance, policymakers should view non-voluntary licensing of patented inventions as but one item in an arsenal of tools that may be used to promote national systems of innovation. What matters is not so much the use made of any particular tool, but rather the overall coherence and effectiveness of any given system. Absent a coherent strategy for promoting national and regional systems of innovation, excessive reliance on compulsory licensing of patented inventions may simply mask deeper structural problems and make them harder to solve in the long run.

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Problem Areas on Compulsory Licensing under TRIPs

Summing up discussions so far, the Chair of the TRIPs Council on 17 October identified areas where further work is needed in order to address the difficulties faced by countries, which lack sufficient capacity to manufacture medicines making 'effective use' of compulsory licensing under the TRIPs Agreement. According to paragraph 6 of the Declaration on the TRIPs Agreement and Public Health, the Council must find an 'expeditious solution' to this problem by 31 December 2002 (see also page 11).

Areas of disagreement include the scope and coverage of the compulsory licenses (i.e., which drugs to treat what diseases and the inclusion of diagnostics); eligibility criteria for beneficiary countries, particularly transition and high-income developing country Members; whether developed, as well as developing countries could supply the drugs; safeguards against diversion in both exporting nations (through mandatory controls on the quantity manufactured and exported, as well as labelling/presentation) and importing countries (through – perhaps mandatory – controls on distribution); as well as provisions related to notifications and information to rights holders. Also pending is whether the solution would come under TRIPs Article 31(f) or Article 30.

The Chair specified that the summary note was issued under his 'exclusive responsibility' and did not commit any delegation. The next formal Council meeting is scheduled for 25-27 November.