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I. INTRODUCTION AND BACKGROUND

It goes without saying that Canada and the United States would both be highly receptive to any initiative which could enhance their respective positions in the aggressive arena of global competition. While it cannot be touted as a panacea or salvation for this phenomenon of global competitiveness, the notion of harmonizing patent laws among major trading partners is regarded by many experts as a tangible and timely initiative which deserves strong support.

Many legal experts scoff at the idea of achieving a new international treaty which would introduce identical patent laws throughout the world. Many regard this concept as unrealistic and fruitless. Some critics argue that, even if an international harmonization treaty were to emerge from the World Intellectual Property Organization ("WIPO") within the next year or two, few countries would ratify the treaty.

However, serious tripartite (trilateral) discussions are proceeding among representatives of the Japanese Patent Office ("JPO"), the European Patent Office ("EPO"), and the U.S. Patent and Trademark Office ("USPTO"). While it is too early to make predictions on the success or the outcome of these trilateral talks, the main topics on the agenda should attract the attention of all major industrialized countries which purport to offer hospitality to intellectual property rights.

This Paper highlights the major items of substantive patent law which have occupied the agenda in the trilateral consultations. Focus on these key issues may serve to alert other industrialized nations to the kinds of patent law principles which could be susceptible to ultimate adoption in a harmonization agreement.

Much patience and understanding is required by the trilateral participants as they sit with each other and seriously move forward in an effort to ultimately forge a meaningful harmonization package. The agreement must transcend the diverse legal, economic, cultural, political and social traditions represented by each of the constituencies.

Ironically, despite the differences in national traditions and backgrounds represented by the trilateral participants, there is *not* an enormous gulf between the three states in many important areas of patent

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practice. Therefore, the notion of achieving trilateral harmonization in certain fundamental areas of patent practice is more feasible than many of the critics would suggest. For example, it is clearly feasible to seek uniformity in the duration of patents, i.e., the official patent term. Following are the current practices of the respective trilateral patent offices on the matter of patent duration, together with a model patent term proposed for harmonization purposes.

DURATION OF PATENTS

U.S. System	European System	Japanese System
Term: 17 years without regard to filing date.	Term: 20 years from filing date.	Term: 15 years from publication, not to exceed 20 years from filing.

Proposed Harmonization Model: Minimum term 20 years from the earliest domestic filing date.

With respect to Canadian practice, the patent term has traditionally been the same as the current U.S. practice. However, under Sections 45-48 of Canadian Bill C-22 which received Royal Assent on November 19, 1987, the new patent term will be 20 years from the date of filing the application in Canada. If the Amended Patent Act comes into force as expected, Canada will already be in line with the proposed harmonization model. It should also be noted that several other provisions of the Canadian Bill C-22 are in line with proposals in the trilateral harmonization model. An example is the issuance of patents to the first-to-file inventor rather than the first-to-invent inventor. Canada's adoption of the first-to-file priority system would leave the United States and the Philippines the only countries still using a first-to-invent priority system.

II. BROAD SCOPE OF PATENTABLE SUBJECT MATTER

Here is a substantive issue of patent law which can have significant impact on global competition. Perhaps the best illustration of the importance of the broad scope of patentable subject matter is whether or not a given country will grant product protection for pharmaceutical compounds. There is an enormous amount of research and development costs required to discover a new drug and to bring it through clinical trials, government approval and market introduction. The latest quantitative estimates by the U.S. Pharmaceutical Manufacturers Association ("PMA") report that the introduction of a single new drug typically requires a period of ten years coupled with an expenditure of approximately $110 million. The need for patent protection to shelter marketing profits in order to simply break-even in such a high stakes game must be obvious.

Yet many countries of the world *still* have not seen fit to provide

adequate protection within their patent laws for pharmaceutical compounds. Indeed, those same countries which resist granting pharmaceutical patent protection on the grounds that such protection would be deleterious to the national health interests of that country's inhabitants are often the same countries that blatantly misappropriate, pirate or counterfeit the pharmaceutical inventions of others. Thus, the pharmaceutical field represents one science where global reform is long overdue for the protection of the intellectual property rights of inventors.

The following comparison illustrates the current disparity now existing among states with respect to scope of patentable subject matter.

U.S. System	European System	Japanese System
Broad scope of patentable subject matter.	Somewhat limited scope of patentable subject matter.	Somewhat limited scope of patentable subject matter.

Proposed Harmonization Model: Broad scope of patentable subject matter.

An objective of the proposed model is to make patent rights available for *all* technologies. An example for needed reform is found in the biotechnology brought about in the past decade through molecular biology and genetic engineering. These new and powerful techniques of gene splicing and cloning have led to the creation of genetically engineered plants and seeds. Unfortunately, article 53(b) of the European Patent Convention prohibits the granting of patents for "plant and animal varieties." In contrast, the USPTO, in the decision of *Ex parte Hibberd*,[1] held that genetically transformed plants are susceptible to utility patent protection under 35 U.S.C. section 101.

Thus, a European agrichemical firm can obtain a utility patent for a genetically transformed plant or seed in the United States under the *Hibberd* doctrine, thereby obtaining exclusivity for the claimed subject matter. That same European firm is unable to obtain patent protection in the EPO for the same invention. The situation is even more severe for the U.S. agricultural firm which is barred from utility patent protection in Europe under EPO article 53(b) and, in addition, must compete against its European competitor who can take advantage of U.S. patent shelters. Thus, the case for patent harmonization is an urgent matter affecting global competition.

III. First-To-File Priority System

Mention was made earlier of the fact that the United States still adheres to the first-to-invent priority system. The EPO and JPO have long adhered to the first-to-file system. In a good faith effort to advance trilateral harmonization the USPTO has indicated a willingness to change from the first-to-invent to the first-to-file practice but only as part of a balanced package to improve international standards of patent

[1] *Ex Parte* Hibberd, 227 U.S.P.Q. 443 (1985).

protection. Once again, this underscores the fact that trilateral harmonization is not merely a fantasy but rather a reachable goal which is achievable if the delegates remain open-minded and cooperative.

IV. Eighteen Month Publication

One feature expected in any model harmonization treaty, whether a trilateral model or a WIPO model, is a provision for publication of patent applications eighteen months from the effective priority filing date. The EPO and JPO already follow this practice and the trend is clearly in this direction. The Canadian Bill C-22 section 10 provides that patent applications and documents will be open to public inspection after the expiry of eighteen months from the effective filing date. At present, Canadian patent applications and related documents are kept secret until the Canadian patent is issued.

V. Other Proposed Harmonization Items

The trilateral harmonization negotiators are faced with several other prominent issues. These include a one year grace period prior to the convention priority date. This permits inventors to publicly disclose their inventions before filing a patent application without losing patent rights. An objective test for nonobviousness is being discussed, along with a plan which would permit any number of independent and dependent patent claims, separately enforceable. The states are also considering adoption of: a peripheral claiming practice (i.e., the claim recites the metes and bounds of the invention), a broad claim interpretation, and a post-grant re-examination of patents.

Another caveat which deserves mention is the posture of the EPO delegates at the trilateral talks. The EPO delegates have been very careful to reiterate that, in the area of *substantive* patent law, they have no mandate. That is, the member states of the European Patent Convention have not given the EPO any mandate to negotiate in this area. Furthermore, the EPO points out that the European Patent Convention itself is nearly impossible to change. All of this portends lengthy negotiations.

VI. Conclusion

While many skeptics in the patent community scoff at attempts by WIPO and others to genuinely seek greater harmony among national patent laws, there is an unmistakable current of optimism and palpable progress emerging from the trilateral talks. While the trilateral talks are only a modest beginning, it is incumbent on patent lawyers in the North American patent community to support the momentum which our governments have initiated toward meaningful reform and harmony within the global context of patent laws.

Canada is to be commended for its most recent initiative with Canadian Bill C-22 which seems to anticipate the ultimate results being sought

not only in the trilateral context, but also in the global context of harmonization. If the trilateral talks bear fruit, there will most certainly be a salubrious effect on the global competitiveness of Canada, the United States and other industrialized nations.