The Unique Problem of Inventions Which Are Fully Enabled and Fully Described, But Not Fully Understood (Merrell Dow's Terfenadine Revisited)

H. Samuel Frost of Bereskin & Parr
2007

Intellectual Property Journal
October 2007
**Introduction**

For the vast majority of patentable inventions, the invention is fully understood, so that a disclosure in a patent specification, meeting common requirements for a complete and enabling written description, necessarily discloses all the information necessary to carry out the invention. Once any patent rights have expired, then this information is in the public domain and the public are free to use the invention.

However, many patent systems recognize that patent law is not concerned with scientific understanding of technology, but rather is concerned with inventions that have practical and commercial utility and that can be described in sufficient detail to be carried out. Thus, many patent systems do not require an inventor to have full knowledge of the science and technology behind the invention, but merely be in possession of sufficient information to describe the invention and to enable others skilled in the field to carry out the invention.

For some inventions, this necessarily results in the patent specification for the invention being 'incomplete' and missing some element of understanding. In many cases, the missing element may be no more than a pure scientific discovery or principle, that may be meritorious in a scientific sense but that may not be suitable subject matter for patent protection. There are, however, a set of such inventions where a missing element may be patentable in its own right, and more importantly, in a smaller subset, such patent protection in a secondary patent can circumscribe or limit use of the invention disclosed in the primary patent.

For this small subset, an analysis of judicial decisions shows that, in most jurisdictions, courts really only have two effective options: (1) refuse to recognize protection for any secondary patent on the missing element, so as to prevent apparent recapturing of subject matter already covered in the primary patent; or (2) find claims in the secondary patent of the missing element valid and enforceable, which can affect the right to practice an invention disclosed in the primary patent. The current legal framework therefore provides two drastically different options, and no option for any middle ground.

In addition to not providing any middle ground between these two options, it will also be argued that there are two separate but corresponding public policy issues that are not often identified, namely that when a patent expires the public should be free to use the invention and also that the patent system should provide an incentive to inventors to improve the understanding of incomplete inventions and to discover any such missing element.
It will be argued that, for the small but important subset of inventions, it is necessary to find a balance or some middle ground between these two public policy issues. It will be further argued that, most patent laws are, surprisingly, silent on the issue of any general or public right to use an invention in the public domain, and after expiry of any patent rights. Consequently, defining such a middle ground can only be achieved by inclusion of a new provision providing such a public right to use of an invention, a provision that, to the author's knowledge, is not found in any current patent laws.

This paper addresses general principles, rather than reviewing the law of any country in detail, and reference will be made to decisions from Canada, U.S. and Europe.

Inventions that are Not Fully Understood

Patent laws in many countries recognize that a complete and enabling disclosure need only be complete in a practical or utilitarian sense. That is, the disclosure must contain sufficient information to enable a skilled person to carry out the invention. More specifically, there is no requirement that an inventor be in possession of a full understanding and explanation of the physical or chemical process, or other science, behind the invention. This merely underscores the fact that patent law is concerned with the useful and practical arts, and is not, fundamentally, concerned with pure science.

Such a full understanding and its disclosure are here labeled a "scientific disclosure" to contrast it with an "enabling disclosure". In many cases these will be one and the same. However, as noted in the introduction there can be significant cases where the difference or missing element between these two types of disclosure amounts to more than just a scientific explanation and may amount to subject matter that is patentable separately.

Indeed, one can argue that an inventor can never, with complete certainty, assert that a full "scientific disclosure" has been made, since we can never delimit what we do not understand. For example, before the concepts of atoms and molecular structure were developed, early chemists could detail "enabling" instructions to mix certain starting ingredients under certain conditions to yield a useful end compound - the inventor, at the time, could only have provided a disclosure entirely silent on details of the chemical reactions occurring, but could have honestly believed that it was a complete "scientific disclosure".

Such inventions will often arise in pharmaceutical and biotechnology related inventions, since chemical and biological processes taking place in living organisms are complex and often not amenable to easy analysis.
Thus, while patent laws only require an "enabling disclosure", practice of the invention necessarily, even if unknowingly, requires using the full "scientific disclosure".

Public Right to Use an Invention

It is fundamental to any patent system with a limited term that, once a patent is expired, the public should be free to use the invention and the invention should not be subject to or limited by any later granted patent rights. The public’s right to use an expired patent, or more generally any old technology in the public domain, is not commonly defined, and is usually implicit in provisions limiting patent term and determining patent expiry dates. It is submitted here that an important corollary to the requirement for a full and enabling disclosure is that, it is only this disclosure that ensures the public has unfettered use of the invention after expiry of an initial patent for the invention. Put another way, if any later applicant attempts to craft claims covering the subject matter of an earlier patent, provided the earlier patent does indeed have a complete and enabling disclosure, it will destroy the novelty of such later claims.

Prior User Rights

Patent laws usually are confined to defining the rights of patentees and patent terms; rights of third parties or the public to use an invention are usually not addressed. A notable exception is the provision found in many patent laws for a "prior user" right, whose common characteristic is to provide that someone, who is in possession of an invention before a relevant date but did not disclose it publicly, is provided with some limited right to continue to use the invention.

U.S. patent law provides a defense to infringement for persons who "acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.‖ However, this is limited to a defense for infringement for inventions that are methods, and a "method" is further defined as a method of doing or conducting business.

There is no such explicit provision in the European Patent Convention (EPC); however it appears that some form of a prior user right has developed in most individual European countries. For example, the U.K. Patent Act provides that, where a patent is granted for an invention, a person who in the United Kingdom before the priority date...

---

1 Section 273(b)(1) of Title 35 of the United States Code
2 35 U.S.C. § 273(b)(1)
"...does in good faith an act which would constitute an infringement of the patent if it were in force, or...makes in good faith effective and serious preparations to do such an act, has the right to continue to do the act or, as the case may be, to do the act..."™

A similar provision is found in Canadian Law⁴. These provisions are generally thought to be fairly limited, and in the case of the U.S. provisions, are narrowly limited to business methods. Importantly, for the present purposes, they depend on someone either commencing to use, or at least making preparations to use, an invention before the critical date; there is no recognition that there is any necessity to define the right of the public, at any time, to adopt and to use technology in the public domain.

Remarkably therefore, although the intent of most patent laws is to promote the dissemination of technical knowledge, patent laws do not usually define any general right of the public to use an invention. It is submitted that, when analyzed completely, any public right (i) to use the disclosure in an expired patent and (ii) to have an assurance that this right will not be circumscribed or limited by a later granted patent, is only arrived by a fairly complex interaction between provisions governing novelty, the requirement for a full and enabling disclosure of a patent specification and patent term and expiry.

Novelty Requirement

It is commonplace that one of the basic intents of patent law is to promote innovation, and as such patent rights are only granted for inventions that are new or novel. The wording of novelty provisions may vary, but their common characteristic is that patent protection will not be granted for any invention that is already in the public domain.

For example, relevant portions of the novelty provisions in Europe and the United States are as follows:

Europe:
(1) An invention shall be considered to be new if it does not form part

⁴ Section 64 of the Patents Act 1977 (as amended)
⁵ In Canada, see s.56(1) of the Act - Patent not to affect previous purchaser: Every person who, before the claim date of a claim in a patent has purchased, constructed or acquired the subject matter defined by the claim, has the right to use and sell to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for so doing.
of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. […]

U.S.:
A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or […]

Requirement for a Fully Enabling Disclosure

Again, a commonplace provision is for the patent specification to provide a full written description that enables a skilled person to practice the invention. This derives from the basic concept behind modern patent law that, in exchange for disclosing an invention and not keeping the invention a secret, the inventor will be given a monopoly for some prescribed period. The fundamental intent is that, once the patent term has expired, than the public will have free use of the invention, encouraging competition. However, as noted the extent of this right to use the invention is not defined, and in any event is dependent upon the inventor disclosing the invention in sufficient detail to enable the public, or at least people skilled in the relevant art, to carry out the invention. Exemplary provisions from Europe and the United States are as follows:

The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

---

6 Article 54 of the EPC
7 35 U.S.C. § 102
8 Article 83 of the EPC
which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.  

Patent Term

Patents have a limited term, and a twenty year term calculated from the filing date has become an international standard, and is found in the patent laws of major European countries, the NAFTA countries (United States, Canada, Mexico), Japan, and many other countries. Further, most countries require that maintenance fees be paid to keep a patent in force, which has the benefit of providing an additional income to governments providing the patent rights and of removing dead wood from patent registrars, i.e. those patents no longer of any interest to their proprietors, and placing them in the public domain.

Maintenance fees are usually payable annually, but some countries provide different terms.

Public Right to Use an Expired Invention

As noted, it is in some senses remarkable that, while the goal of most patent laws is to promote the disclosure of inventions, with the intent that, after expiry of any patent term, the public will have free use of the invention, this right is usually nowhere defined in any patent statute. It is usually derived from or is a necessary consequence of the limited term of the patentees' rights. However, one needs also to consider the other two requirements listed above, namely those of a full and enabling disclosure and the novelty requirement, to delineate any right to the public to use an invention.

Clearly, if the patent expires, either at the end of its term or through failure to pay the relevant maintenance fees, then that patent right has expired, and the patentee can no longer enforce any rights against the public, who are then free, with respect to that patentee, to use the invention. But is there any possibility that the invention could be recaptured or circumscribed by claims issuing to another person that cover all or part of the invention disclosed in the first patent?

---

9 35 USC § 112
10 35 U.S.C. § 41 provides that maintenance fees are due every four years with the first payment being 3 1/2 years from the issue date of the patent. Article 86 of the EPC provides that renewal fees shall be due in respect of the third year and each subsequent year, calculated from the date of filing of the application. Rule 37(1) of the Implementing Regulations for the EPC states: "Renewal fees for the European patent application in respect of the coming year shall be due on the last day of the month containing the anniversary of the date of filing of the European patent application."
Assume that the only disclosure is in the published patent (and its application), i.e. that there has been no public use. Under European standards, anything that is implicit\textsuperscript{11} in the content of the patent specification, including the drawings, or is undeniable unambiguously from it, constitutes prior art. Additionally, at least in the U.K. following the Merrell Dow decision\textsuperscript{12}, the prior art also includes any product that is inevitably produced by carrying out a method taught in the patent. In the U.S., the prior art encompasses anything that is "inherent" in the disclosure in the patent; following the Schering decision\textsuperscript{13}, which parallels the facts in the Merrell Dow case, a product that is inherently produced by a disclosed method will constitute prior art.

Even with the expired patent given this sort of breadth, as a prior art document, is it still possible for some features of the invention not to have been disclosed? This seems possible where the invention is not fully understood, so that necessarily the disclosure is incomplete, or where the disclosure is, for whatever reason, flawed and omits an essential feature, i.e. where the invention is fully enabled but the disclosure falls short of a full "scientific disclosure".\textsuperscript{14}

Thus, the answer to the question above will be negative, only if the specification of the original patent did indeed provide a full and complete disclosure of all the details of the invention, i.e. a full "scientific disclosure". Then, any attempt, in a later application, to encompass part of the subject matter of the first application should properly be rejected as lacking in novelty.

It is noteworthy that it is only the interaction of these provisions that give any sort of guarantee to the public at large that they are free to use an invention disclosed in an expired patent. Consider the situation where the disclosure in a first or original patent has been defective or has missed some part of the invention. The patentee may have been able to enforce the patent, successfully, throughout its life; for example, perhaps the defect in the patent is not apparent, or the patentee, perhaps aware of the defect, offered licenses to competitors, which were clearly preferable to the costs and risks of potential litigation.

If the original patentee, or possibly some other person, becomes aware of this defect or omission in the original patent and then "discovers" or "invents" the missing component of that disclosure, could this amount to a separately patentable invention? If it can be established that the missing part or element was not, indeed, disclosed in the original patent specification, even after taking into account features that are inherent or implicit, and is inventive over the

\textsuperscript{11} EPO June 2005 Guidelines for Examination, Part C, Chapter IV, 7.2 and 7.5.  
\textsuperscript{12} Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76  
\textsuperscript{13} Schering v. Geneva, 339 F.3d 1373, 1377 (CAFC 2003)  
\textsuperscript{14} But see the decision in Merrell Dow and Schering supra note 12.
original disclosure, then it does appear there is the possibility for the second patent issuing for such a missing part. In many cases, a patent issuing for that missing element will include claims that would be infringed by working of the original invention.

The foregoing paragraph describes a situation where a patentee, either accidentally or deliberately, obtains a patent based on a flawed disclosure of the invention. A more difficult case arises where an applicant for a patent does indeed use his or her best efforts to comply with the requirements of a relevant patent statute and does, to the best of his or her knowledge, fully disclose the invention. Most importantly, it is assumed that the disclosure is fully enabling, while at the same time the inventor does not fully understand the invention.

The question arises whether despite the missing element from the original patent, the disclosure or public use of the invention is nevertheless sufficient to result in anticipation of the invention of the second patent detailing the missing element.

**The Dual Role of the Novelty Standard**

While the preceding sections have emphasized that it is the interaction of a number of provisions that results in any right of the public to use older, unpatented technology, the key provision is the novelty standard.

It is submitted that it is a little appreciated fact that the novelty standard, of most patent statutes, provides two distinct provisions, namely ensuring that: (i) only new inventions can be patented; and (ii) the public has unhindered access to any technology already in the public domain.

The common wording of most novelty standard is clearly directed at the first provision; the second provision, it seems, is treated as a natural corollary. Another way of looking at the problem is to ask: are the provisions always coextensive or of equal extent? It is submitted that this is only clearly the case where either: (i) the "enabling disclosure" is indeed complete and of the same scope as a "scientific disclosure"; or (ii) any difference between the two amounts to no more than a scientific explanation or theory, i.e. not subject matter that could be patented separately.

What if, as anticipated in the introduction, the invention is in that small subset where an "enabling disclosure" omits an element of the invention that is capable of separate patent protection, then any "scientific explanation" seems clearly not to be of the same scope. In such a case it seems that the two functions of the novelty standard will only be of the same extent, if some way is found to stretch, expand or to add to the "enabling disclosure" so that it is indeed of the same
scope as a "scientific disclosure". This is illustrated below, by reference to relevant case law.

**Merrell Dow (Terfenadine) Decisions**

Marion Merrell Dow is a corporation that owned a patent to the anti-histamine "Terfenadine". After securing patent rights in various countries for Terfenadine in the early 1970's (which in turn were due to expire in the early 1990's), scientists learned a few years later that the drug is metabolized in vivo. The active ingredient suppressing the effects of allergies was, in fact, the metabolized version of the drug or the Terfenadine Acid Metabolite (hereinafter referred to as "TAM"). A subsequent patent was secured for TAM several years later (early 1980's) after the issuance of the Terfenadine patents.

After the expiration of the Terfenadine patent, various generic manufacturers sought to compete with Marion Merrell Dow by selling Terfenadine. Marion Merrell Dow commenced litigation proceedings in Germany, the United Kingdom and the United States against the generic drug manufacturer Norton, relying not on the expired Terfenadine patent, but instead on the TAM patent, which had not yet expired. As the TAM patent appeared to provide a de facto extension of the original and expired patent, the question arose as to whether it was valid and enforceable.

**Germany**

This review is based solely on Dr. Paul Tauchner's article *Reflections on the German Terfenadine Prodrug Case*, which provides an English language overview of the case made by the Munich District Court on June 25, 1992, and the subsequent appeal in the Higher District Court in June of 1993. The German Federal Supreme Court did not hear the appeal.

Marion Merrell Dow alleged that Baker Norton violated both a substance claim and a use claim, and participated in contributory infringement of the TAM patent, because of efforts to induce end users to make TAM by consuming Terfenadine.

---

15 Marion Merrell Dow is now known as Hoescht Marion Roussel. In 1995, Hoechst AG purchased 71% of Marion Merrell Dow stock from Dow Chemical Co. Hoescht Marion Roussel's global headquarters are in Frankfurt, Germany.

16 The first U.S. patent, No. 3,878,217 was filed July 12, 1973 and was a continuation in part of the first application, which was filed January 28, 1972 and issued April 15, 1975. The TAM patent (U.S. 4,254,129) was filed April 10, 1979 and issued March 3, 1981. The gap between the patents is about 7 years.

The Munich District Court rejected the plaintiff's submissions based on what Dr. Tauchner calls "equitable" principles. Tauchner summarizes the decision, writing:

[N]o...circumvention [of the substance claim] occurred... because Terfenadine produced and marketed by the defendant is the same as the compound for which the plaintiff's patent had expired. ...[O]ne cannot speak of a circumvention and thus, the Court decided, there was no infringement of the substance claim...  

The same logic was applied to both the use claim and the claim of contributory infringement. The District Court held that "contributory patent infringement cannot give rise to claims by the plaintiff when no features other than those contained in a prior art patent are practiced."  

Questions relating to the validity of patents under German patent law cannot be answered by judges adjudicating infringement proceedings. As such, questions regarding the validity of the TAM patent, questionable by virtue of their potential shortcomings with regard to novelty or inventiveness, were not answered in the German proceedings.

The Munich District Court's decision was subsequently appealed and dismissed by the Higher District Court (HDC) in June of 1993. According to the HDC, "anyone is entitled to freely use a teaching of a patent which has expired, because the inventor of the expired patent has been adequately rewarded." A subsequent attempt to appeal the decision of the HDC to the Federal Supreme Court failed because the issues were not considered of fundamental importance and there were "scant prospects of success." 

The United States

In the United States, Baker Norton was successful in winning a motion for summary judgment for non-infringement of Merrell's U.S. TAM patent. The main issue in this proceeding was the interpretation of the word "compound" in Merrell's TAM patent; Baker Norton argued that "compound" was meant to only include "synthetic" compounds, Merrell arguing that the term was to include both synthetic compounds and those generated in vivo.

After evaluating the context in which the word "compound" was used in the claims as a whole, the lack of reference to "metabolized TAM" in the specification, and the prosecution history of the TAM patent, the court concluded

---

18 Id.
19 Id.
20 Id.
that this patent was limited to synthetic TAM, and did not include TAM metabolized in a human liver after the consumption of Terfenadine.

Once again, the validity of the TAM patent was not questioned. By limiting the interpretation of the TAM patent to synthetically produced TAM, there was no need to question whether or not the TAM patent would extend Merrell's right in the Terfenadine patent.

**The United Kingdom**

Of the three countries in which cases were launched, it appears the only court that fully addressed the validity of the TAM patent was the House of Lords in the UK.\(^{22}\)

In England, the House of Lords dismissed an appeal initiated by Merrell Dow, appealing the decision of a lower court judge to grant a motion brought by Norton to strike out Merrell's claim as disclosing no cause of action. The lower court held that since the plaintiff included within the TAM patent the manufacture of TAM by the action of Terfenadine in the human body, that specific claim was invalid because it was not new.

Lord Hoffman, in writing the decision on behalf of the court, invalidated the patent for having been anticipated by disclosure, as opposed to having been anticipated by use.

*Anticipation by Use*

This "use" doctrine is influenced by the definition of "use" in the European Patent Convention, namely Article 54. The definition of the state of the art, setting the boundaries as to what constitutes anticipation, is not simply something which has been done before. Rather, it "requires that information about what was being done should have been made available to the public"\(^{23}\).

Lord Hoffman writes that an invention is a piece of information. As such, information is required to be communicated to the public in order for something to comprise prior art. Acts done secretly or without full knowledge of the relevant facts, which would amount to infringement after the granting of a patent, would not count as anticipation as the relevant information was not communicated to the public.\(^{24}\)

\(^{22}\) Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76

\(^{23}\) Merrell Dow, supra p. 84.

\(^{24}\) This is in contrast to the old law (Patents Act 1949) as previously interpreted before the 1977 amendments to the Patent Act, which were passed to give effect to the European Patent
Since users of Terfenadine, prior to the discovery of TAM, did not know what the effective anti-histamine agent was, it could not have been anticipated. While this may seem contrary to public policy, there is a provision in English patent law, allowing those who have used the invention, or discovery, to use the product.\textsuperscript{25}

\textit{Anticipation by Disclosure}

While the Terfenadine patent did not constitute prior art in terms of "use" of TAM, Lord Hoffman writes that TAM was "disclosed" in the Terfenadine patent, and as such was anticipated. Lord Hoffman poses the question as follows: "The question is whether the specification conveyed sufficient information to enable the skilled reader to work the invention"\textsuperscript{26}. It was not necessary for one to describe the chemical formulation of TAM; things do not have to be described in such a manner in order to be fully disclosed. They can be described in a variety of ways, including the way in which they look, how they are made, what they do, to name but a few.

According to Lord Hoffman, the state of the art includes information which has been disclosed enabling the public to know the product under a description sufficient to work the invention. While knowledge of the chemical composition of an invention may be required in order to work an invention for a product claim, it will not in all cases be necessary in order for a product to comprise part of the state of the art.

Reference was made to \textit{CPC/Flour concentrates}\textsuperscript{27}, which was a case concerned with actual recipes for cooking. The patent application was for a process for making flavour concentrates from certain animal and vegetable substances, extracted under pressure with fat solvents in the presence of water. An opposition was based on two cookbook recipes to pressure-cooking chickens and making stews. It was held that, while not expressed in technical terms, the recipes did disclose that same process so as to be anticipatory. The Technical Board of Appeal said\textsuperscript{28}:

\begin{quote}
Convention. Under the old law, prior uninformative use of an invention would be anticipatory. Lord Hoffman in paragraph 25 of his decision relates that this was based on two principles of UK patent law. First, the crown can not grant a patent that would enable the patent holder to stop another trader from doing what they have previously done. Second, the test for infringement was identical to the test for anticipation- therefore if an earlier activity would have been infringing if carried out later, the invention must have been anticipated. The 1977 amendments to the Patent Act defined novelty in Section 2 so as to bring the Act in line with Article 54 of the EPC.

\textsuperscript{25} Section 64 of the Act. See Note 4, \textit{supra}.

\textsuperscript{26} \textit{Merrell Dow, supra} p. 87 per Lord Hoffmann.

\textsuperscript{27} T303/86 [1989] 2EPORa5

\textsuperscript{28} Fd of page 98
\end{quote}
"It is sufficient to destroy the novelty of the claimed process that this process and the known processes are identical with respect to storing material and reaction conditions (...) processes identical in these features must inevitably yield identical products."

Or, as the House of Lords expressed it and applied it to the fact situation before them in an oft quoted statement:

"...if the recipe which inevitably produces the substance is part of the state of the art, so is the substance as made by the recipe."\textsuperscript{29}

Hoffman held that TAM was described in the Terfenadine patent as "a part of the chemical reaction in the human body produced by the ingestion of Terfenadine and having an anti-histamine effect"\textsuperscript{30}. As such, the public was able to "work" the invention by making the acid metabolite in their liver.

While the language and analysis are different, the overall approach and effect seem close to the U.S. concept of "inherency", discussed below.

\textbf{Summary of the Merrell Dow Decisions}

What is striking is that in all three decisions it seems clear that the courts were bound and determined to find the TAM patent either not valid and/or not infringed, since to find otherwise would have effectively extended Merrell Dow's monopoly beyond the term of the original, expired patent for Terfenadine itself. This was achieved in different ways in different courts. In Germany, as the court could only consider infringement, not validity, the court appears, to this writer (not an expert on German law) to have made sweeping statements limiting the scope of the claims, so that they did not encompass Terfenadine of the expired patent; the analysis seems to blur the distinction between infringement and validity. In the United States, the court neatly construed the word "compound" to be limited to synthetic TAM, i.e. so as to exclude the natural TAM produced in vivo by the metabolic breakdown of Terfenadine. This seems a little surprising, since the word "compound" was not qualified in the claims, but it did serve to find the TAM patent not infringed. The UK decision, as noted, was the only decision to squarely address the question of validity. The Court managed to interpret the novelty provision so as to find that the earlier patent had, actually, put information about the Terfenadine metabolite into the public domain, despite not publicly teaching the 'missing element' in the patent specification.

\textsuperscript{29} Merrell Dow, supra page 90.

\textsuperscript{30} Merrell Dow, supra page 90.
Theoretical Variations of the Fact Situation in the Merrell Dow Cases

The Merrell Dow TAM patent seemed to cause particular consternation, as the patent was obtained by the same patentee as the original patent and it appeared to be a clear attempt to obtain an effective extension of the patent term for the original invention. It is submitted that it is of interest to consider varying fact situations.

In the following examples, it is assumed that a first patent was obtained for an invention that was not fully understood (but which did meet the requirements for a complete and enabling disclosure), and that at least one element of the invention had not been characterized at the initial filing date. Later, this missing element is identified and characterized, and a second patent has issued for it. Like the Merrell Dow situation, it is further assumed that the scope of claims of the second patent would limit, to at least some extent, practice of the invention disclosed in the first patent.

First and Second Patentees are Different Entities

Unlike Merrell Dow, what would be the situation if the second patentee was different from the first patentee? Since none of the Merrell Dow decisions turned around the identity of the second patentee, it would seem that this should make no difference.\(^{31}\)

However, it is submitted that, absent an appropriate one of the Merrell Dow decisions as a precedent, it would be easier for a court to find the second patent both valid and infringed. On its face, the fact situation suggests that identifying a missing element was not trivial since apparently the first patentee was unable to identify the missing element. Further, in jurisdictions with an adequate prior user right, a court could comfortably find the second patent valid and enforceable, while noting that the first patentee could continue to produce the invention of the first patent relying on such a prior user right.\(^{32}\)

Clearly one difficulty with this approach is that it changes the result for third parties. Third parties would no longer be able to freely practice the invention of

\(^{31}\) Note the comment on paragraph 83 of the House of Lord's decision that stated that "the argument would have been exactly the same if someone else had discovered and patented the acid metabolite."

\(^{32}\) US prior user right limited to business methods. In Canada, see s.56(1) of the Act - Patent not to affect previous purchaser: Every person who, before the claim date of a claim in a patent has purchased, constructed or acquired the subject matter defined by the claim, has the right to use and sell to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for so doing.
the first patent upon its expiry, but rather would be subject to the rights of the second patentee.

Excessive Elapsed Time Between Filings

In the Merrell Dow fact situation, the patentee was the same and there was no excessive time period between the filing of the two applications, which suggests that identifying TAM was little more than routine development of the original invention.\(^{33}\)

If, on the other hand, an original patentee has failed to identify a missing element of the invention, and assume further, that it can be shown that the first patentee was well aware that there was an unidentified element and had strenuously sought it, then this argument is weakened. Further assume that the missing element is later identified by a separate identity, for example, more than twenty years after filing the initial application and hence after expiry of the first patent, then the analysis of the British Court seems questionable. Surely, in such a situation, the argument that the first patent has put information about the missing element in the public domain seems more fictional than realistic; surely, there is then a stronger argument that the original patent did not provide "enabling information" about the missing element.

Identification of Missing Elements Requires a Novel Technique

What would be the result if it can be shown that, at the date of the first patent, known analytical techniques were simply inadequate to identify the missing element, and that it could only be identified once some later, novel and analytical technique was developed? Again, like the preceding example, the very theoretical analyses of the British Court and the U.S. court in the Schering case discussed below become even more questionable\(^{34}\).

Inadequacies of Present Statutory Provisions

It seems that the problem with this type of fact situation is that known statutory provisions provide no middle ground. Where a second patent is obtained covering a missing or unidentified element of a first invention, courts have only one of two options, namely: find the second patent either invalid or unenforceable, so as to leave the invention of the first patent free for anyone to practice, subject only to any remaining term of the first patent; or find the relevant

\(^{33}\) The first application for U.S. Patent No. 3,878,217 was issued from a C.I.P. of a first application filed January 28, 1972. The second (TAM) patent, U.S. 4,254,129 was filed April 10, 1979. The gap between the filing dates was just over 7 years.

\(^{34}\) Schering Corp. v. Geneva Pharm. (2003), 339 F.3d 1373 (Fed. Cir.).
claims of the second patent valid and enforceable, so that, when the first patent expires, the public may not be free to use the invention of that first patent. It is submitted that careful consideration of these possible outcomes suggests that there are two opposite but complementary public policy issues that have not been identified in most commentaries on the Merrell Dow decisions, or on similar U.S. or other decisions on inherency.

First, as is the intention of any patent law, when the first patent expires, the public should be free to use the invention. More particularly, as in the Merrell Dow decisions, the patentee should not be able to obtain a second patent providing an effective extension of the patent term, and more generally, it should not be possible for any other inventor to obtain a patent that has the effect of taking out of the public domain an invention or technology that the public can otherwise freely access.

Second, and less well recognized, when an invention is not fully understood, i.e. an original enabling disclosure falls well short of a full scientific disclosure, should the patent system not provide some incentive to encourage inventors, including those additional to the first inventor, to discover the missing element? In appropriate cases, where the missing element is susceptible of independent protection, then should not a patent be granted for it? (As noted, in many cases, the missing element is a scientific principle on theory that does not meet the test for patentable subject matter).

**Other Case Law, Including Inherency Doctrine, Reverse Engineering Concepts and the Like**

Implicit Disclosure and Recent UK Decisions

The following quotation from *Minnesota Mining & Manufacturing Co.’s (Suspension Aerosol Formulation) Patent,*\(^{35}\) neatly summarizes the current U.K. approach. This case cites *Merrell Dow*\(^{36}\) with respect to anticipation by prior disclosure:

> It seems from the decision of the House of Lords in *Merrell Dow v. Norton*, [1996] R.P.C. 76, 87-90, that in the case of an invention consisting of a product, the requirement for an enabling disclosure in this context requires only that the skilled man be able to work the prior disclosure without knowing what it is he is working if it is in fact the product.

---

This emphasizes again that no full or scientific disclosure is required; it is sufficient to provide an enabling disclosure.

**Synthon BV v. Smithkline Beecham plc.**

More recently the House of Lords dealt with the requirements for anticipation in *Synthon BV v. Smithkline Beecham plc*\(^{37}\). The disputed patent covered a crystalline form of paroxetine methanesulfonate (and all polymorphs) – a form of paroxetine, which is the active ingredient in Smithkline Beecham’s – now GSK – antidepressent Seroxat. Synthon challenged this patent for being anticipated by its own unpublished application, which was filed at a similar time as Smithkline’s and also covered paroxetine methanesulfonate.

It was held that the skilled person could synthesise and then crystallize PMS using the disclosure of the Synthon application together with his common general knowledge. Thus, the SKB patent was held to be invalid.

The issue was whether the Synthon application enabled a skilled man to make the crystalline form of paroxetine methanesulfonate. The general teaching (and also the general teaching of the patent in suit) indicated that the techniques for crystallization were not critical. While the fact situation is dissimilar from the other Smithkline decisions and the Merrell Dow decisions, it does discuss Merrell Dow and, importantly, clarifies the prior disclosure and enablement requirements for anticipation.

Lord Hoffman noted that there are two requirements, which are distinct concepts: prior disclosure and enablement. Thus, one must first establish if disclosure has been made which falls within the scope of the claim in issue; then, establish if that disclosure has been enabled.

Prior Disclosure

Lord Hoffman commented on the two well known authoratative statements regarding anticipatory disclosure, from Lord Westbury in *Hill v. Evans*[^38^], and from the Court of Appeals judgment in *General Tire and Rubber Co v. Firestone Tyre and Rubber Co Ltd*[^39^] where it was stated that for the purposes of assessing disclosure “the prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee”[^40^].

Within this context of the law on anticipation, Lord Hoffman noted:

If I may summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. **But patent infringement does not require that one should be aware that one is infringing:** "whether or not a person is working [an] ... invention is an objective fact independent of what he knows or thinks about what he is doing": *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76, 90*. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so. (paragraph 22)

[^38^]: *Hill v. Evans* (1862) 31 LJ(NS) 457, 463. "I apprehend the principle is correctly thus expressed: the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent."

[^39^]: *General Tire and Rubber Co v. Firestone Tyre and Rubber Co Ltd*. [1972] RPC 457, 485-486. The quote by Lord Hoffman included: “A signpost, however clear, upon the road to the patentee’s invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.”

[^40^]: See *Synthon BV* supra, paragraph 21.
Lord Hoffman went on to comment on the *Merrell Dow* and the necessity of the anticipatory prior art entailing the impugned invention:

Thus, in Merrell Dow, the ingestion of terfenadine by hay-fever sufferers, which was the subject of prior disclosure, necessarily entailed the making of the patented acid metabolite in their livers. **It was therefore an anticipation of the acid metabolite, even though no one was aware that it was being made or even that it existed.** But the infringement must be not merely [be] a possible or even likely consequence of performing the invention disclosed by the prior disclosure. **It must be necessarily entailed.** If there is more than one possible consequence, one cannot say that performing the disclosed invention will infringe. The flag has not been planted on the patented invention, although a person performing the invention disclosed by the prior art may carry it there by accident or (if he is aware of the patented invention) by design. Indeed, it may be obvious to do so. But the prior disclosure must be construed as it would have been understood by the skilled person at the date of the disclosure and not in the light of the subsequent patent.\(^{41}\) (Emphasis added in above quotations)

---

**Enablement**

---

\(^{41}\) *Merrell Dow*, *supra* paragraph 23.
The second requirement for a finding of anticipation is enablement, which Lord Hoffman defines as whether the ordinary skilled person would have been able to perform the invention based on the disclosed information. Further, the extent of permissible experimentation was also addressed:

"But once the very subject-matter of the invention has been disclosed by the prior art and the question is whether it was enabled, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. If, therefore, one asks whether some degree of experimentation is to be assumed, it is very important to know whether one is talking about disclosure or about enablement."

Again, cognizant of the existing framework laid out in Merrell Dow, Lord Hoffman was careful to comment on the proper approach to enablement:

"There is also a danger of confusion in a case like Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76, in which the subject-matter disclosed in the prior art is not the same as the claimed invention but will, if performed, necessarily infringe. To satisfy the requirement of disclosure, it must be shown that there will necessarily be infringement of the patented invention. But the invention which must be enabled is the one disclosed by the prior art. It makes no sense to inquire as to whether the prior disclosure enables the skilled person to perform the patented invention, since ex hypothesi in such a case the skilled person will not even realise that he is doing so. Thus in Merrell Dow the question of enablement turned on whether the disclosure enabled the skilled man to make terfenadine and feed it to hay-fever sufferers, not on whether it enabled him to make the acid metabolite."

U.S. Inherency Doctrine

This is a large body of case law in the U.S. analyzing the doctrine of inherency. For present purposes reference is made to some relevant and recent decisions.

In Schering v. Geneva Pharm., Schering has obtained, in August 1981, a patent for loratidine, a new non-drowsy antihistamine, and related drug products and a method of use; loratidine is the active ingredient in Claritin. In a very similar fact situation to the Merrell Dow case, Schering continued their research and later identified desloratidine as another ingredient, for which they were

42 Synthon, supra paragraph 30.
43 Id. paragraph 33.
44 Schering Corp. v. Geneva Pharm. (2003), 339 F.3d 1373 (Fed. Cir.).
awarded a patent in April, 1987. Unknown to Schering and others at the time, loratidine is metabolized in the liver to form desloratidine.

Beginning in 2002, a number of generic drug manufacturers sought permission from the Food and Drug Administration to begin marketing generic versions of Schering's immensely successful Claritin product. In order to do so, those generic versions had to contain loratidine. However, by that time Schering's loratidine patent had expired. But, the desloratidine patent would not expire until April 2004, and Schering decided to sue the generic drug manufacturers for infringement of that patent. Schering argued that, because the loratidine in the generic formulations would be converted in the body to desloratidine, this constituted infringement of its desloratidine patent. The generic drug manufacturers countered with a defense of inherent anticipation, arguing that, even though Schering (or anyone else, for that matter) did not know that loratidine is metabolized by the body to form desloratidine, the loratidine patent inherently discloses desloratidine, thereby rendering the desloratidine patent invalid.

The Federal Circuit held that the loratidine patent contained an enabling disclosure of "a metabolite of loratidine," namely desloratidine:

"An anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more. To qualify as an enabled reference, the [loratidine patent] need not describe how to make [desloratidine] in its isolated form. The [loratidine patent] need only describe how to make [desloratidine] in any form encompassed by a compound claim covering [desloratidine], e.g. [desloratidine] as a metabolic in a patient's body. The [loratidine patent] discloses administering loratidine to a patient. A person of ordinary skill in the art could practice the [loratidine patent] without undue experimentation. The inherent result of administering loratidine to a patient is the formulation of [desloratidine]. The [loratidine patent] thus provides an enabling disclosure for making [desloratidine]."45

Two points can be taken from this. First, the analysis and conclusion are remarkably close to the reasoning of the British House of Lords (see below). Second, if the disclosure is "enabling" for desloratidine, even without a specific disclosure of it, would the disclosure have been sufficient to support claims to the metabolite desloratidine? Arguably, based on this precedent, a patentee should claim the inherent but undisclosed metabolite.

45 Id. page 1381.
One can also contrast this decision with that of *Minnesota Mining and Manufacturing* mentioned previously. The UK court held that it was only necessary for the disclosure to enable a skilled person to make the prior art compound, and not the previously unknown form of the compound; the US court found the disclosure enabling for the previously unknown desloratidine.

**SmithKline Beecham v. Apotex**

In *SmithKline Beecham v. Apotex*, the Court of Appeal for the Federal Circuit held, in part, that inherent anticipation be found when the prior art produces trace amounts of a compound, even if this was not recognized at the time by those skilled in the art.

In the late 1970s, Ferrosan developed crystalline paroxetine hydrochloride ("PCP") in anhydrate form (without water) and was awarded a patent on the compound. SmithKline licensed the patent from Ferrosan and then developed PHC in a hemihydrate form (with a water molecule) and was awarded a patent in the late 1980s claiming only the hemihydrate form of PHC. SmithKline used the patented PHC hemihydrate in its antidepressant drug Paxil. Apotex filed an Abbreviated New Drug Application ("ANDA") seeking approval of its antidepressant drug with its active ingredient being PHC anhydrate. SmithKline sued Apotex for infringement asserting that PHC anhydrate tablets necessarily contained amounts of PHC hemihydrate. Ferrosan's earlier efforts producing PHC anhydrate created an unstable form that "morphed" into the more stable form of PHC hemihydrate. Once PHC hemihydrate was produced, it then "seeded" the general environment with crystals of PHC hemihydrate that converted the anhydrate form into the hemihydrate form. This "disappearing polymorph" and "seeding" phenomena make it impossible to create pure PHC anhydrate because "it changes naturally into the new polymorph, PHC hemihydrate."

---

47 *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). Judge Richard A. Posner, sitting by designation at the U.S. District Court for the Northern District of Illinois, found no infringement because the presence of the claimed hemihydrate was an insignificant and unavoidable impurity resulting from the development of the generic product. In April 2004, the Court of Appeal for the Federal Circuit ruled that the patent was invalid because clinical trials of the drug more than one year before filing was a public use under Section 102(b) of Title 35 (365 F.3d 1306). On April 8, 2005, the Court of Appeal for the Federal Circuit (en banc) vacated the original Federal Circuit opinion (without offering a replacing opinion). On the same day as the en banc decision, The same court released a three-member rewritten opinion that avoided the experimental use issue and found, rather, that the patent was "inherently anticipated". This decision has been appealed to the U.S. Supreme Court, which has recently asked the Solicitor General to submit the government's views on the issue.
48 *Id.* at 1334.
The Federal Circuit held that PHC hemihydrate was inherent in the earlier disclosures of PHC anhydrate because of the "disappearing polymorph" process that makes the manufacture of PHC anhydrate naturally produce PHC hemihydrate. Thus, the earlier teaching of PHC anhydrate necessarily taught PHC hemihydrate, even if it produced only "trace amounts" of PHC hemihydrate.

The majority noted:

"inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created."\(^{49}\)

"to ensure that [t]he public remains free to make, use or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate."\(^{50}\)

This is fine as it stands, but only addresses the one public policy objective of ensuring that the public is free to use technology in the public domain, even if incompletely understood; where a missing element may require considerable research, should public policy provide a reward for finding that missing element, in the form of a patent grant?

**Recent Canadian Decisions**

**Paroxetine hydrochloride**

*Glaxo SmithKline Inc. v. Genpharm Inc.*\(^{51}\)

This decision is the Canadian parallel to U.S. decision summarized above, relating to paroxetine hydrochloride in its anhydrate and hemihydrate forms\(^{52}\). While the decision cites the House of Lords judgment in *Merrell Dow*, the judge noted:

"I do not accept the argument that as long as the public is aware of the existence of the end "product", then knowledge of the product's composition is immaterial."\(^{53}\)

---

\(^{49}\) Id. at 1343.

\(^{50}\) Id. at 1346.

\(^{51}\) *Glaxo SmithKline Inc. v. Genpharm Inc.* 30 CPR (4th) 360

\(^{52}\) SmithKline Beecham v. Apotex, cited at 34 *Supra*

\(^{53}\) *Glaxo SmithKline Inc. v. Genpharm Inc supra*, at paragraph 100.
Further, the court distinguished the case and noted that English decisions are not binding:

"The present decision is different form the situation outlined in Merrell Dow …while there was some literature about paroxetine hydrochloride available to the public prior to 1984, such literature did not, in my view, "inevitably" lead to the invention of crystalline paroxetine hydrochloride hemihydrate. Secondly, this authority comes from the English Courts…and is by no means binding as precedent".\

Abbot Laboratories v. Canada (Minister of Health) and Ratiopharm

Abbot claimed to have discovered three forms of clarithromycin, known as Forms “0”, “I” and “II”. Form “0” is unstable and is produced in the process of making form “I” or “II”, and was also covered by one of Abbot’s patents.

Ratiopharm alleged invalidity of the patent covering Form “O” on the basis that it was inherently anticipated by prior disclosure of Form “I”. Justice Sharlow, referencing Lord Hoffman in Smithkline Beecham, noted that “(a) skilled practitioner who makes Form I or Form II following the teaching of the prior art inevitably would make Form O, even if no steps are taken to stabilize it. The Form O might not be recognized, but that does not matter".

Justice Sharlow went on find that the disclosure of Form I anticipated Form O, quoting the famous line:

[...] what would infringe if late, anticipates if earlier.

The two cases cited above represented relatively easy fact situations; the courts have yet to address a fact situation where this type of limited interpretation of the prior art could result in finding a patent valid, that effectively prevents use of technology that would otherwise be in the public domain.

---

54 Ibid. at paragraph 101.
55 Abbot Laboratories v. Canada (Minister of Health) and Ratiopharm. 2006 FCA 187 at paragraph 24.
Proposed Solution to the Problem

As argued, existing statutory provisions simply provide no middle ground between these two outcomes. The question is how can one provide a reward in the form of an enforceable patent right for a second inventor who does indeed discover the missing or unidentified element of a first invention, while at the same time ensuring that, upon expiry of the first patent, the invention enters the public domain and the public have free access to it? It is submitted that this can only be achieved by providing some new provision.

The proposal here is to provide a "right to continue to use", as an exception to infringement. Fundamentally, this recognizes that any invention (whether disclosed in the patent literature, other non-patent literature, or otherwise in the public domain) may not completely characterize the invention, i.e. that there can indeed be a substantial gap between an "enabling disclosure" and a full or complete "scientific disclosure". It would recognize that, the patent system should not permit anyone to take away from the public their right to use an invention which is in the public domain, in the sense that information that enables full and complete working of it is publicly available. This right would not be associated with any person or class of persons, but rather would be available for any invention of this sort. This right would provide that, where any person simply carries out directions for an invention that is already in the public domain and for which any patent rights have expired, then that use of the invention cannot be limited or restricted by a later or second patentee who uncovers some missing element of the invention and obtains a patent for it, where the practice of the first invention necessarily results, and in the past may have unknowingly resulted, in the formation of the second invention.

Consider the effect of such a provision on a situation similar to the Merrell Dow situation or the situation in the U.S. SmithKline case, where a first patent has issued for a first drug, and it is later discovered that the first drug is metabolized into a metabolite in the human body. A second patent later issues for this metabolite, and it can be reasonably suspected that, knowing the metabolite, other drugs can be developed that would be metabolized by different metabolic pathways to produce the metabolite of the second patent. In such a situation, this right of continued use would give anyone, including the first patentee or the public at large, the right to produce and sell the first drug, after expiry of the first patent. The second patent, granted for the metabolite, would be held valid and enforceable, but, and this is the key effect of the "right to use", it would not be enforceable against anyone making, using, selling, etc. the drug according to the first patent. However, this second patent would be enforceable against anyone who develops a different drug that metabolized to form that metabolite; effectively, this recognizes that identification of the metabolite, was a key step to
identifying such a different or second compound or drug. Clearly, depending upon the exact facts, it is possible that a separate, third patent could be granted for that second compound, and there may be scope for cross licensing between the second and third patentees. Note that the owner of the second patent does not require a license from the third patentee, if their own intent is to produce and sell the metabolite; in some situations, it may be that the metabolite is unstable or has other undesirable characteristics, and as a practical matter, one would only use it to identify possible formulations, which are more stable and which can be metabolized in use to form the actual active metabolite.

**Conclusion**

It is a little appreciated fact that the novelty standards of many countries serve a dual function. The first, clearly apparent, is to ensure that patents are only granted for new inventions. The second, present only by implication and conventional interpretation, is to ensure that public access to old technology remains unrestricted.

The presence of old technology necessarily requires, at a minimum, that there be "enabling" information about it in the public domain. If this "enabling" information amounts to full "scientific disclosure", then these two functions (defining novelty and ensuring public access to old technology) will be coextensive. If not, it is possible that the difference or missing element can amount to a separately patentable invention.

Thus, inventions that are fully described and fully enabled, within the meaning defined by patent law, but not fully understood, can continue to present problematic fact situations. If a fact situation similar to that in Merrell Dow appeared before most courts, a court would have to select between the two options identified, namely: either refuse to recognize protection for the second patent for the missing or unidentified element of the first invention; or find the second patent valid and enforceable, with the result that it may result in additional limitations on the usage of the first invention.

As argued, this cannot accommodate what appear to be the two public policy issues, namely: a public expectation that, upon expiry of a first patent, the public should have right to free use of the invention, and more generally that the public should have ongoing and unfettered access to any technology in the public domain, even if it is not fully understood; and a policy of encouraging research and development into inventions that are not fully understood, which necessarily requires that a reward in the form of effective and enforceable patent protection be provided for any element of known technology that is identified and is patentable.
It is argued that, the only way to provide some middle approach is to provide a "Right to Continue to Use". It is expected that there will be little support for such a right. The concern here is with a very specialized fact situation that requires that: there be a first invention that has some missing element or component; this missing element or component be identified later; the missing element or component amount to more than a mere scientific theory or discovery so as to be susceptible of separate patent protection; and the discoverer of the missing element or component does indeed seek and obtain patent protection; and the scope of claims obtained has the potential to curtail or limit practice of the original invention.

The Merrell Dow patents are now approximately thirty years old, demonstrating this type of difficult fact situation is clearly rare, but note the recent U.S. decisions. As in the findings of the three Merrell Dow decisions, if another comparable fact situation arose, the courts, of any country, could likely find sufficient flexibility in existing statutory law and jurisprudence to reach a decision that will appear acceptable and that will not require too much distortion of any principle of patent law.

57 For example, Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005) and SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed. Cir. 2005) (supra, footnote 47).