Patentability of Chemical Intermediates: The "Nelson" Case In Perspective

By EDWARD H. VALANCE
Patent Attorney, Geigy Chemical Corporation, Ardsley, New York
Received June 22, 1962

The patent literature relating to chemical intermediates has recently been influenced by a series of judicial decisions in the Court of Customs and Patent Appeals. These decisions clarify the requirements for a description of how to use novel chemical compounds which are "building blocks" for research. Beginning with a decision concerning steroid intermediates (*In re Nelson et al.*) and continuing with several others (*In re Johnson; In re Haven*), the law in chemical patent cases has been continually clarified. Present trend seems to be toward greater liberality when interpreting the Patent Statute with respect to the requirement of utility for new chemical intermediates.

To be patentable, a compound must be *new*: hitherto unknown or unpublished. Moreover, such a new compound must also be *unobvious*: structure and properties must not be within the skill of the ordinary scientist. Finally, a new and unobvious compound must be *useful*. What this means is being continually defined by the Courts in the light of the Patent Statute.

Patentability of all inventions—including chemical inventions—is founded on the Constitution under which authority is granted Congress to promote technological progress by granting inventors a limited monopoly on their inventions. The latest revision of the Patent Statute was made in 1952 and is embodied in Title 35 of the United States Code. The most pertinent passages from Title 35 are Sections 101 and 112 which deal generally with the requirements for utility of patentable inventions:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.. . . "

"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 make and use the same.. . . "

With regard to the general concept of utility, in 1817 Mr. Justice Story wrote in *Lowell vs. Lewis:*

"All that the law requires is, that the invention should not be frivolous or injurious to the well being, good policy, or sound morals of society."

It thus appears that the concept of utility is an extremely simple one. Whatever is beneficial, whatever is capable of producing a result that is desirable, whatever is of some value, even for recreation or pleasure, is deemed by the law to be "useful" to the extent required by the constitution. Furthermore, the degree of utility required is rather small. Almost anything which has some useful purpose will be considered "useful" according to the patent law, as was held by the Court of Customs and Patent Appeals in the 1940 case of *In re Oberweger.*

It is clear that several classes of subject matter are patentable. Here, however, there is question of but a single class of patentable subject matter, namely, that composition of matter which is a pure chemical compound useful as an intermediate for the synthesis of further compounds. The central question for study is whether chemical intermediates are useful *per se.*

REQUIREMENTS OF UTILITY: TWO VIEWS

There seem to be two views as to the requirements for disclosure of utility in patent applications for chemical intermediates. For simplicity, we shall call these theories the "strict" view and the "liberal" view.

THE STRICT VIEW

The strict view seems to be of the opinion that merge "suggestions" of an intermediate's use as "possibly" valuable for the production of other compounds is insufficient because the applicant without "taking any risk of error in the designation of usefulness, without expending time, effort and resources on determining whether the concepts and theories of uses are well founded, without the need of making a convincing showing that the new compound, if it has pharmacological action, is effective and non toxic . . . a patent monopoly may be secured on the compound."[1] The strict view would seem to ask the question whether it can "really be said, that the statutory requirement of detailed disclosure, as the *quid pro quo* for the patent grant, is satisfied, if nothing is known, except what the patent discloses, and the patent disclosure only hints at possible usefulness?"[2]

The strict view of utility for chemical intermediates thus appears to demand that the disclosed and claimed intermediates must have been shown to be useful for making at least a specific class of useful compounds. Those who hold the strict view are reluctant to extend this principle so as to make it unnecessary to specify in particular all the details as to the practical end products when it would be obvious to a skilled chemist in the particular field.

THE LIBERAL VIEW

The liberal view as to utility of intermediates is not limited to merely "commercial" utility. Whatever is beneficial to mankind is "useful": for example, in promoting and stimulating further research so that in turn new and valuable chemical end-products are discovered, the result is that the sum of human knowledge has been increased so that sciences and useful arts are augmented by some degree, no matter how small.

Many compounds "for which no true commercial utility has been developed but which are obviously usable as intermediates in order that others may use the intermediates or building blocks in their research to develop products which do not have commercial utility"[3] are often advertised in the chemical literature. "These intermediates or building blocks are very little different from bricks which as individual pieces of cermic material have no utility but which do have utility because they can be fabricated into a wall or other structure."[3] Those who espouse the liberal view of utility for chemical intermediates are of the opinion that such intermediates "are no less useful to a skilled chemist than bricks to an architect or mason."[3]

The soundness of the liberal view is illustrated by the practice of the chemical industry in advertising its new intermediates as "building blocks." This is often seen on the pages of current chemical magazines such as *Chemical and Engineering News*. For example, some chemical intermediates have been offered, to the skilled in the art, merely as having interesting possibilities for further research. It is frankly admitted by those who made these chemical intermediates that they do not always know of any specific end use; however, it is felt that the compound some day will be useful for making a specific useful compound. They are immediately useful, however, in carrying out further research in the never ending search for new and better chemical substances.

In *Chemical And Engineering News* of Febrary 2, 1959, for example, tetrapropenyl succinic anhydrate was offered as a "building block" for making chemical compounds. Similarly, in *Chemical And Engineering News* for July 7, 1958 *n*-butyl mercaptan and *n*-octyl mercaptan were offered as intermediates and as "building blocks" for producing further useful products. Other examples could be added, but these should suffice to emphasize the attitude of the chemical industry toward the usefulness of chemical intermediates which are "building blocks."

The proponents of the liberal view argue that research and development will be stifled by secrecy and failure to encourage publication by allowing patent protection for chemical intermediates. Particularly convincing cases arise in the steroid field, for example, in compounds useful in the treatment of arthritis. In 1952, hydrocortisone was probably the most potent agent for treating arthitis. However, there were problems with side effects such as sodium and water retention, potassium loss, nitrogen loss, osteoporosis, ulcerogenesis, etc. Two years later, by making a slight change in the molecule, 9-α-fluorohydrocortisone was discovered, which was ten times more potent than hydrocortisone but unfortunately also had undesirable side effects which made it impractical for arthritis therapy. A year later an improved structure was unveiled. Simply the presence of a double bond in the molecule made a big difference, since the new compound was found to be four times as powerful as hydrocortisone and yet eliminated the side effects of sodium and water retention and potassium loss. Still later, in 1956, by the combination of the double bond and an extra hydroxyl group in the 16-position, a new steroid was produced with an activity six times greater than hydrocortisone. A fifth new steroid compound was developed having about the same potency as the previous compound. Finally, in 1958, still another new steroid was developed with an activity thirty times as great as hydrocortisone.

It is seen from this evolution of six new steroid compounds that by disclosure of the basic structure of hydrocortisone to research scientists in the steroid field, further research was stimulated so that more and more useful compounds were developed.[4]

LIBERAL CASES

The extreme liberal view as to patentability of chemical intermediates was seen in the case *Ex parte Watt* in the year 1942. According to the *Watt* decision, new organic chemical compounds were *assumed* to have utility (at least as "intermediates") on the grounds that it would be obvious to any skilled organic chemist that any organic compound could be used as an intermediate in producing other organic compounds. In 1943, *Ex parte Borglin* held that

> "... one discovering a new chemical compound is not required to show reduction to practice of said compound for any particular use. If he can make any showing of utility of said compound that is deemed sufficient."

A similar holding was made recently by the Court of Customs and Patent Appeals in the case *Blicke vs. Treves* in 1957. In another recent case in 1956, *Reiners vs. Mehltretter*, there was the holding that

> "... in order to establish utility of a product it is not necessary to show that it can immediately and without change perform a useful function. Products are useful if they serve as starting materials or intermediates in producing other materials or articles which are directly useful."

While the "liberal" view with respect to utility requirements for chemical intermediates appears to have continued through the years down from the *Watt* decision almost to the present time, there is another line of decisions both in the Patent Office and in the Courts which reflects the "strict" view as to utility for chemical intermediates.

STRICT CASES

The central decision, around which the strict view as to utility turns, appears to be the 1950 case, *In re Bremner*.

The *Bremner* case developed the rule that:

"no 'hard and fast' ruling properly may be made fixing the extent of the disclosure of utility necessary in an application, but ... the law requires that there be in the application an assertion of utility and an indication of the use or uses intended."

Thus, it is seen that the practice with regard to disclosure of utility for chemical intermediates became greatly modified in the light of the strict *Bremner* decision which was handed down only 8 years after the liberal *Watt* case.

The *Bremner* decision and others like it were relied upon by the Patent Office in rejecting patent applications for chemical compounds as intermediates on the basis of lack of utility.

One of the first decisions of the Patent Office Board of Appeals to follow and interpret the Bremner case was the 1954 decision *ex parte Tolkmith*. The *Tolkmith* case rejected the concept of sufficiency of utility for a chemical intermediate unless the final product of that intermediate in known, specified, and its use spelled out clearly in the patent application for the intermediate.

In the case *Ex parte Ladd*, the Patent Office Board of Appeals laid down the rule in 1955 that:

"... when a newly discovered compound belongs to a class of compounds the members of which have become well recognized to be useful for a particular purpose, and it is evident from the prior art that it is within the skill of the art to use the claimed compound for this purpose, the disclosure that the claimed compounds may be so used is sufficient to meet the requirement of section 35 USC 112...."

The 1957 case of *Petrocarbon Limited vs. Watson* held insufficient a disclosure of utility since the Federal District Court felt that one skilled in the plastic art would not know how to use a "film." This viewpoint is representative of the "strict" view with regard to disclosure of utility. The Court of Customs and Patent Appeals, however, disagreed with the District Court and reached an opposite result on the same point in the *Nelson* case, which is discussed below.

THE NELSON CASE

We have seen a change of practice toward a "strict" view which would require spelling out the details as to *how* useful end products might be obtained from chemical intermediates. A reappraisal of the "strict" view has, nevertheless, resulted primarily from the 1960 case *in re Nelson*.

The issue in *Nelson* was whether a "building block" in the synthesis of other compounds is "useful" for a beneficial purpose within the meaning of the Patent Statute.

The subject matter of the *Nelson* case involved steroids, in particular steroid hormones. We have seen how in the case of hydrocortisone, research had taken one basic material and by various chemical steps brought about an evolution of a much more useful and potent material than was the original compound. Thus, the original compound hydrocortisone was an "intermediate" for the production of those related compounds which followed.

The rule of the *Nelson* case appears to be that chemical intermediates *can be* useful in themselves. However, not every chemical intermediate is useful, and what determines whether a chemical intermediate satisfies the requirement *that* it have utility, according to the Patent Statute, depends upon the circumstances of each case, nor is it possible to lay down any "hard and fast rule" as to *what* is useful with regard to chemical intermediates generally. The Court of Customs and Patent Appeals, in deciding the *Nelson* case, spoke as follows in connection with the question as to whether the claimed androstene compounds of Nelson were useful according to the standard of the Patent Law:

"... new 'building blocks' *of value to the researcher* have been supplied which have *utility as intermediates* in the search for cheaper and shorter routes to the synthesis of steroids having therapeutic or similar ultimate utility.

The Patent Office position seems to have been that there must be a presently existing 'practical' usefulness to some undefined class of persons.... Surely a new group of steroid intermediates is *useful to chemists doing research* on steroids, and in a 'practical' sense too.... They are often actually placed on the market before much, if anything, is known as to what they are 'good' for, other than experimentation and the making of other compounds in the important field of research. Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys, which disclosure the potential protection encourages. This would tend to retard rather than promote progress."

Thus, it is clear that the Court of Customs and Patent Appeals found that intermediates are useful if chemists can make use of them for doing future research which ultimately may result in important advances of science and the useful arts. The Court concluded that the Nelson compounds were useful within the meaning of the patent statute.

While the Court found in the *Nelson* case that the real issue was whether or not the claimed chemical intermediates which were useful for research purposes under the circumstances of that case, satisfy the requirements that they be useful, there still remained a further question as to whether or not the manner of using these intermediate compounds was *sufficiently* disclosed. The law requires that an applicant for an invention disclose the best mode of practicing his invention and describe the same in such full, clear, concise, and exact terms so as to permit other persons skilled in their art to practice his invention.

The Court in the Nelson majority opinion makes it clear that

"... the test is what the application as a whole *communicates* to one skilled in the art. In some cases an applicant may, merely by naming his new instrument or material, indicate *what* its use is, as, for example, by saying he has invented a 'match,' 'hammer,' 'paint,' 'adhesive,' or 'detergent.' He may or may not have to go further in order to *enable* others to use the invention, depending on its nature and on how much those of ordinary skill in the art know. In other words, compliance with the law does not necessarily require specific *recitations* of use but may be inherent in description or may result from disclosure of a sufficient number of properties to make a use obvious; and where those of ordinary skill in the art will know *how* to use it, the applicant has a right to reply on such knowledge. If it will not be sufficient to enable

them to use his invention, he must supply the know how. As this Court has often said before, each case must be judged on its own facts."

THE JOHNSON CASE

Another recent case (1960) appears to extend and amplify the principles discussed in *Nelson*. That case is *In re Johnson*. In the *Johnson* case a chemical compound was described as being useful as an intermediate "for organic synthesis, for solvent uses and for the preparation of toxic substances such as insecticides, fungicides, etc." This statement of utility was found by the Court of Customs and Patent Appeals to be an adequate statement of *what* utility the claimed composition possessed. There was no question as to the sufficiency of disclosure in reference to the properties of the compound in question. What was disputed was whether or not it was clear *how* to use the claimed composition. The Patent Office felt that it was *not* clear how to use the claimed composition. The Court on the other hand, felt that those skilled in the art would know *how to use* the composition when they were told that said composition might be used as an "intermediate" or as a "solvent" or as a "fungicide" or "insecticide."

THE HAVEN CASE

Just as the *Johnson* case depends upon the principles elaborated in *Nelson*, so also the recent 1961 decision *In re Haven* rests on the same foundation. The situation in *Haven* was essentially the same as in *Nelson* except that a different field of chemistry was involved and there was added to *Haven* the principles clarified by *Johnson* with regard to sufficiency of disclosure of utility for chemical intermediates.

In *Haven*, the dispute turned upon the adequacy of the utility statement in teaching the *manner* of using the claimed intermediate for the production of certain dyestuffs. At the outset, the Court laid down that dyestuffs "as a group are inherently useful and that one skilled in the art need not be told to how use dyestuffs." The issue was narrowed to the question as to whether or not an organic chemist skilled in the art of dyestuff chemistry would know without any further teaching in the patent specification how he could prepare useful dyestuffs from the claimed intermediate compound. The majority of the Court found that such a chemist would be able to so practice the invention.

CONCLUSION

Looking at the *Nelson* case, in the perspective of *Johnson*, *Haven* and other recent decisions, this writer does not think that the basic *principles* of the law have changed; rather *facts* have changed. Voices are heard to remark that "*Nelson* does not change the law!" True, there has been no *real* change. But there must be a change in practice away from the "strict" view, if the spirit of the recent *Nelson* decision is to be followed by all concerned.

There has been a change by the return to a more liberal view. The "new" liberal view is, however, tempered by a conservative spirit not found in the early *Watt* case. It is difficult, indeed, to think of many chemical compounds, for which there does not exist at least the possibility of utility as tools for research. Every new compound is a potential stepping stone along the way to future end products of indisputable technological value. Chemical building blocks *are* useful; it is hould happen, however, that a compound is made for which no use is visualized, not even use in further research, then even according to *Nelson*, such a compound would not be patentable. The *facts*, therefore, do change and do control the answer to the question whether a chemical intermediate is "useful."

REFERENCES

(1) *In re Nelson*, Patent Appeal No. 6338, Petition of the Commissioner For Rehearing, page 26.
(2) *Ibid.*, p. 27.
(3) Patent Appeal No. 6338 (*In re Nelson*), Amicus Curiae Brief of Connecticut Patent Law Association, page 10.
(4) *Chemical And Engineering News*. June 30, 1958, pages 42 and 43.

SELECTED BIBLIOGRAPHY

(5) Cohen, S. H., and Schwartz, C. H., "Do Chemical Intermediates Have Patentable Utility?" *George Washington Law Review*, **29**, No. 1, 109.
(6) Burke, J. J., "Utility of Chemical Inventions: Chameleon of the Patent Law," *Journal of the Patent Office Society*, No. 3, 217 (1961).
(7) Reardon, D.J., "The Utility Requirement in Chemical Patent Applications," *Journal of the Patent Office Society*, **38**, 282 (1956).