

PATENT PROTECTION IN THE DRUG FIELD

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INTRODUCTION

It is part of human nature and the quest for security to seek to amass material goods and to increase wealth. One of the characteristics of a well-ordered State is, therefore, a constitutional and legal basis for the protection of material property. Curiously enough in earlier centuries rights in the field of the intellectual property, such as inventions and works of art and literature, were not clearly defined. In the Middle Ages, and even some centuries later, because protection for inventions was lacking the inventor had to try to keep them secret in order to be able to utilize them industrially without unwarranted interference by others. One consequence of this situation was that, on account of the need for secrecy, large scale industrial production could not take place. Large scale production would inevitably have required the employment of large numbers of people and, under these conditions, the inventor would not have been able to keep his invention really secret.

Patent Law first came into being as long ago as the year 1400 in Venice and developed as a result of the coming into force of the Statute of Monopolies in England in 1624. In the United States of America in 1789 the concept of the promotion of Science and Technology by the granting of patents was enshrined in the Constitution: 'The Congress shall have the power . . . to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries'. About one year later, on 10th April 1790, George Washington signed the first Patent Law of the United States, which laid down the pre-requisites for the obtention of patents and the protection conferred thereby. France followed and also included patent protection in its Constitution. In the 19th century most of the other European countries also passed laws for the protection of inventions by patents. This was the beginning of a new era in which there was no longer an anomalous distinction between rights concerning material property and rights concerning intellectual property. Works of literature and art were automatically protected on publication by the so-called copyright; protection for inventions was obtainable by special procedures involving application to the patent offices established by the governments.

The considerations leading to the introduction of patent protection were not so much the protection of the inventor by assisting him to make commercial profits, but rather the promotion of progress and industrialization by research, invention and publication of all the details of inventions. It was no longer necessary for the inventor, in his own interests, to keep his inventions

secret. On the contrary, by describing his invention in the patent documents, he was able to obtain for a limited period, protection for his invention. Such description, on the one hand, determines the scope of protection for the inventor and, on the other hand, increases the documentation of technical achievements and promotes technological development. Patents as a whole represent an important compilation of our technical achievements and form the basis for further research and industrial development. The expectation clearly laid down in the American Constitution, namely that protection of intellectual property would promote scientific and technical advance, has been fulfilled. No other country has developed so much during the past 150 years as the U.S.A., and there is no doubt that this progress is intimately related to the existence of patent protection. Dr. Hans Harms, President of the German Federation of Chemical Industry, has made the following pertinent remark: 'No technical science without constant new developments; no developments without recognition of intellectual property rights'.

Drug research, which is still a young science, has been amazingly successful during the past 30 years. Hundreds of new preparations have been developed for medicinal purposes. Such preparations have caused a profound change in medicinal therapy. Many feared diseases have lost their lethal character and recovery is quicker. The mortality rate for small children has decreased, life expectancy has increased, chronic illnesses have been alleviated, and incapacity for work because of illness has been reduced. Everyone has therefore profited from the results of pharmaceutical research. It would consequently be expected that the basis on which this progress was achieved, namely the protection of intellectual property by patents, would be jealously guarded all over the world, and, indeed, extended in recognition that it is a pre-requisite for the further development of medicine. It can be said with satisfaction that this is so in several countries, e.g. Germany, France, Switzerland and Japan and, above all, the U.S.A. In the course of the last few decades these countries have extended and improved the degree of patent protection obtainable for inventions in the pharmaceutical and other fields. Unfortunately, some highly industrialized countries and also some under-developed countries take a contrary attitude, or even aim at abolition or weakening of patent protection for pharmaceuticals. This development could have serious, far-reaching consequences, and it is essential to realise what the consequences would be, to discuss them in public and to strive to prevent them before it is too late. This is particularly so as the arguments of those official authorities supporting the abolition of the patent protection of pharmaceuticals are not only on a feeble basis but also involve highly dangerous nationalistic considerations which must not be allowed to set a precedent. The Canadian Hall Report may be regarded as an example. The author does not hesitate to maintain that the abolition of the patent protection for pharmaceuticals in Canada would cause no disadvantages—in Canada! 'There appears little reason to believe that the abolition of patents in Canada would have any effect on research activities in the United States or Europe.' This is a clear condonation of piracy and parasitic reliance on the intensive research of the private industry of other countries. Such an attitude in a prosperous country is extremely dangerous and will have repercussions in less developed parts in the world. The aim of this speech is, therefore, to give a rough picture of

such developments, in order, so far as possible, to be of assistance in combating them.

For the sake of clarity, we should like to discuss the whole matter under four headings: (i) Drug research and its effects on human health. (ii) Sources of new drugs. (iii) Patent protection as basis for drug research. (iv) Discrimination against patent protection for pharmaceuticals and its consequences.

DRUG RESEARCH AND ITS EFFECTS ON HUMAN HEALTH

As Fleming's discovery of penicillin (1928) despite the publication of all significant data did not meet with appropriate interest from either the universities or the pharmaceutical industry, and did not, therefore, give rise to any noteworthy consequences until the forties, it is reasonable to state that Domagk's discovery of the bactericidal effect of Prontosil rubrum marked the beginning of a new era in the field of drugs. Since that time drug research has been so intensely active that it is quite impossible to survey all the results in detail. The following discussion is therefore restricted to the most spectacular developments. The recently published analysis of the American Medical Association, which compiled the most important classes of agents discovered since 1935, may serve as a basis for this discussion. The development of the group of penicillin agents and other antibiotics can be regarded as the most important achievement in the field of drugs. Adrenocorticosteroids; vaccines (e.g. against poliomyelitis); synthetic anticoagulants; Isoniazid and *p*-aminosalicylic acid (PAS), which are the most important agents for combating tuberculosis; psychopharmaceutical drugs and mild tranquilizers; hydantoin for the treatment of epilepsy; antihistaminics; salidiuretics such as thiazide; sulphonamides with a bactericidal effect; analgesics such as Mepridine; oral antidiabetics; new antimalarial and anti-amoebic agents such as Chloroquin; anticholinergic agents; various antihypertensive agents; new types of anaesthetics; muscle relaxing agents; Oestrogen-Progesteron contraceptive agents; and agents for combating Parkinson's disease also belong to the more important pharmaceuticals of today and (except for sulphonamides) have been developed since 1940, and introduced into therapeutic use.

A comparison of these agents with those used by doctors before 1940 demonstrates the enormous progress achieved. The advances in therapeutic treatment and the resulting beneficial effects on human health have directly resulted from these new drugs. Sulphonamides have enabled the treatment of pneumonia, which hitherto was greatly feared, as well as meningitis and urogenital infections. Antibiotic agents have been successfully used in direct treatment of all known pathogens, and *p*-aminosalicylic acid and Isoniazid have enabled the successful treatment of tuberculosis. The accidental discovery of the psychotropic effects of reserpine and chlorpromazine has led to a profound development in this field and thus to a basic change in the methods of psychiatric therapy. A patient suffering from a mental disease and hospitalized in 1932 had to stay in hospital for at least 30 years on average or sometimes even for life; today two-thirds of all hospitalized patients become outpatients after 12 months at the latest. In developed countries smallpox

has practically disappeared as a result of vaccination, poliomyelitis has been successfully treated and typhus, paratyphus, cholera and measles have been controlled. Mortality as a result of disease has been generally reduced, infectious diseases such as flu and pneumonia, and childrens' diseases are no longer the primary causes of death.

The question of incapacity for work as a result of illness is of further interest in this connection. This was particularly examined in England: 300 million working days were lost on account of illness from June 1962 to June 1963, i.e. about 14 days per person, and these figures include only patients belonging to the National Health Scheme. During that time the NHS paid out sickness benefit amounting to about 1.7 billion DM, corresponding to 1/6 of the entire expenses of the National Health Scheme! What diseases caused this incapacity for work? Firstly, flu and bronchitis, followed by circulatory diseases, mental disorders and arthritic conditions. There was remarkably little incapacity for work caused by tuberculosis or other infectious diseases.

In spite of all the progress of the past 30 years we have to recognize that many problems still remain to be solved. There are still numerous diseases which can only be treated symptomatically or even not at all because of a lack of suitable drugs. Above all, cancer, heart and circulatory diseases as well as suicide lead to mortality. Tropical diseases are also for some reason still an unsolved problem. We therefore stress the hope that the research-based pharmaceutical industry in close collaboration with the universities and clinics working on this difficult task will not in the future be prevented from making the invaluable contribution that they have made in the past.

SOURCES OF NEW DRUGS

In the preceding paragraph we have dealt briefly with the developments in the field of pharmaceuticals since 1935 and their consequences. It is now of particular interest to discuss the sources of new drugs and the factors underlying their discovery and preparation. In his highly regarded speech 'Academic and Industrial contributions to Drug Research' the Nobel Prize winner Ernst Chain estimated that 75 per cent of new drugs are developed in industrial research establishments. This figure is a realistic one; indeed, in my view, the correct figure is somewhat higher. The research-based pharmaceutical industry is *the* supplier of new drugs and it has taken an active part in medical change. Research in this industry is extremely complex and includes practically all areas of natural science and medicine. A large complex organisation is essential and it requires large and high-risk investment. Accordingly, research on a large scale can only be started and maintained by a large enterprise. This can be seen from figures characterizing the growth of the American pharmaceutical industry during the past 25 years.

In 1951 the pharmaceutical industry of the U.S.A. spent about 50 million dollars on drug research. By 1966 this expenditure had risen ninefold, namely to somewhat more than 400 million dollars. In 1959 the total number of employees and workers in this industry was about 83 000; 11 400 of these were doing research work. In 1965 the total number of persons employed had increased to 94 000, of which 16 440 were employed in research.

But not only the extent of industrial drug research has changed. Many factors, such as the rapid development of chemistry and physics, new results in biochemistry, new pharmacological and clinical methods of investigation, the impact of electronics on natural sciences and, last but not least, the ever decreasing probability of discovering new drugs, have led over the past few years to a complete change in the nature and extent of research compared with earlier times. Instead of individual inventors, as was the case at the time when Domagk and others made their inventions, we have research teams, and these are ever growing larger and more complex. The individual person has become an integral part of a team and the independent inventor has been largely superceded by Corporation Research in pharmaceutical industry. A private enterprise can only consider carrying out research work involving such high expense and risk if there is some assurance that the rare positive results can be utilized industrially under patent protection. This is an essential condition. Otherwise industry cannot justify the large capital investment required for research, particularly in view of the high risk involved. Furthermore, only when this condition is fulfilled can the financial basis for further expansion, and the associated risk, be secured.

In his highly regarded work *Drugs, Doctors and Diseases* Brian Inglis recently clearly formulated this necessary condition in the following terms:

‘The recent pharmaceutical discoveries which have done so much for mankind would not have been made were it not for the protection which the patent system provided for researchers. Without it they would have no incentive to pursue their labours—knowing, as they would, that if they discovered a valuable new drug, any rival could latch on to it, market it, and reap the benefit’.

An expert in this field, Etienne Junod, in his speech at the 175th anniversary of the instigation of a patent system in the U.S.A. analysed the situation as follows:

‘Drugs which have not been patented are subject to free competition. The inventor of these substances has to adapt his prices to those of the competing firms which did not have any research expenses. It is obvious, therefore, that he is in a disadvantageous position. It is therefore generally recognized today that current research costs can only be recouped by the sale of some few patented products. Only such products give rise to the necessary profit for financing current research costs and other investments’.

We shall, however, see that, even if patent protection is granted to the inventor of a preparation involving a new class of substances, i.e. for a pioneer invention, competing preparations containing active ingredients which are different from but related to the new class, and possibly superior, will very soon appear on the market. The monopoly of the first inventor is thus soon impaired and he is forced to continue his research work in order to counteract competition.

Pharmaceutical research today is mainly carried out in the industrial laboratories of a few countries, above all in the U.S.A., Switzerland, Germany, England and France. Research-based industry must have large financial resources available in order to be able to accommodate this high

risk research. The firms involved must, therefore, have a certain minimum size and only few firms are able completely to fulfil all the basic pre-requisites for drug research. An analysis by the PMA of all drugs that have come into therapeutic use in the U.S.A. since 1940 showed that out of about 800 drugs developed during that period 500 came from the U.S.A., 54 from Switzerland, 39 from Germany, 36 from England, 22 from France, 11 from Denmark, and 6-9 each from Mexico, Holland, Sweden, Belgium and Japan. Austria and Canada each developed 3 new drugs, Hungary 2, whereas Czechoslovakia, Argentina, Australia, India and Italy each contributed only 1. These statistics do not, of course, take into account those pharmaceuticals which were developed by the major Italian pharmaceutical firms for other markets.

The number of new drugs produced is proportional to the money invested by industry in the leading countries. In the U.S.A., Switzerland and Germany, between 10 and 12 per cent of the total turnover was invested in research work. This is possible because firms in these countries can count on patent protection for the few of their new substances which are useable in practice (it is estimated that today only 1 out of 3000-5000 compounds investigated becomes a useful drug product) and, therefore, be assured that they alone are in a position to commercialise their research results and so finance new research for some years.

A more detailed analysis of the protection for drugs conferred by patents in the above mentioned countries is provided hereinafter.

PATENT PROTECTION AS THE BASIS OF DRUG RESEARCH

Although, especially during the past few years, patents have been publicly—but not always rationally—discussed quite frequently, in many circles fundamental misconceptions still exist concerning their function, field of application and their consequences for the public and the inventor. Patents are legal titles granted to the inventor or his legal representative by the Government. They confer the right on the inventor of preventing unauthorised persons from using his invention. Like other property, e.g. land, they may be sold or licenced. We have already demonstrated how patents stimulate science, technical progress, industrialization and enable investment in private industry to take place. In return for this worthy contribution, the State protects the inventor by granting him a monopoly right for a limited period. Inventions, however, are only successfully protected by patents if they meet some prerequisites, of which the most important are novelty, technical advance and unobviousness. In some countries, a patent application is subjected to a thorough investigation by the Patent Office. In other countries, there is only a formal investigation and the patent is granted without examination and the questions of novelty and merit of the invention, industrial utility and other elements of patentability are left for determination by the Court. While both systems have advantages and disadvantages, these will not be discussed here. It may be of special interest to examine the different kinds of protection granted by patents for inventions in the field of chemistry. The possible types of protection are as follows: for a new product,

for the process for its production, for a special method of preparing a product, or for a special use of a product. There are countries which provide for all of these forms of protection in their patent laws whereas others only provide for certain of them.

Apart from the type of patent protection, the duration of patents is of great importance. This is usually about 15 years. In view of the fact that development of a new pharmaceutical product to the point where it can be marketed inevitably takes much time, currently about 5 to 10 years, in practice the invention can only be used under patent protection for a short time, namely about 10 to 5 years, often even less.

Moreover, the patent laws of most countries contain a further regulation which is of great significance to the inventor. Thus, nearly all patent laws have paragraphs relating to Government use of patented inventions enabling the Government in states of emergency, such as war or epidemics, effectively to take over any desired patent. These regulations ensure that the Government is not prevented by patents from taking any necessary steps in an emergency. Some countries have discriminated against pharmaceuticals and considerably weakened patent protection therefore generally, i.e. even when there is no state of emergency. In such countries not only may the Government itself obtain a compulsory licence (e.g. for the purposes of a State-organised Health Service), but so may any third party who is interested.

In the list of countries producing new pharmaceuticals, Italy, is only on the same level as countries which are scarcely developed industrially at all. Nevertheless, Italy has an efficient and developed pharmaceutical industry which would be in a position to use its research organisations for the development of new drugs, as is the case with other highly industrialised countries. However, since there is no patent protection for pharmaceuticals in Italy at all, research can only be done in an insufficient way. Thus most Italian firms limit themselves to the imitation of the inventions of foreign countries and make no recognisable contribution to progress in therapy. This situation is most unfortunate for those few Italian pharmaceutical firms which, despite the lack of patent protection, do carry out intensive research; as soon as they obtain results which can be applied in practice, the fruit of their labour is copied by the small Italian firms, thus depriving the research-based firms of the profits which are needed for the continuation of their research. On this basis, only very few Italian pharmaceutical firms are able to develop effective drug research of their own and the majority (approximately 1000 firms) merely exploit the situation. In having no patent protection for pharmaceuticals, Italy is on a par with Ethiopia, Afganistan, Turkey and Communist China, whereas all other countries, the Soviet Union and the whole Eastern Bloc included, do have such patent protection.

Italy is now being put forward as an example that imitation pays by the various developing countries which are thinking of either complete abolition or a very considerable weakening of patent protection for inventions in the field of drugs. A well-known expert in this field, Professor Bergami, leading a Government-sponsored Commission, recently thoroughly and critically examined the drug situation in Italy. One of the conclusions reached by the Bergami Commission was that the lack of patent protection was neither advantageous to the industry nor to the sick. Ill people in Italy not only

do not get drugs cheaper than in comparable countries, but in many cases must in fact pay higher prices for the same medicine; lack of patent protection has also resulted in there being no incentive for research investment in the Italian drug industry. With the exception of the few large pharmaceutical Companies, this industry in Italy, struggling to profit as much as possible from the research efforts of foreign companies, lags behind the industry of other countries and the troubles involved in succeeding in this aim are demonstrated by the many reports on the difficulties with which they are faced. In strong contrast is the Italian plastics industry which, under adequate patent protection, has been able to develop and achieve a leading international position.

The opponents of patent protection often argue that patents grant the inventor too strong protection and an absolute monopoly, exceeding admissible standards and leading to an exploitation of the ill human being. This argument may easily be overcome; experience during the past 30 years has unequivocally shown that an inventor practically never succeeds in monopolising the new product first discovered by him and in exploiting it commercially over a long period. To the contrary, we have learnt by experience that soon after the first introduction of a representative of a new class of substances into therapy other firms introduce competing substitutes. The patents of the first inventor have forced the competing industry to do its own research which often results in the invention of new independent agents. It is obvious that this leads to serious competition for the first inventor. However, such competition leads not only to further progress but also causes the prices of the different firms all to be within a certain range, which range is determined by the free competition, and avoids abuse of the limited monopoly granted. Some examples of such developments are given below.

Sulphonamides. The first compilation (Sulphonamides; *Figure 1*) expressly indicates that, soon after announcement of the action of Prontosil, extremely intensive research work started and soon led to the introduction of competing bactericidal sulphonamides by many firms.

Salidiuretics. The modern salidiuretic agents represent a further particularly interesting example. The investigations of the MSD laboratories, lasting for about 15 years and culminating in the introduction of the new salidiuretic Chlorthiazide in 1958, incited competing firms to take up analogous research. Thus, soon after the introduction of Chlorthiazide into therapy, another enterprise developed the dihydro derivative and somewhat later different firms brought other highly effective salidiuretics on the market. MSD laboratories had performed a great pioneer work, but despite the patents it had obtained, was unable to establish a monopoly in the field of synthetic salidiuretics. The present situation in this field is illustrated in *Figure 2*.

Antidiabetics. The oral antidiabetics show a similar picture (*Figure 3*). After a German pharmaceutical firm succeeded in introducing Carbutamide,

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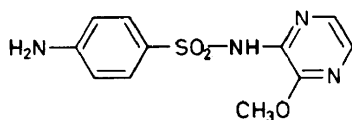
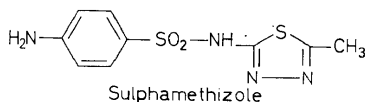
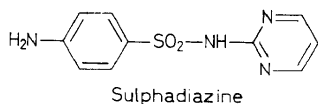
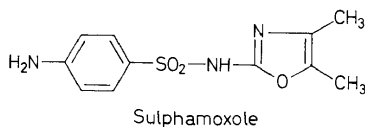
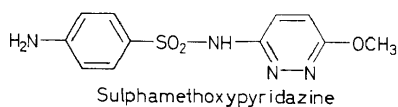
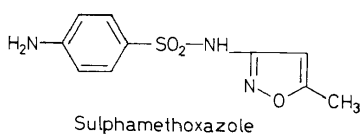
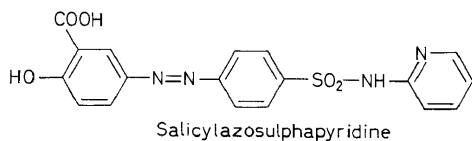
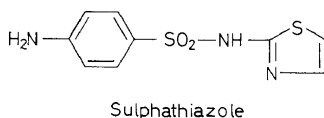
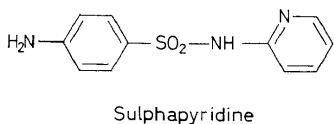
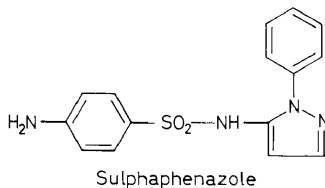
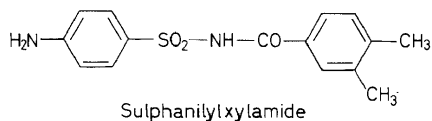
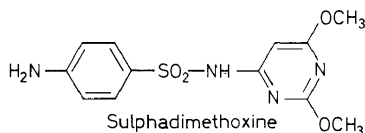
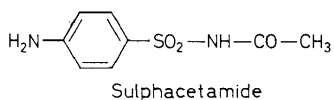
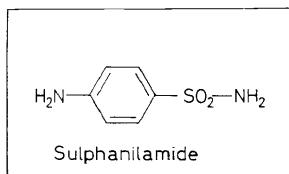
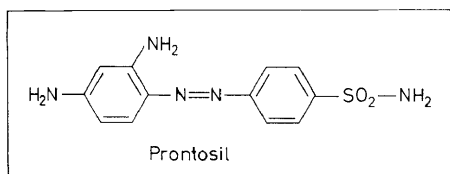


Figure 1. Sulphonamides in current use.

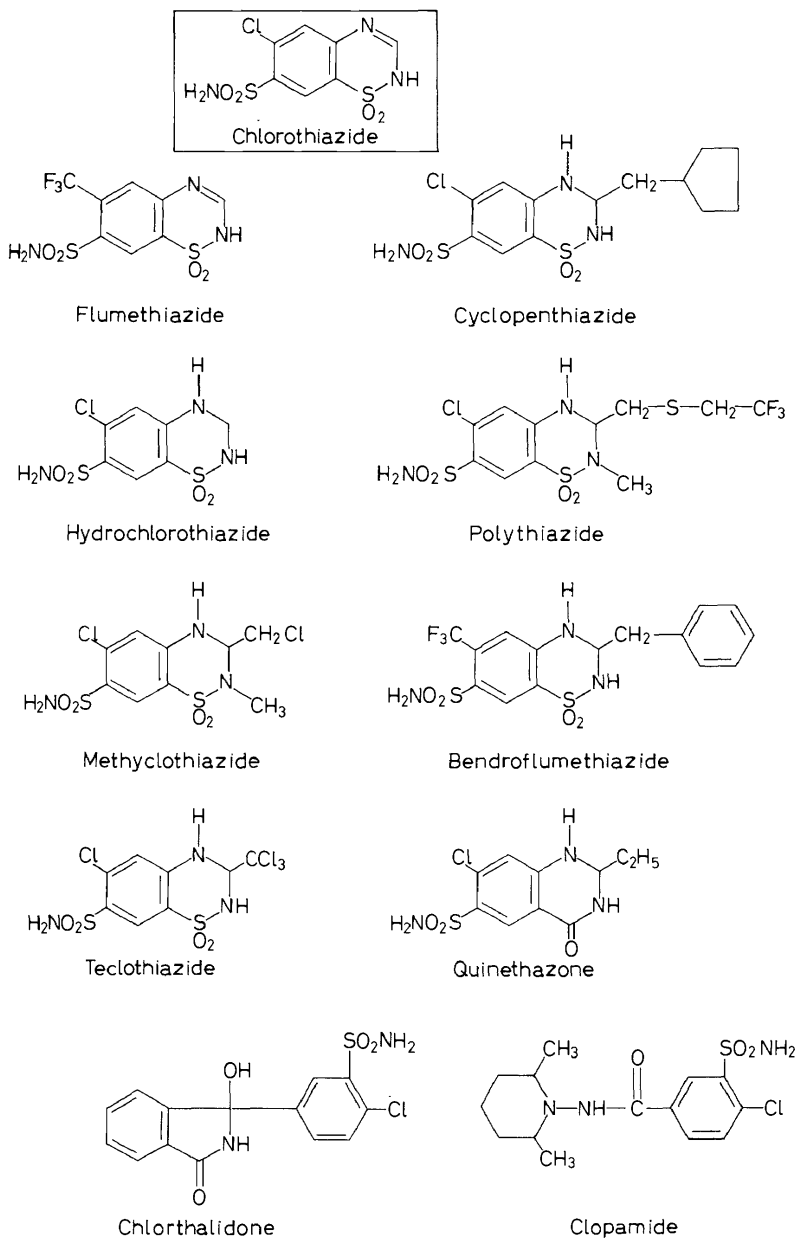


Figure 2. Salidiuretic agents.

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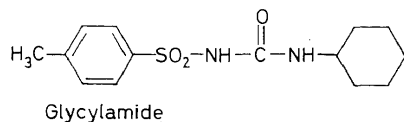
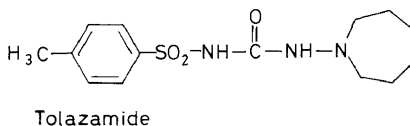
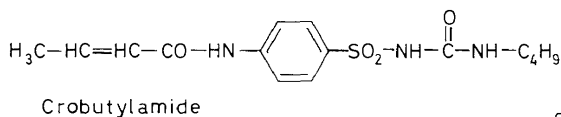
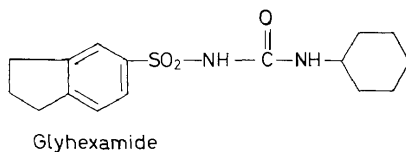
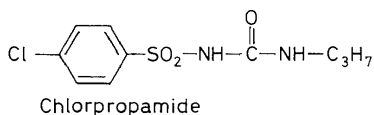
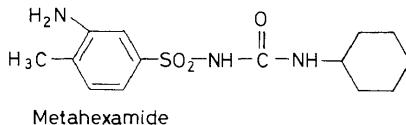
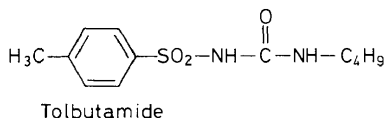
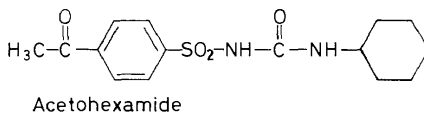
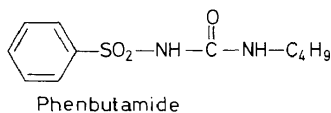
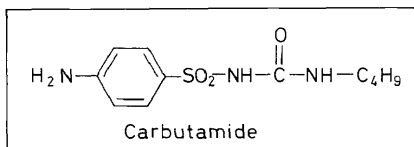


Figure 3. Oral antidiabetics.

which was the first orally effective antidiabetic substance, a number of other antidiabetics were developed in other research laboratories. Again, the first inventor was unable to gain a monopoly and was forced to combat competition from other firms.

Psychopharmacological drugs. At the beginning of the fifties, psychopharmacological drugs came to the forefront with two prototypes, which are completely different chemically but possess very similar action. These prototypes were reserpine and chlorpromazine. The fact that both the firms introducing these agents protected their results by patents, did not save them

from competition. *Figure 4* shows only a small selection of the present range of psychopharmacological drugs. There was an analogous development in the thioxanthene, benzazepine and other groups of psychotropically effective aromatic tricyclic compounds.

Corticosteroids. Finally, we consider the field of corticosteroids (*Figure 5*), the prototype of which, Cortisone, has opened up new aspects in the treatment of rheumatic diseases. Again, the firm having carried out the basic research work at great expense, despite good patent protection, was unable to gain a monopoly. Research work carried out in other industrial laboratories soon enabled this highly interesting field to be penetrated and strong competition for Cortisone to be established.

These comparisons show unequivocally that, with the present thriving state of chemical research, even the best patent protection does not adequately protect the inventor. It is precisely this patent protection which compels laboratories to carry out their own investigation with the aim of avoiding the scope of protection of the first inventor. At the same time these investigations promote technical and economic advances.

Despite the fact that only in a negligible number of cases has an inventor of a new drug been able to secure his monopoly and protect his research work from competitors through patents, patents have been subject to public political attacks on this basis for many years, and in numerous countries their effectiveness has either been severely undermined or completely eliminated. In the following paragraph, this particular problem is dealt with in detail.

DISCRIMINATION AGAINST THE PATENT PROTECTION OF DRUGS

We have already briefly mentioned that Italy, the only industrialized country which does not grant patent protection for drugs, is only on the same plane of development as Ethiopia, Afghanistan and Communist China. In view of the negative effects of the lack of patent protection on the Italian pharmaceutical industry, it is almost incomprehensible that the Italian Government does not put an end to this situation. However, those forces in Italy which unite to defeat any Bills for patent protection for drugs have prevailed for several decades. It was in 1926 when the well-known research worker Horlein said that:

‘intellectual property in the pharmaceutical and medical field is still unprotected in numerous countries in the world. The countries concerned do not grant protection for the production of new drugs and, moreover, they encourage their industry to copy all important inventions. It could be said that this situation resembles that of the robber-knights in the Middle Ages even though the invention of drugs to combat tropical and other infectious diseases is a matter of great concern to the human race and requires the widest collaboration between chemical undertakings to succeed’.

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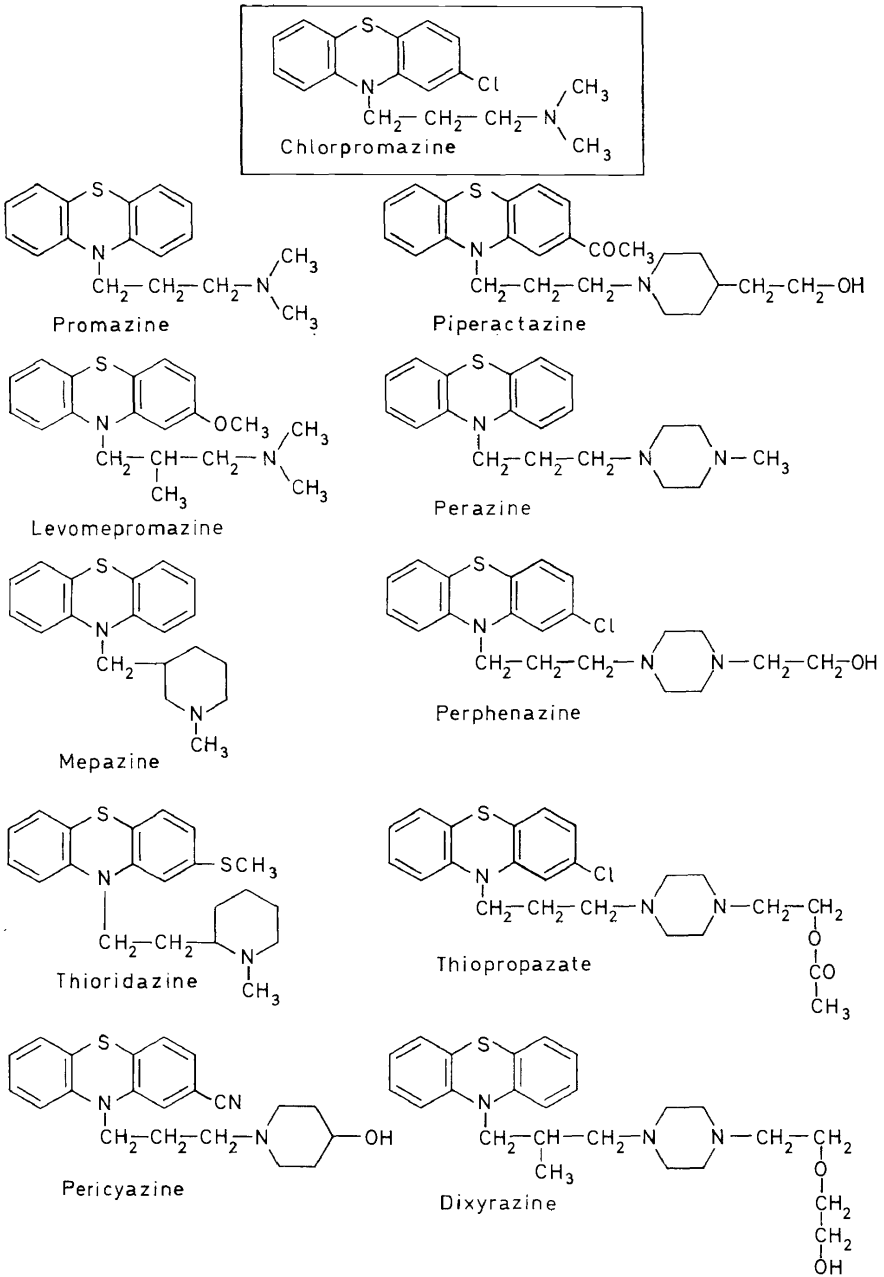


Figure 4. Some of the better known psycho-pharmacological drugs.

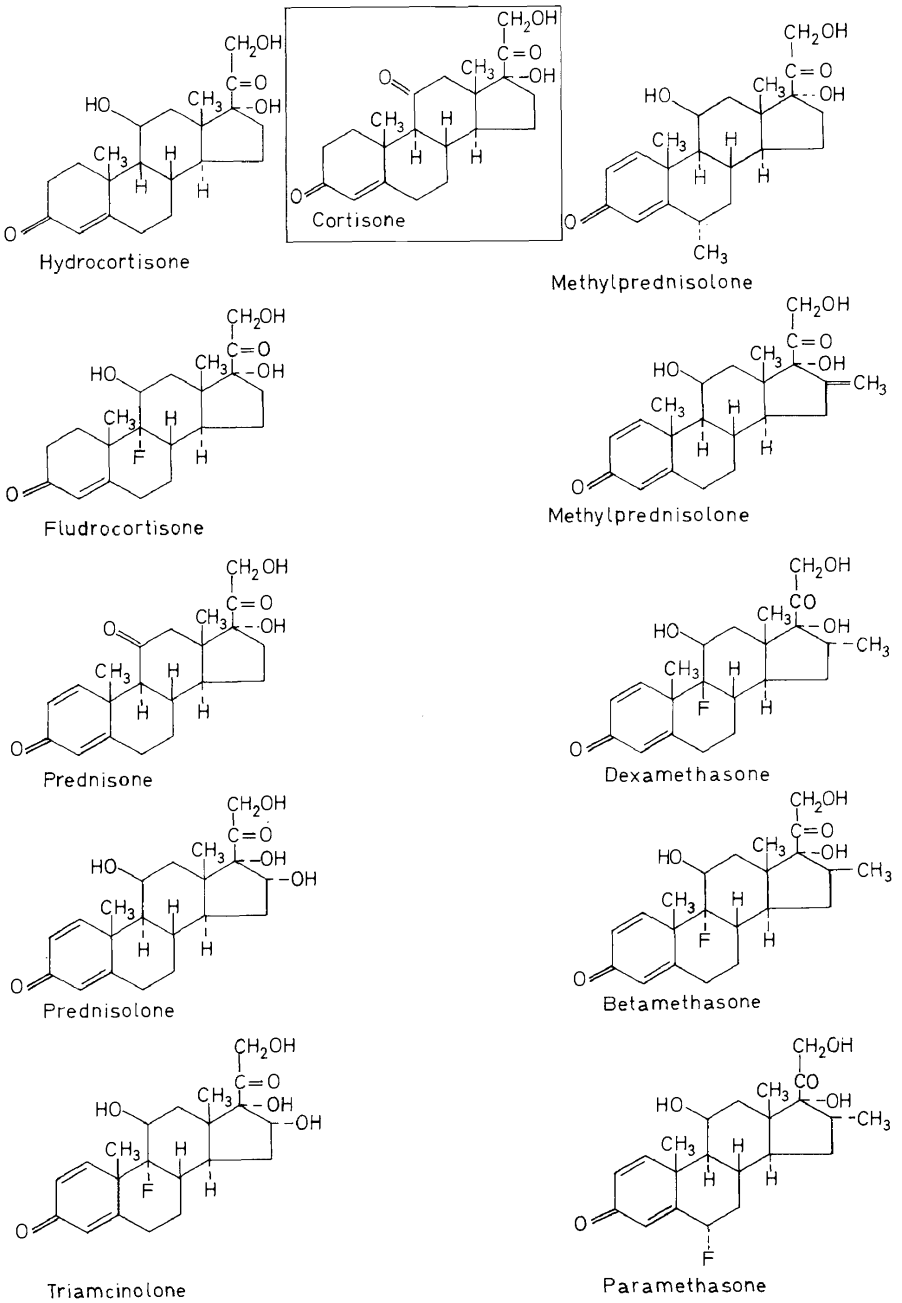


Figure 5. Corticosteroids.

Since, at that time, pharmaceuticals were included in the patent laws of practically all developed countries apart from Italy, the above statement must refer mainly to Italy. Thus anyone is free to manufacture drugs in Italy, even though the drugs have been discovered and patented abroad. This, of course, is an important infringement of the rights of the foreign inventor, who apart from other things depends on exporting to those countries to which Italy also supplies (and of the few larger Italian Companies, whose activities are also based on research). A simple consideration shows that the Italian imitator, who has only manufacturing costs and does not even need to make his substances known to the customers (since this has been done by the first inventor), can sell his substances more cheaply than the first inventor. Since the Italian imitator has no research costs, does not bear the burden of supplying information to medical practitioners and is not putting himself at risk (he is only interested in selling drugs providing assured, quick returns), a completely different calculation and an unfair undercutting of prices is possible, prices which research-based industry must maintain in order to be able to finance steadily increasing research work.

In the past few years other countries have followed Italy's example. Thus not only India and other Asian countries and Latin American countries such as Argentina, Brazil, Columbia and Mexico, but also industrialized countries, such as Canada, have introduced laws or bills which aim at the abolition or strong weakening of patent protection for drugs.

Further, developing countries are playing with the same idea and the research industry of the few countries responsible for the production of most new drugs is confronted by alarming official discrimination. It would be interesting to know the real background to this development. It is, of course, impossible to consider this in detail in this speech, but the following points can be mentioned. It is certain that for wide circles the origin of drugs is wrapped in obscurity. It is true that the ill person receives tablets, salves, injections or drop bottles from the dispenser or doctor with whom he is in personal contact. However, the pharmaceutical industry, which is behind these agents, and the way in which it operates, is completely unknown to him. Neither he himself nor the persons representing him in political matters appreciate the risks of this industry, the expenses thereof, the research costs and all the problems and difficulties which arise in the production of a new drug and its introduction into therapy. For the general public the pharmaceutical industry is an anonymous entity and they do not take into consideration that emotionally or politically based attacks on this industry can have disastrous results on medicine and thus also on general health. The public overlooks or forgets the large extent to which it is indebted to industrial research for the abundance of new drugs, and also does not realise that these attacks delay or hinder the output of new pharmaceuticals and reduce the willingness to invest in new and particularly risky research projects, such as cancer research.

Apart from such purely emotionally and politically based negative attitudes towards industry, there are other and even more dangerous attacks; as the State develops into a guardian of general health, it increasingly becomes the greatest customer of the pharmaceutical industry. You are aware of countries in which the Government provides medicinal preparations

for patients and sells them for very low prices or even gives them away free. The Governments of these countries are interested in obtaining drugs at prices which are as low as possible. They thus not only save public funds, but, perhaps even more important, also gain political credit. The relationship between industry and Government takes on a new aspect, the Government being able to dictate the terms of the relationship, if necessary by legal measures. For these reasons the pharmaceutical industry in various countries is in great difficulties, the first step of this unfair battle nearly always being a weakening of the specific patent protection for drugs and the threat to import patent-free or virtually unpatented drugs from sources other than those of the inventor, for example from Italy.

We have briefly mentioned that most new drugs come from the industrial laboratories of the U.S.A, Switzerland, Germany, England and France. What are the facts about the distribution of these drugs throughout the world? Most countries depend on drugs which have been developed and introduced in therapy elsewhere. These drugs are either imported into the non-producing countries from the producing countries, or factories are established, partly subsidiary companies of foreign pharmaceutical firms and partly as national enterprises. In any case the expenses entailed in producing the achievements of private industry, which achievements are for the benefit of the whole world, have to be financed by the proceeds from the world market, including sales in the pure consumer countries. As long as the latter are not able to produce the necessary drugs themselves, they should not restrict imports from other countries. At the same time, they certainly will have the possibility of expediting industrialization in their own country and, in this, they can rely on the know-how of the industrialized countries. As a matter of fact, intensive industrialization in the drug and other fields has only taken place in those countries which have established patent laws. It is also true that countries such as Japan, which until recently belonged to the developing countries, have become rapidly industrialized under the protection of Patent Laws. It, therefore, appears to be absolutely essential that those countries which are still underdeveloped as far as drug production is concerned establish patent laws including particularly strong protection for drug inventions. Present economic trends in this sphere leave much to be desired; the exporting pharmaceutical industry is losing important markets with the consequence that in future the industry will have to operate on a smaller basis and therefore reduce significantly, or possibly even partly cease, its research work. The U.S.S.R., which has developed practically no new drug of its own, demonstrates that the State cannot replace the private sector as a source of future drugs. The example of Italy shows clearly that the elimination of patent protection leads to a situation which is extremely unfavourable for the development of an efficient research-based pharmaceutical industry. One of the consequences is the establishment of a very great number of small firms which do not contribute anything at all towards the development of therapy. Moreover, the absence of patents does not result in a reduction of the prices of drugs for the patients. The weakening of patent protection in the field of drugs has only negative results; one of the most important effects is that in future private industry will scarcely be able to involve itself with risky research fields, i.e. fields where the chances of

success are low, e.g. cancer research. In view of many problems of medicine which are still unsolved, the worthwhile and successful development of the last years must be allowed to continue undisturbed. This development is closely connected with the research work of the private pharmaceutical industry, and the basis for this research, namely adequate patent protection for drug inventions, should be upheld and extended, certainly not weakened or eliminated. The elevation of social and economic levels is directly dependent on the protection of intellectual property, since this protection represents the most important basis for investment by private industry and is thus the pre-requisite for industrialization. These factors should be given increasing consideration and their positive aspects, particularly in the field of drugs, must unceasingly be brought to the attention of the public and influential political circles.