THE LAW & MONOPOLY

The Case of Tetracyclene

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The law and monopoly: the case of tetracyclene

by Richard Goodman

Editors' comment: Richard Goodman, a graduate of the University of Chicago Law School, has made an intensive study of the drug industry. The situation described in the article raises serious questions about the effectiveness of the traditional legal means of controlling monopoly in the U.S. economy.

Since 1958, the U. S. Federal Trade Commission has been investigating fraud and monopoly in the antibiotics industry. Few consumer goods are as vital to so many Americans as drugs. And few drugs are as important, even vital, as antibiotics.

As Senator Kefauver said:

"Antibiotics constitute the largest single segment of the ethical drug industry. Estimates place the annual volume of sales at the manufacturer's level at over $400 million a year. Antibiotics are roughly classified into two groups — narrow spectrum and broad spectrum. The principal products of the former are penicillin and streptomycin. The older forms of penicillin are not patented, and streptomycin, though patented, has been licensed out for manufacture by a number of firms . . .

"In contrast, all of the leading broad-spectrum antibiotics are patent monopolies. For these drugs the patient normally pays about 50 cents per tablet; and his prescription usually calls for a minimum of 12 to 16 tablets to be taken over 3 or 4 days. Thus, his initial prescription usually runs from $6 to $8, or double that amount if it is refilled. If the patient does not respond, the physician may prescribe a different antibiotic, usually sold at the same price. Hence, it is not surprising that ordinary families, particularly those with children, spend sizable sums on prescriptions for antibiotics, and that in complaints received by the subcommittee concerning prices of prescription drugs, the product group most frequently singled out for criticism is antibiotics."

In August of 1963, the Commission finally issued an opinion regarding the cornerstone antibiotics, the tetracyclenes, and their owners – Pfizer & Co. and American Cyanimide Corporation – two of the world's largest drug manufacturers. The commissioners agreed on two fundamental points. First, that Pfizer had improperly procured the patent on tetracyclene in 1954 and 1955, and had misrepresented to the patent office in this connection. Second, that major American drug firms involved in the case had conspired to fix the prices of the broad spectrum antibiotics in the United States, including tetracyclene, oxytetracyclene and chlortetracyclene. This opinion effectively idicts the largest American pharmaceutical manufacturers for bilking Americans of literally millions of dollars over the last decade. The story behind these events is positively incredible.

How Pfizer got the patent

In the late 1940's, American Cyanimide, one of the world's largest pharmaceutical manufacturers, developed and obtained a patent on a drug, the patent name of which is chlortetracyclene (widely known in the United States as aureomycin). This particular antibiotic was one of the first of the major wide-spectrum antibiotics developed in the United States. Its emergence in the field was a development of first-rate significance for American physicians and their patients, and the development of this drug was widely recognized as a scientific, pharmaceutical, and pharmacological break-through.

However, after the patenting of chlortetracyclene, it quickly became clear that there would be advances in the "wonder drug" field, and that chlortetracyclene would not remain the dominant drug for long. Consequently, many other American pharmaceutical firms, including Pfizer, Bristol, and Hayden, began intensive research into the structure and action of chlortetracyclene. It soon appeared that a new antibiotic much more effective than chlortetracyclene could be and would be developed, and would then become the dominant antibiotic on the American market. Everyone in the industry saw immediately that the company that first obtained the patent on the new,

less-toxic, harder-hitting antibiotic would be in a position to do very well indeed. Thus, between the years 1950 and 1955, at least four American companies filed patent applications for patents on the new drug called "tetracyclene" – Cyanimide, Pfizer, Bristol, and Hayden. Each claimed prior development of the product or the process for manufacturing it, and each claimed exclusive rights on the new patent.

Then things began to happen very fast. Hayden stock was bought by Cyanimide at a price greatly in excess of Hayden's then net worth, while Bristol simply did not have the resources and talent necessary for attaining victory in the battle of giants. Pfizer was the ultimate winner; but, as the opinion of the Trade Commission of August, 1963 revealed, victory was achieved as a result of an agreement between Pfizer and Cyanimide to permit Pfizer to obtain the patent, which allowed the companies to divide the U.S. and world market with Cyanimide, Bristol, and Upjohn, the latter two coming in for a smaller portion of the market.

Pfizer "tests" itself

The history of how Pfizer induced the patent office to issue the patent on tetracyclene forms a large part of the Trade Commission's opinion. This story is significant not only in terms of the drug industry itself, but it also speaks importantly about the operation of the patent system; it was the patent that proved to be the real "open sesame" for Pfizer and Cyanimide.

The final decision as to whether the United States would grant or deny this enormously valuable patent to Pfizer lay in the discretion of a man by the name of Lidoff, the Chief Examiner of Chemical and Pharmaceutical Patents in the United States Patent Office. Lidoff still remains a Chief Examiner in the Patent Office in this field, and is, of course, a civil servant. Lidoff's view of this patent was sceptical from the outset. He took the position that the teracyclene Pfizer patent application should not and could not be granted under United States patent laws, because tetracyclene was really not an innovation over the formerly existing knowledge and art in the pharmaceutical field covering the broad spectrum of antibiotics. Specifically, he objected that tetracyclene existed before Pfizer "invented" it, and that it was in fact co-produced inherently and necessarily in the production of chlortetracyclene, on which Cyanimide already held the patent. This was Lidoff's view, and relying on it, he actually issued a denial and rejection of Pfizer's application.

Pfizer was then forced by the language of Lidoff's rejection to consider how to prove to Lidoff that there was no prior inherent co-production. Lidoff permitted Pfizer to submit affidavits testifying to the results of tests which were conducted by Pfizer to determine whether or not the antibiotic tetracyclene was inherently co-produced with aureomycin. Thus, Lidoff permitted Pfizer *to run its own tests* to determine whether or not the production of chlortetracyclene necessarily and inevitably resulted in the production of tetracyclene. Pfizer

performed its tests, and claimed that there was no inherent co-production of tetracyclene in aureomycin production. However, as the Trade Commission found almost a decade after issuance of the Pfizer patent on tetracyclene, and after five years of lengthy investigation and hearings, the Pfizer scientists and attorneys who had submitted the affidavits testifying to the fact that there was no inherent co-production of tetracyclene in aureomycin production had misrepresented the results of their own tests in order to convince Lidoff to issue the tetracyclene patent. The real results of these tests, showed that there was inherent co-producion in aureomycin production of up to 20 per cent.

This led the Trade Commission to conclude that Pfizer was directly and culpably responsible for the procurement by misrepresentation of a monopoly over a product which had cost the American public millions of dollars. The Trade Commission also found that Cyanimide withdrew its own application for the tetracyclene patent after a deal was made with Pfizer to divide up the American market for the product and that the procurement of these patents had enabled Cyanimide and Pfizer to establish non-competitive and fixed prices for oxytetracyclene and chlortetracyclene from 1949 through 1953, to the great damage of millions of Americans.

The international market

The obtaining of the patent by misrepresentation, and the rigging of prices which followed as a result of the fraudulent procurement, had effects outside the United States, since the patent system applies throughout the Western world. The ease with which U.S. patents may be registered almost everywhere abroad, ensues that a U.S. patent-holder will not be bothered by foreign competition. (The drug industry, of course, shares the benefit of the Patent Treaties.) The only problem is Italy, which does not recognize drug product or process patents. Consequently, anyone in Italy may, with impunity, produce any drug patented elsewhere, which has long made the Italians the plague of the American drug monopoly (as they still are today).

Much to the dismay of the Pharmaceutical Manufacturers Association and the American Medical Association, the U.S. government military purchasing agents have for many years (since 1955) purchased their drug requirements abroad, from Italian manufacturers whose prices are substantially lower than the prices for the same antibiotics in the American market. The government purchasing agencies have been defiled and criticized in the drug and medical field; they have been called aiders and abettors of thieves and worse; but as recently as November 3, 1963, the military reaffirmed their policy of purchasing the cheapest drugs available.

The drug monopoly had struggled continually against the Italian drug laws (which, ironically, were originally passed by the Mussolini regime in the late 1920's) in every way possible. including attempts to influence the Italian Chamber of Deputies, and the absence of drug laws – patent laws – in Italy has produced weird political alliances

there. Thus, on the drug patent law issue, Republican *laissez-faire* deputies vote with Communist and Socialist deputies to prevent passage of a drug patent law in Italy. However, even the free-wheeling Italians fall into line in the Western Hemisphere. Thus, in Latin America where drug patent protection is theoretically limited, and would ordinarily be of little protective value to the drug patent holder, prices are equivalent to those in the United States, and in some cases substantially higher. For example, a drug like tetracyclene, which costs perhaps 1 cent per 250 mgr. capsule to produce and manufacture, is sold both in the United States and in Colombia for 32 or 33 cents. In the United States, of course, this is the result of strong drug patent laws; in Colombia, where the Italians compete freely with the Americans, the price structure is the direct result of world cartel pressure, to which even the Italians succumb. (This is the background behind the current Senate Anti-Trust Monopoly Sub-Committee investigations into the Colombian drug debacle.) Where the cartel is less efficient, as in Brazil, tetracyclene sells for one-third less than in the United States.

Are anti-trust laws effective?

What is important about these events? First, it is of critical importance that monopoly capital in the United States may obain a monopoly in the form of a patent in relatively closed-door, unpublicized proceedings, namely the United States Patent Office. In this case, for example, in order for Pfizer to unlock a billion dollar market, it was necessary to move *only one man* in the United States Patent Office and to resolve only his doubts. Is it conceivable that a firm with millions of dollars in resources would be unable to satisfy the demands of even the most scrupulous examiner in a situation of this kind? Moreover, once the patent is issued, firms the size of Pfizer can afford to make it very expensive for anyone interested in testing out the validity of the patent in the courts.

Second, despite the Trade Commission opinion and the public reaction to it, the drug companies are likely to be able to keep most of the booty – they have already reaped profits of millions of dollars a year between 1952 and 1963. The Trade Commission cannot order them to restore this money to the public, and it would be impossible for any single private litigant to do this in any way. The fact is that if the Trade Commission decision is affirmed on appeal, these major American firms will have pirated millions of dollars which they may not have to return. One cannot help but feel that there is a lesson in this for those who believe that the Anti-Trust laws provide a remedy for monopoly capitalism.

The hearings on the drug industry formed part of the work of the Senate Committee on the Judiciary, Sub-committee on Anti-trust and Monopoly, headed by the late Senator Estes Kefauver, from 1958 to 1961. Transcripts of the hearings can be obtained from the Government Printing Office or from the Sub-committee itself, and copies of the Federal Trade Commission's report are available through the Clerk of the Commission.