26-4-1991.

SMITH KLINE & FRENCH LABORATORIES

(AUSTRALIA) LTD & ORS

v.

THE SECRETARY TO THE DEPARTMENT OF COMMUNITY SERVICES

AND HEALTH

This is an application for an interlocutory injunction pending the hearing of an application for special leave to appeal and, if special leave to appeal is granted, pending the determination of the appeal or until further order.

The application is brought by a group of companies which I shall designate as "SK&F", without seeking to differentiate between them in terms of the interest which each of them has in the subject-matter of these proceedings.

The interlocutory injunction which they seek is expressed in these terms in the summons:

> "[P]ending the determination by this Court of the applicants' application for the grant of special leave to appeal and, if special leave to appeal is granted by this Court, pending

> the final determination of the appeal or until further order, the ... respondent by himself, his servants and agents be restrained from without the prior written consent of the first applicant using or applying the information, documents and materials which are identified as 'Confidential' in Exhibits 6A and 6B in proceedings numbered G298 of 1990 and G299 of 1990 in the Federal Court of Australia, for any purpose other than the exercise of decision-making powers vested in him or them in relation to 'Tagamet' and 'Duractin' brands of the drug cimetidine."

In form, the injunction thus sought appears to be similar to the permanent injunction which the applicants would claim if they succeeded in obtaining a grant of special leave and the appeal was successful.

The circumstances in which the applicants sought relief, including relief by way of declarations and permanent injunction in the Federal Court may be shortly stated. The applicants supplied certain information comprised in Exhibits 6A and 6B in the Federal Court proceedings and alleged to be confidential to the respondent with the object of securing governmental approval of a pharmaceutical of therapeutic compound, cimetidine. Cimetidine has proved to be of great value in the treatment of gastro-intestinal ulcers and has been a large revenue earner for companies in the SK&F group which held the

patent for it. The Australian patent expired on 15 February 1988 but an application for its extension is pending.

The respondent and his Department are responsible for the grant of approvals to import and dispose of pharmaceutical and therapeutic substances. Without the approval of the respondent such substances would be prohibited imports under the Customs (Prohibited Imports) Regulations. The Department requires applicants for permission to import pharmaceutical and therapeutic substances to provide information in accordance with guidelines known as the NDF4 guidelines. Section B1 of the information to be provided requires details of the chemistry of the active ingredients of the substance. B1 data includes an outline of the method of manufacture, a list of known impurities and methods of detecting and eliminating their presence from the active drug.

Commencing in June 1975 the first applicant sought permission to import cimetidine and later sought approval to market the substance. In connection with these and subsequent applications the first applicant submitted to the respondent a considerable amount of information concerning the substance, including B1

data. The applicants claim that much of this B1 data thus submitted is confidential proprietary information belonging to them and was submitted to the Department solely for the purpose of enabling the Department to make decisions about the applicants' brands of cimetidine which are known as 'Tagamet' and 'Duractin'. Pursuant to approvals granted by the respondent, the applicants have imported cimetidine and marketed it under the above brand names.

In July 1988 Alphapharm Pty. Limited, which is a respondent in the principal proceedings and which has been granted leave to intervene in the proceedings now before me, applied for governmental approval of its version of cimetidine, the patent then having expired. Its version of the compound is called "generic" in the industry to distinguish it from the initial compound patented by the innovator. In connection with its applications for approval Alphapharm provided information in accordance with the NDF4 guidelines, including B1 data. In evaluating the Alphapharm applications, the respondent wishes to make use of the B1 data supplied by the applicants but the applicants claim that such use of their data would be in breach of an equitable obligation of confidentiality owed by the

respondent to the applicants and that the breach would have detrimental consequences for the applicants.

The detrimental consequences would arise in this way: recourse to the applicants' B1 data would enable the Department to process applications by Alphapharm and other companies intending to market generic versions of cimetidine more expeditiously and at less expense to the marketers of the generic compounds. It might even result in their marketing generic compounds in an improved form. The likelihood is that recourse by the Department to the applicants' B1 data would expose them to the rigours of market competition earlier and on more disadvantageous terms than would be the case otherwise. Further, it would assist the applicants' competitors in selling at a lower price than the applicants' price. By reason of this circumstance and the likelihood that the Department would require the applicants, as a condition of retaining their listing on the Pharmaceutical Benefits Schedule, to lower their market prices accordingly, the applicants would sustain financial detriment if the Department were to use their B1 data in the manner proposed.

So far the applicants have been protected by the grant of interlocutory injunctions. At first instance Gummow J. granted such an injunction pending trial and a further injunction was granted pending the determination of an appeal to the Full Court of the Federal Court, the applicants having failed to make out a case for relief at first instance and before the Full Court. Following the dismissal of the applicants' appeal to the Full Court, Sheppard J. granted an interlocutory injunction up to and including 29 April 1991, evidently in terms similar to the injunction now sought.

This Court has jurisdiction to grant injunctive relief to preserve the subject-matter of litigation pending the determination of an application for special leave to appeal or of an appeal pursuant to the grant of leave. The jurisdiction is inherent and in my view may be exercised by a single Justice, as in fact it has been exercised from time to time. The jurisdiction is an extraordinary one and will be granted only in exceptional circumstances.

In this case the respondent has, by its counsel, given an undertaking that it will not use the sample provided by the applicants for the purpose of

evaluating applications for approval of generic versions of cimetidine, pending the determination of the application for special leave and, if special leave is granted, pending the determination of the appeal. Apart from giving that undertaking, the respondent has not presented argument against the grant of an injunction, indicating that it is willing to leave the question to the Court. However, Alphapharm has opposed the grant of the injunction sought.

In deciding whether I should exercise the jurisdiction to grant relief in the present case the first point to be made is that the applicants have been unsuccessful all the way along the line; initially at first instance and unanimously before the Full Court. Both Gummow J. and the Full Court rejected the applicants' case that the circumstances in which the first applicant came to deliver its B1 data gave rise to an equitable obligation of confidence which would prevent the respondent using the sample and data provided by the applicants in evaluating applications for approval of generic versions of cimetidine. Moreover, Gummow J., whose statement of the relevant legal principles the applicants accept, made significant findings of fact which are adverse to the applicants. His Honour found, first:

> "that the Department did not know that the B1 data was furnished for a purpose which excluded the use to which the Secretary now seeks to have it put in evaluating the Alphapharm application".

Secondly:

> "that the Secretary and his officers did not know that the information was supplied to them for the sole purpose of evaluating applications made by SK&F, so as to exclude any subsequent use by the Department ... in the way in which the Department contends it is at liberty to have recourse in evaluating the Alphapharm application".

Thirdly:

> "that, when SK&F furnished the B1 data between 1975 and 1987, it did so on the implicit understanding I have described. SK&F did not furnish the B1 data with any other purpose which could be described as a 'sole' purpose, so as to exclude use within the Department in the course of evaluating other products."

And, fourthly, that the circumstances were not such that the respondent ought to have known of the limited purpose of the disclosure.

As I read the reasons for judgment of the Full Court of the Federal Court, I do not understand their

Honours to have departed from these findings of fact. Their Honours said:

> "Some attempt was made to displace his Honour's conclusions as to the facts. It is unnecessary to recount the many points which were made on either side, because the case was plainly one in which his Honour's conclusions are able to be supported."

Their Honours did not refer to all the findings which I have set out but they did specifically refer to the second of those findings immediately before the above-quoted paragraph in their judgment, and they went on to examine in some detail arguments designed to show that Gummow J. was wrong on the facts, arguments which they eventually rejected. In particular, they quoted the following passage from Gummow J.'s judgment:

> "The position is if officers of SK&F had turned their minds to the question over this period from 1975, they would have said that they regarded the NDF4 information as 'confidential' in the sense that it was not to be disclosed to competitors or potential competitors, without the prior permission of SK&F. But no one, before the steps taken by Mr. Perrin which I have described, focused attention upon the question of use by the Department of B1 data in the manner which is the subject of this case."

Following that quotation, their Honours said:

"There is no ground for disturbing this finding, which accords with common sense."

In the result, it seems to me that the applicants face the very considerable burden of showing, if they are to succeed in their proposed appeal, that findings of fact made by the primary judge and accepted by the Full Court should be overturned. Add to that the circumstance that the existence and scope of a confidential obligation is very much dependent on the particular facts of a given case and it will be seen that this is not a case in which it can be said, at this stage, that the applicants have a strong case for securing a grant of special leave. In saying that, I acknowledge that the relevance of some of the factors to be taken into account in determining the scope of the respondent's obligation of confidence in his capacity as a public officer discharging public responsibilities in the public interest is a matter of public importance which, in an appropriate case, might well warrant the grant of special leave to appeal. But I am not presently left with a clear impression that this is such a case.

In this respect, I am by no means persuaded of the correctness of the applicants' submission that the Full

Court of the Federal Court applied substantive principles different from those applied by Gummow J. It may be that the Full Court attached greater significance to the responsibilities that the Department was called upon to discharge in the public interest, but that is a different matter.

The applicants also claim that the courts below were wrong in rejecting an argument based on s.51(xxxi) of the Constitution. That argument, it seems to me, again depends upon the contention that the B1 data provided to the respondent was the subject of an equitable obligation of confidence and constituted property.

Having regard to what I have already said, I do not regard this case as one of exceptional circumstances such as to justify the grant of the relief sought. The applicants will be left with a claim for equitable compensation if the injunction is refused and the appeal were to succeed. I acknowledge that there would be difficulty in quantifying the amount of compensation, even taking into account an undertaking offered by Alphapharm to keep accounts and records of sales and receipts in connection with its generic compound "Cimet", but I do not think that these

difficulties are so great that it can be said that the refusal of an injunction would amount to the destruction of the subject-matter of the litigation. In one sense that is by the way. Even assuming that the jurisdiction to grant the relief sought is engaged on the basis that the subject-matter of the litigation would be destroyed, I do not consider that this is a case in which interlocutory relief of the kind sought should be granted.

In passing, I note that Sheppard J. granted an injunction for a very limited period. I should draw attention to the comments of Brennan J. in *Jennings Construction Ltd. v. Burgundy Royale Investments Pty. Ltd. [No.1]* (1986) 161 C.L.R. 681, where his Honour said (at p.684):

> "In future, there should be no inhibition on the court in which the matter is pending framing a stay order, if a stay be appropriate, to avoid the necessity for application to this Court."

His Honour's remarks in that case apply with equal force to an application for an interlocutory injunction pending the determination of a special leave application and, if special leave is granted, pending the determination of the appeal.

In the result, the application for an interlocutory injunction is refused.